Agricultural Handlers Exposure Task Force (AHETF)

VOLUME VIII

AHE55 – IIRB Materials

April 7, 2008

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Volume VIII, Part A:

Transmittal of Initial Submission for AHE55 2-28-08

LS Consulting

From: LS Consulting [lsconsulting@oh.rr.com]
Sent: Thursday, February 28, 2008 10:42 AM
To: Kim Lerner (klerner@iirb.com)
Subject: AHETF Protocol Submission
Importance: High

Kim,

It's been a while since we talked. Agricultural Handlers Exposure Task Force is finally ready to submit a study to IIRB for review and approval. Help me out with your procedures.

I've assembled the forms forms from iirb.com including the protocol, draft ICF, CVs for researchers, a recruitment flyer, labels and MSDSs for the possible test substances, and product risk statements as appropriate for specific sites to be attached to individual consent forms. Anything else needed? Do you accept these via email?

Do you need a signed contract from the sponsor?

Give me a call if we need to discuss.

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, OH 44060
440/255-1954

LS Consulting

From: Iirb105@aol.com
Sent: Thursday, February 28, 2008 12:10 PM
To: lsconsulting@oh.rr.com
Cc: RROOGOW@IIRB.COM
Subject: Re: AHETF Protocol Submission

In a message dated 2/28/2008 10:42:48 A.M. Eastern Standard Time, lsconsulting@oh.rr.com writes:

> Kim,
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>
> Larry D. Smith, Ph.D.
>
> LS Consulting Service, LLC
>
> 7919 Champaign Dr.
>
> Mentor, OH 44060
>
> 440/255-1954
>
> This e-mail may contain confidential or privileged information. If you are not the intended recipient, please advise by return e-mail and delete immediately without reading or forwarding to others.

Hi!

It's a pleasure that we have gotten this far! Robert Roogow, Director of Operations can walk you through the actual submission process and is the best resource to over see the submission process.

He is copied on this email and his phone is the same - he will also be able to let you know who is your project leader.

kim

Kim Lerner, Chairman
Independent Investigational Review Board, Inc.
6738 West Sunrise Blvd. #102
Plantation, FL 33313

office: 954.327.0778
Fax: 954.327.5778

KLerner@iirb.com
www.iirb.com

LS Consulting

From: Robert Roogow [rroogow@iirb.com]
Sent: Thursday, February 28, 2008 2:53 PM
To: lsconsulting@oh.rr.com
Subject: RE: AHETF Protocol Submission
Attachments: EPA Site Questionnaire.1-06.doc; EPA Protocol Checklist.doc

Dear Larry,

It was a pleasure speaking with you today. Here are the documents that we discussed. I look forward to working with you. Please call if you have any further questions.

Regards,
Robert

Robert Roogow, MS, CIM
Director of Operations
Independent Investigational Review Board, Inc.
Ph: 954-327-0778
Fax: 954-327-5778
rroogow@iirb.com

From: Iirb105@aol.com [mailto:Iirb105@aol.com]
Sent: Thursday, February 28, 2008 12:10 PM
To: lsconsulting@oh.rr.com
Cc: RROOGOW@IIRB.COM
Subject: Re: AHETF Protocol Submission

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>
> Larry D. Smith, Ph.D.
> LS Consulting Service, LLC

7919 Champaign Dr.
Mentor, OH 44060
440/255-1954

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He is copied on this email and his phone is the same - he will also be able to let you know who is your project leader.

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Kim Lerner, Chairman
Independent Investigational Review Board, Inc.
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Plantation, FL 33313

Office: 954.327.0778
Fax: 954.327.5778

KLerner@iirb.com
www.iirb.com

LS Consulting

From: LS Consulting [lsconsulting@oh.rr.com]
Sent: Thursday, February 28, 2008 10:54 PM
To: Robert Roogow (rroogow@iirb.com)
Cc: 'David R Johnson'
Subject: Submission Protocol, ICF, and Documents for AHE55
Attachments: AHE55 IIRB Submission 2-28-08.zip

Robert,

Attached find the submission documents for a study from Agricultural Handlers Exposure Task Force (AHETF). I believe I have included all the necessary documents for an IIRB review. If not, please let me know what else is needed.

You'll note AHETF is requesting a translation into Spanish of the ICF, a recruitment flyer, and product risk statements (PRR) for 7 pesticide products. Please let me know if there is any confusion about these documents.

I look forward to hearing from you when you've had a chance to review the package. Do not hesitate to call me if you have questions.

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, OH 44060
440/255-1954

INDEPENDENT INVESTIGATIONAL REVIEW BOARD INC.

SUBMISSION LETTER

DATE: **2/28/2008**

TO: Kim Lerner, Chairman
Independent Investigational Review Board, Inc.

FROM: Larry D. Smith, Ph.D.

SUBJECT: Please forward for IRB approval

X **New Study for IRB Approval** - *(Include Copy of Protocol)*
☐ **Additional Site for an Approved Protocol**

Principal Investigator: Larry D. Smith Sponsor: Agricultural Handlers Exposure Task Force (AHETF)

Protocol Number: AHE55 Protocol Title: Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

☐	**Investigator's Brochure/ Device Brochure**	X *Not Applicable*
X	**Informed Consent Form**	(*e-mail or include disc*)
X	**CV's and License**	(*for all investigator's listed on 1572*)
X	**Site Questionnaire**	☐ *Not Applicable: Already on File*
☐	**Facility License/Certification**	*(if research is conducted in a hospital/outpatient center)*
☐	**IRB Waiver**	(*if research is conducted in a hospital/outpatient center or federal or state funded clinic)*
☐	**FDA Form 1572**	X *Not Applicable*

Please call if you have any questions. Thank you.

Note: Meetings are held weekly, usually on Tuesdays (all correspondence for review should be submitted no later than the Friday before the scheduled Tuesday meeting. If all material is not available please call the IIRB to discuss. (Emergency meetings can be scheduled if necessary.)

INDEPENDENT INVESTIGATIONAL REVIEW BOARD INC.

Study Specific Instructions

Protocol Title: Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

Sponsor: Agricultural Handlers Exposure Task Force
Contact Info: c/o David R. Johnson, Ph.D.
1720 Prospect Dr.
Macon, MO 63552
(660) 395-9590
davejohn@marktwain.net

Contact/Title Sponsor Representative

CRO: LS Consulting Service, LLC
Contact Info: c/o Larry D. Smith, Ph.D.
7919 Champaign Dr.
Mentor, OH 44060
(440) 255-1954
lsconsulting@oh.rr.com

Contact/Title AHETF Study Director

PROGRESS REPORT NOTIFICATION PROCEDURES: (To whom do we send the notice, etc.)

Dr. Larry D. Smith

SPANISH LANGUAGE REQUIRMENTS: (If it is determined that a Spanish language ICF is necessary).

X Use translations Services through IIRB (Americo Gomez)

___ We will provide our own Spanish Translations

Mailing Instructions: address for Sites do NOT need to be listed – just identify as "sites" (so that we have on file who get copies and who gets originals!)

Originals to: Agricultural Handlers Exposure Task Force
Address: c/o David R. Johnson, Ph.D.
1720 Prospect Dr.
Macon, MO 63552
Sent by (choose one): USPS

Copies to: Dr. Larry D. Smith
Address: LS Consulting Service, LLC.
7919 Champaign Dr.
Mentor, OH 44060
Sent by (choose one): USPS

Notes: (include if routine correspondence get copies sent to CRO/Sponsor, sent US Mail, etc.)

Routine correspondence may be sent via email or USPS to sponsor with copies to Dr. Larry Smith.

Progress Report Information:

Dr. Larry Smith

Billing Instructions: Agricultural Handlers Exposure Task Force
Billing Address: c/o David R. Johnson, Ph.D.
1720 Prospect Dr.
Mcon, MO 63552

Today's Date: 2-28-2008

INDEPENDENT INVESTIGATIONAL REVIEW BOARD INC.

SITE QUESTIONNAIRE

NON-LOCAL REVIEW

Protocol # & Complete Study Title: AHE55 Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

Principal Investigator: Larry D. Smith

Sub Investigator(s): TBD: Tami Belcher, Brian Lange, or Aaron Rotondaro

Please indicate the location where study activities will be performed (where patients will be seen excluding Diagnostics) If more than one location is being used you may attach additional pages.

Site Address: TBD
Polk or Hillsborough County, Florida

PI's Mailing Address: (If different) LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, OH 44060

If the study is being conducted at more than one location and information requested differs for each location, please provide separate information for each location.

Regulatory/Study Coordinator: Larry D. Smith Phone: 440-554-2812 Fax Number: NA

Office Phone: 440-255-1954 24 Hour Phone: 440-255-1954

Please complete the following: **You may attach copies of relevant procedures.**

1. Is this study federally funded requiring review under HHS standards? X No ☐ Yes

2. How will Study Participants be recruited?
   - ☐ *Principal Investigator's Clinical Practice*
   - ☐ Data base of potential Volunteers
   - ☐ Referrals from other clinical Practices
   - X Advertising in the community* *(*advertisements **Must** be approved by the IIRB)*
   - X Other *(please specify):* Study participants recruited from eligible grower crews with selection criteria specified in the protocol.

3. Will you recruit volunteers from vulnerable study populations? ☐ No X Yes *(please specify below)*
   - ☐ Persons kept in detention
   - ☐ Nursing Home Resident/Elderly
   - ☐ Patients in emergency situations
   - ☐ Persons of limited capacity
   - ☐ Minors
   - ☐ Pregnant women
   - ☐ Illiterate
   - X Other: Non-readers
   - ☐ Members of the Armed Forces
   - ☐ Patients with incurable disease
   - ☐ Unemployed/on Public Assistance
   - ☐ Homeless
   - X Employees (Site or Sponsor, etc)
   - ☐ Disabled

   If yes, describe procedures to be followed (if applicable): Volunteers are recruited from growers, grower employees, commercial applicators, and commercial applicator employees. Eligible growers who are willing to participate in the study are selected from a randomized list. Growers are required to certify in writing they will not coerce or exert undue influence on their workers to either participate or not participate and that the volunteer decision to participate will have no effect on their current or future employment.

4. Do the subjects that you intend to enroll in this study come from any type of ethnic background or cultural environment that might have an impact on their ability to understand that participation in the

study is voluntary and refusal to participate or discontinuing their participation will not have any adverse impact on the care that they will receive? None recognized.

5. Indicate the approximate demographics of your site's anticipated subject population:
_____% African American 90% Caucasian 10% Hispanics _____% Asian _____% Other

6. Will you be enrolling only subjects who speak English in this study? ☐ Yes X No
If No, Is a "local dialect" or translation needed? Translation needed: X Spanish ☐ Other _____

7. Who will discuss the research study with the volunteer and obtain informed consent (signed informed consent)? *(Check all that apply)*

X Principal Investigator X Sub Investigator ☐ Study Coordinator
Explain consenting procedures: The study director or designated researcher meets with the volunteer privately to review the study, consent form, test substance, risks and benefits associated with participation, remuneration, and other aspects of the study such as procedures to minimize risks.

8. Describe the circumstances and methods for presenting information to potential human subjects in order to obtain informed consent.

Once eligible growers who are willing to participate are located and the grower agrees to the ethical aspects of study conduct (i.e. non-coercion or undue influence statement), a researcher or study director meets privately with the eligible grower's workers (without the grower or supervisors present) to make a presentation about the study and the need for research volunteers. Afterwards, interested volunteers are requested to contact the study director for additional information. As appropriate for a grower with several to many workers, a recruitment flyer may be posted in a common area of the facility to inform the workers of the need for volunteers. Ultimately, the potential volunteer will meet privately with the study director or designated researcher to discuss all aspects of the research study and is provided an opportunity to have all questions answered. All potential volunteers who meet privately in this type of meeting receive a $20 payment for the inconvenience of attending such a meeting. Potential volunteers who express an interesting in participating are given an opportunity to take a copy of the informed consent form to review if they so desire. Volunteers who decide to participate during the meeting or at a later time are offered an opportunity to enroll in the study by signing the consent form.

In all cases, if the potential volunteer requires a witness (for non-readers) or requires a Spanish version of the consent form and documents, provisions are made ahead of the private meeting.

9. Describe the setting(s) where the study will be conducted (ie, private office, clinic, hospital environment) and if the Investigator is required to seek any type of administrative or Corporate approval in order to implement the study:
The study will be conducted on commercial citrus farms in Polk or Hillsborough Counties, Florida. All participants will be experienced at the work used in the study. Approval to conduct the study is required by the grower or owner of the farm.

*If being done in a Hospital or Outpatient Surgery Center, please provide a copy of that facility's License/accreditation and/or Hospital IRB Waiver Form.

10. Distance between the nearest hospital and research site: TBD, however, expected to be less than 40 miles.

11. Describe the on-site emergency equipment available for the subjects: An EMT or nurse will be present during all monitoring activities to provide emergency treatment for an accident, heat-related illness, other event.

12. How long has the PI been conducting clinical research? 10 years conducting worker exposure studies: this is not a clinical study.

13. **Within the past 3 years has the FDA/OHRP audited your site/Principal Investigator? X No ☐ Yes***
If yes, please provide a copy of all 483's and any applicable correspondence.

14. Has the FDA/OHRP/EPA or any State Medical Board ever sanctioned the Principal Investigator? XNo ☐Yes*
If yes, please provide a summary of the action and applicable correspondence.

15. Are subject files adequately stored and protected to ensure subject confidentiality, i.e. HIPAA, HIV, etc.? ☐ No* X Yes
If no, please explain: _____

16. Does the Principal Investigator, Sub Investigator(s) or any immediate family member have a conflict of interest with the study sponsor, sponsor representatives or other study related entities? X No ☐Yes*
If yes, please provide explanation:
_____
_____

Subject Compensation:

Will subject be paid for participation in this study? ☐ No X Yes*
If yes, please specify the total amount, the amount for each visit and the timing of payment (i.e. at each visit, at the last visit, within 2 weeks of the last visit) in the draft Informed Consent Form. All volunteers who attend a private meeting to learn about the study are paid $20 (immediately after the study) whether or not they are selected to participate in the study. Actual participants are paid an additional $80 at the end of their monitoring.

Site Specific Informed Consent Form Information

Is there any additional wording needed in the Informed Consent Form? ☐ No X Yes*
If yes, please specify the section and additional wording below.
The whole Informed Consent Form and additional materials used during the consenting process must be translated into Spanish.

Investigator Acknowledgment

On behalf of all of the investigators listed on page1, I agree that the responses provided on the Site Questionnaire are true and accurate and I agree to notify the Independent Investigational Review Board, Inc. of any changes in the research activities and to report any unanticipated problems involving risk to the research subjects. In addition, I agree not to make any changes in the research without IRB approval. I confirm that study personnel are familiar with the study and that either an Investigator or a study coordinator acting as my designee will orally explain the Informed Consent Form to all prospective subjects before obtaining their signed informed consent. Furthermore, by signing this form I confirm that I agree to conduct the study in accordance with the requirements of the protocol, for which I am seeking approval.

Dr. Larry D. Smith
Print name of individual completing Site Questionnaire

Larry D Smith _____ 2-28-2008

Dr. Larry D. Smith
Print Name of Principal Investigator

Larry D Smith
Signature Principal Investigator

2-28-2008
Date

Please contact the Independent IRB, if you have any questions regarding this questionnaire 954.327.0778

RESEARCH INFORMATION AND INFORMED CONSENT FORM

TITLE
Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

PROTOCOL NO.
AHE55

SPONSOR AND SOURCE OF FUNDING
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR
Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION
Florida – citrus orchards (e.g., oranges)

CONTRACT RESEARCH ORGANIZATIONS
To be determined and appended to the protocol prior to initiation of the study. You will be told the names of the companies and you will be introduced to the researchers.

INTRODUCTION and PURPOSE
The Agricultural Handlers Exposure Task Force (AHETF) was formed by a group of pesticide companies. The purpose of this study is to measure how much pesticide you might get on your skin and breathe in while you spray using closed cab airblast equipment. This will be done by measuring pesticide residues in the samples we collect from you. About 5 people will be monitored in this study. The results of the study will be used to estimate exposure and risks to workers spraying pesticides with closed cab airblast equipment.

For you to participate in this study, you must understand and sign this consent form and a Product Risk Statement that describes the risks from the pesticide.. If we have used words or presented information you do not clearly understand, please ask me to explain. You may take home an unsigned copy of this consent form to think about or discuss with family or friends or researchers before making your decision. If you agree to be in this study, you will be given a signed and dated copy of this consent form and the Product Risk Statement

ELIGIBILITY

1. Experience making closed cab airblast applications in the last year.
2. Provide proof you are at least 18 years old (government-issued photo ID).
3. Confirm you do not work for a pesticide company or a contractor of AHETF.
4. General health status is "good enough to do the work". Tell us whether you have any medical conditions that affect your ability to participate in the study.
5. Pregnant or nursing women cannot participate in the study. If you are female, you must take an over-the-counter urine pregnancy test before the study. This test will be supervised by a female researcher. You do not have to tell anyone if you have a positive test. Results of a negative test must be confirmed by the female researcher or you cannot participate.
6. Confirm that you do not normally wear personal protective equipment in excess of the label requirements for closed cab airblast applications. Confirm that you will follow label directions.
7. Have a private meeting with a researcher to go over this consent form. The purpose is to make sure you understand what you are agreeing to and to have your questions answered. You may have a friend, family member or advisor with you during the meeting. If you are an employee, this person may not be from the operation's management.
8. You must understand English or Spanish.
9. You must understand and sign this consent form and Product Risk Statement.

PROCEDURES

If you participate in this study, you will do the following:

1. Provide your name and years of experience making closed cab airblast applications.
2. Confirm whether you have received pesticide safety training or are exempt from pesticide safety training.
3. Allow researchers to measure and record your height and weight.
4. Allow researchers to record your gender, age, and preferred language.
5. Allow me to take notes on our discussions during the informed consent session(s).

If you read only Spanish, a Spanish version of the documents will be provided, along with a translator during our meeting. If you have trouble reading these documents in your language of choice (English or Spanish), we will read them to you.

PROCEDURES ON THE DAY OF THE STUDY

1. Wash your long-sleeved shirt and long pants before participating in the study to remove any residues of the product we are studying.
2. Bathe or shower the evening or morning before participating in the study to remove any residues of the product we are studying.
3. Wear all personal protection equipment required by the product label (see Product Risk Statement).
4. Work about 4 to 8 hours applying a commercial pesticide according to your normal practices and spray at least 3 loads.
5. Wear new long underwear underneath your long-sleeved shirt and long pants. Wear your choice of personal undergarments under the long underwear. The long underwear will be supplied by AHETF and collected at the end of the day. You will

be asked to dress and undress with the assistance of a researcher of the same sex. A changing area will be provided for privacy. When you complete your participation, you will put on your own clothes and return to your normal work.

- With the long underwear, you have a risk of becoming overheated and suffering heat illness.

6. Have a tube attached to your shirt collar and connected to a portable air-sampling pump on a belt worn around your waist.
    - This may be uncomfortable or annoying.
7. Have your face and neck wiped with gauze pads moistened with a mild detergent and water mixture. This will be done before you eat anything, any time you would normally wash your face, and at the end of the day.
    - There is a risk of eye or skin irritation from the detergent and water.
8. Have your hands washed in a mild detergent and water mixture. This will be done before you eat anything, any time you would normally wash your hands (such as when you use the toilet), and at the end of the day.
    - There is a risk of skin irritation from the detergent and water.
9. Allow researchers to watch all of your work activities and take notes on what you do.
10. Allow photographs and video recordings to be taken. You will not be photographed or video recorded while dressing or undressing. AHETF will own all rights to the photos and videos and may use them for any purpose.

PRODUCTS HANDLED

You will be asked to handle a pesticide product that is registered by the US Environmental Protection Agency (EPA) and approved for spraying citrus with airblast equipment. A variety of pesticide active ingredients might be used and farm management will select the product. However, you will know what product you will handle before you are asked to sign this consent form.

In addition to the pesticide you will spray, farm management may require tank-mixes with other registered or approved products according to label directions. You will be told before your participation which materials will be in the tank mix. We will have no knowledge of any risks to you other than those provided to you on the tank-mix product labels.

RISKS AND DISCOMFORTS

In this study you will have the usual risks of handling the spray equipment. You will only use equipment you have experience operating.

You will be asked to sign a separate document, called the Product Risk Statement, that identifies the product you will spray, indicates how much of that product you might handle, and specifies the risks of handling that product. It also describes what personal protection equipment you must wear.

You will review the product label with me to identify the airblast use directions and precautions. From the label, and Product Risk Statement, you will learn of any possible side-effects (such as skin irritation) and the signs and symptoms of overexposure. If you feel any of the signs or symptoms during or after the workday, or do not feel well for any reason,

notify a researcher immediately. Otherwise, there are no reasonably foreseeable harmful effects related to handling the test products or tank-mixed products. A copy of the product Material Safety Data Sheet (MSDS), is available for your review and discussion any time you desire.

Because you will wear long underwear underneath your normal work clothing, you have a risk of becoming sick from being too hot. This is known as heat stress or heat illness and can be serious or life threatening. Early signs and symptoms include feeling overheated, tired, dizzy, irritable, and having decreased concentration. If you feel any of these signs or symptoms during or after the workday notify a researcher immediately. If you don't feel well for any reason, notify a researcher immediately. You will be observed by a researcher watching for these symptoms. AHETF will stop your work if the weather gets too hot.

As a precaution, AHETF will have a paramedic, physician's assistant, nurse, or emergency medical technician on site during the study. If needed, this professional will also observe you for signs of illness and will provide medical attention.

You may have other risks or discomforts, including:

- Eye or skin irritation from the detergent and water mixture
- Discomfort from wearing a portable air sampling pump around your waist
- Being embarrassed during dressing and undressing
- Being concerned about taking an over-the-counter pregnancy test
- Working longer than normal because of the time it takes for sample collection

There may be other risks that are unknown at this time. You will be told of any new information that might change your decision to be in the study.

INJURY TO PARTICIPANT

If you are injured or get sick during or after the workday, medical treatment will be available at your workplace and at a nearby health care facility. If necessary, AHETF will arrange transportation for you to receive medical attention. You may refuse medical treatment unless you get sick from too much pesticide exposure or from getting too hot, or if we believe you are too sick to make a rational decision about receiving medical treatment. AHETF will cover the cost of reasonable and appropriate medical attention that is not covered by your own insurance or insurance provided through your employer. Treatment records will not become part of the research records for this study. However, AHETF will make note of the event and this will be reported in the study report. For further information about this, you may call the AHETF Manager at 660-349-4601 (David Johnson).

CONFIDENTIALITY

Your name will appear on the consent form, the Product Risk Statement, and an optional form for you to request your personal study results. All other study information will identify you only by a unique code. Records with your name will be stored in a secure, limited access archive.

Information about your participation in this study will not be given to your employer.

A study report will be written by AHETF and will be available to member companies. It will be sent to the US Environmental Protection Agency (EPA). It may also be sent to state government agencies and to governments of other countries. Your name will not be included in any study report.

We cannot promise you absolute confidentiality because of the need to give information to some organizations or to parties in legal actions, as required by law. All study information, including records which identify you, may be looked at or copied by the sponsor, by EPA or other government agencies, and by the Independent Investigational Review Board, Inc. (IIRB). IIRB is a group of people who review and monitor research to make sure the people who participate in it are protected.

You may ask the Study Director for a copy of your personal results from this study. You will need to provide your name and a mail or e-mail address.

COSTS
There will be no costs to you for participation in this study.

BENEFITS
You will not directly benefit from your participation in the study. The farm owner may benefit from the product used in the study since AHETF will reimburse the owner for that product. Information from this study will be used to improve the quality of pesticide safety assessments for workers using closed cab airblast equipment.

PAYMENT FOR PARTICIPATION
You will be paid $20 if you meet privately with a researcher to review this informed consent. You will receive the money whether you decide to participate or not. You will receive the money in cash right after the meeting.

You will be paid an additional $80 for the day you participate in sampling. You will be paid $80 for completing the sampling day and allowing us to collect your samples. If you decide to withdraw during the sampling, you will still be paid the $80. If we remove you from the study, you will still receive the $80. Payment will be in cash at the end of the sampling day.

You will also receive your normal pay from your employer.

If more people volunteer than we need, some participants may be selected randomly (for example, by lottery). You may or may not be selected. If not selected, you will not receive the $80.

VOLUNTARY PARTICIPATION / WITHDRAWAL
Your employer has agreed to let us do the research and has confirmed he/she does not encourage or discourage you to participate in this study. Your decision to be in this study is voluntary and entirely up to you. If you decide to participate, you may change your mind

later and drop out of the study at any time and for any reason. A decision not to participate, or to withdraw from the study after it begins, will have no effect on your job or pay.

If you withdraw, the long underwear and air sampling pump will be removed, and the hand and face/neck samples may be collected with your consent.

Your participation in this study may be stopped at any time by the researchers or the sponsor. The long underwear and air sampling pump will be removed, and the hand and face/neck samples may be collected with your consent.

If you withdraw or are removed from the study, or if the study does not last an entire workday, you will be released to resume your usual activities.

ALTERNATIVES

No one can require you to participate in this study. Participation is entirely voluntary. If you choose not to participate in this study, then on the day of the study you will perform your ordinary activities.

QUESTIONS

If you have questions about this study or if at any time you think you have a research-related injury or illness, contact a researcher or call:

Larry D. Smith (Study Director) at 440-255-1954 (collect)
Or 440-554-2812 (24 hours)
Or
David Johnson, Ph.D. (sponsor contact) at 660-349-4601.

If you have questions about your rights as a research subject, you may contact:

Independent Investigational Review Board (IIRB)
6738 West Sunrise Blvd. Suite 102
Plantation, Florida 33313
Telephone: 954-327-0778
E-mail: info@IIRB.com

IIRB is a group of people who perform independent review of research.

Do not sign this consent form unless you were able to ask questions and received satisfactory answers.

CONSENT

I have read the information in this consent form and in the Product Risk Statement (or it has been read to me). All my questions about the study and about being in it have been answered. I freely consent to be in this study.

I authorize the release of my research records, including photographs and video recordings, to the sponsor, to the researchers, to government agencies in other states and/or countries, to EPA, to IIRB, and to other parties as required by law.

By signing this consent form, I have not given up any of my legal rights.

_____ _____

Date Subject's Name (print)

_____

Subject's Signature

_____

Subject's Unique Worker Code

I conducted the private consent meeting with the worker named above and confirm that consent was given voluntarily after being fully informed of the benefits, risks, and procedures. In addition, this worker has reviewed and signed the Product Risk Statement which I will store along with this signed consent form in a secure location:

_____ _____

Date Name of Person Conducting Informed Consent Discussion (print)

_____

Signature of Person Conducting Informed Consent Discussion

_____

Title and Affiliation of Person Conducting Informed Consent Discussion

---------- Use the following only if applicable ----------

If this consent form is read to the worker because the worker is unable to read the form, an impartial witness (who is not associated with the researchers or who is not part of the management of the grower where the study is being conducted) must be present to witness this worker's consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, this worker. This worker freely consented to participate in the research study.

_____ _____

Date Impartial Witness' Name (print)

_____

Impartial Witness' Signature

_____

Title and Affiliation of Impartial Witness

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not read English.

AGRICULTURAL HANDLERS EXPOSURE TASK FORCE (AHETF)

STUDY No. AHE55

Study Title: Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

PROTOCOL AUTHORIZATION

Read and Approved by:

AHETF Sponsor Representative: David R. Johnson, Ph.D.

Signature _____

Date _____

Study Director: Larry D. Smith, Ph.D.

Signature _____

Date _____

TABLE OF CONTENTS

1.0 GENERAL INFORMATION

1.1 Study Title

Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

1.2 Study No. AHE55

1.3 Objective

The objective of this study is to develop data to determine the potential exposure for workers making closed cab airblast applications.

1.4 Timeline

Proposed Experimental Start Date: August, 2008

Proposed Experimental Termination (Field Phase) Date: April, 2009

Proposed Experimental Termination (Analytical Phase) Date: October, 2009

Proposed Final Report Issue Date: December, 2009

1.5 Good Laboratory Practice

This study will be conducted in compliance with the US EPA FIFRA Good Laboratory Practice (GLP) Standards (40 CFR 160) and will adhere to applicable AHETF and/or field facility standard operating procedures (SOPs) and field work practices.

1.6 Pesticide Assessment Guideline

This study is based upon EPA's guidance documents for dermal and inhalation exposure measurement under Series 875: Occupational and Residential Exposure Test Guidelines. Data reporting will follow the requirements defined in these guidelines.

1.7 Institutional Review Board

Independent Investigational Review Board (IIRB)
6738 West Sunrise Blvd. Suite 102
Plantation, FL 33313
Telephone: 954-327-0778
E-mail: info@IIRB.com

1.8 Testing Facility, Sponsor's Representative and Sponsor

Agricultural Handlers Exposure Task Force, LLC
c/o David R. Johnson, Ph.D.
1720 Prospect Dr.
Macon, MO 63552
(660) 395-9590
davejohn@marktwain.net

1.9 Study Director

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, OH 44060
(440) 255-1954
lsconsulting@oh.rr.com

1.10 Principal Field Investigators

Principal Field Investigators may include:

Brian Lange
Access Research and Consulting, Inc.
4720 W. Jennifer Ave., Suite 106
Fresno, CA 93722
Principal Field Investigator:
Phone: 559-277-5272
brian@accessrc.com

Tami Belcher
Grayson Research, LLC
1040 Grayson Farm Road
Creedmoor, NC 27522
Phone: 919-528-5508
tbelcher@graysonfarm.com

Aaron Rotondaro
Paragon Research Services, Inc.

6773 Woodcliff Circle
Zionsville, IN 46077
Phone: 317-733-1243
arotondaro@indy.rr.com

During the consent process, each study participant will be informed of which of the above researchers will be involved with monitoring his/her exposure.

1.11 Field Facilities

Southeast Ag Research
86 Jim Moore Rd.
Chula, GA 31733
Phone: 229-386-8989
smith@seagr.com

1.12 Principal Analytical Investigator and Analytical Facility

To be determined and amended to the protocol prior to initiation of the field phase of the study.

1.15 Quality Assurance Unit

Compliance Assessment and Training, Inc.
Randy Fuller
2309 Patton Ct.
Lexington, KY 40509
Phone: 859-264-8844
randyfuller@windstream.net

2.0 ETHICAL CONSIDERATIONS

This study will be conducted in accordance with EPA's final regulation published at 40 CFR Part 26 that establishes requirements for the protection of subjects in human research. The protocol, informed consent form, and other required documentation for this study will be approved by an institutional review board (IRB) and submitted to the EPA as required by 40 CFR 26.1125. The report of the completed research is subject to 40 CFR 26.1303 requirements to document its ethical conduct.

The proposed research described by this protocol, the informed consent form, and all recruitment materials, such as handouts or visual aids, shall be reviewed and approved by Independent Investigational Review Board (IIRB) of Plantation, Florida. Complete records of the IRB review as required by 40 CFR 26.1125 will be submitted to EPA for review along with this protocol and other documents.

Researchers that participate in the study and interact with study participants must undergo ethics training (SOP AHETF-1.B). The training shall include successful completion of the course from the National Institutes of Health (NIH; Human Participant Protections Education for Research Teams) and/or the Basic Collaborative IRB Training Initiative Course (CITI; The Protection of Human Research Subjects). Copies of the certificates of completion for the ethics courses will be submitted to the IRB and stored in the respective personnel files (maintained by the AHETF and all contract facilities.)

2.1 Inclusion and Exclusion Criteria

AHETF has established the following inclusion and exclusion criteria for this closed cab airblast application study.

Participants in this study must meet the following inclusion criteria;

- Be freely willing to participate and to understand and sign the consent form
- Handle pesticides as part of their job
- Be trained in safe pesticide handling practices in accordance with the Worker Protection Standard (WPS), or be exempt from such training
- Have recent experience (within the last year) with making airblast applications using closed cab tractors and airblast sprayers (including the particular equipment to be used)
- Be at least 18 years old with a government-issued ID to verify age
- Consider themselves to be in good general health with no medical conditions that could impact their ability to participate in the study
- Be willing to follow all label and WPS requirements

In addition, potential subjects who meet the following exclusion criteria will not be allowed to participate in this study:

- Are pregnant females
- Are nursing mothers
- Normally wear personal protective equipment (PPE) that is not required by the label, such as chemical-resistant clothing
- Don’t read or understand Spanish or English
- Are employed by a pesticide manufacturer or a contractor to AHETF (except employees of the Local Site Coordinator)

2.2 Remuneration of Subjects

During recruitment, workers will be offered an opportunity to take part in a group meeting with the Study Director or other designated member of the

study team (but without the workers' supervisors) to learn about participating in this study (Section 6.2). No remuneration is offered for this introductory meeting. Workers who are still interested will attend a private meeting with a researcher who will obtain the informed consent of the worker (Section 2.7). Workers will be paid $20 for their attendance right after the consent meeting, whether or not they decide to participate in the study. Workers who decide to participate in the study will be paid an additional $80 each time they suit up (i.e., put on the long underwear) to participate in the study. Usually, workers will participate in the study on only one day unless their participation is terminated due to weather or other unexpected occurrences. The additional $80 is provided in cash at the end of the monitoring period or at the time the volunteer withdraws from the study. All workers who participate will receive the payment, even if they withdraw or their participation is terminated by the study team.

2.3 Risks to Subjects

Six kinds of risks are associated with the conduct of the current exposure monitoring study. These are:

- The risk of heat-related illness
- The risk of exposure to surrogate chemicals
- The risk associated with scripting of field activities
- Psychological risks
- The risk of exposure to detergents
- The background risk of injury associated with agricultural work

In this study risks to subjects are classified as "greater than minimal", primarily since agricultural work is considered a high risk occupation where the likelihood of harm or discomfort is greater than what is encountered in ordinary daily life. In particular, this study involves the operation of tractors and airblast sprayers which present risks of accidents and physical injury, as well as the use of chemicals (pesticides, fertilizers, additives, etc.) which presents a risk of adverse health effects. In addition, AHETF believes the risk of heat-related illness (resulting from wearing an extra layer of clothing to trap chemical) will at times be increased due to study participation. AHETF has adopted an extensive program to minimize these risks. All of the risk minimization procedures, as described in AHETF SOPs, will be followed during the conduct of the study.

2.3.1 Risk of Heat-Related Illness

This study involves the application of liquid sprays to citrus crops using airblast equipment and tractors with a closed cab. All airblast applications will be made outdoors and some locations and dates are likely to result in hot and/or humid conditions. AHETF expects most

tractors to be air conditioned, thus reducing the potential for heat-related illness. AHETF will not accept tractors without properly operating air conditioners. Researchers will inquire of the participants whether or not the air conditioner units function in their tractors. All participants in the study will be wearing an extra layer of clothing (i.e., long underwear under their WPS-required clothing) that they would not normally wear under such conditions. For these reasons, the study will likely involve an increased risk of heat-related illness due to study participation. AHETF researchers will therefore be vigilant in following the extensive educational and monitoring procedures designed to minimize the risk of heat-related illness that are detailed in SOP AHETF-11.G.

Since heat-related illness may occur during the conduct of the study, Study Directors shall have first aid training that includes recognition of signs and symptoms of heat-related illness. A copy of the certificate of completion of this training will be included in the Study Director's personnel file, maintained by the AHETF.

The following procedures will be followed by researchers to minimize the risk of heat-related illness in study participants:

- Ensure plenty of water and sports drinks are available for the workers.
- During worker orientation immediately before participation in the study, remind the workers of the risk of heat stress, suggest they drink some water before they start work, and let them know how/where they can get water during the monitoring period.
- Urge workers to drink water during the monitoring period and remind them that thirst does not give a good indication of how much water a person needs to drink.
- Observe workers during the monitoring period and be aware of the signs and symptoms of heat-related illness.
- Require workers to take rest breaks when early signs or symptoms of heat illness are present.
- Monitor the heat index (based on air temperature and relative humidity) at least hourly whenever ambient temperature is at or above 70 ºF.
- Stop the participant activity when the heat index (adjusted for direct sunlight, if applicable) reaches 120º F and resume only when more favorable conditions exist.
- Have a medical profession on site to observe for signs of heat-related illness
- Know the location of the nearest medical facility

AHETF anticipates that applicators who participate in the study will spend the bulk of their time in the closed cab tractor; driving the tractor and making applications. This is a "sedentary" activity as defined by the North American Free Trade Association (NAFTA) Technical Working Group on pesticides (1998), so physical exertion is low which will reduce the likelihood of heat-related illness. However, each participant will be required to spray at least three loads of pesticide spray, so there will also be some time spent at a mixing/loading site waiting while another (non-study) worker prepares the next load. During these times, the study participant may exit the cab and be exposed to ambient temperatures and humidity which will increase the likelihood of heat-related illness. Applicators may also exit the cab periodically to adjust or repair equipment, if that becomes necessary.

Since workers may exit the cab, AHETF will monitor ambient conditions outside the cab to determine the heat index and base monitoring decisions on the external heat index. Workers in closed cabs that are not air conditioned will be subject to the heat index cutoff of 120º F as measured outside the cab (note that this situation reflects shaded conditions so the heat index is not adjusted for sunny conditions). However, when a subject is inside an air conditioned closed cab, the external heat index will not be applicable to that subject and exposure monitoring will not necessarily stop if the heat index cutoff is reached or exceeded. A worker will be allowed to exit the cab for short periods of time even if the heat index cutoff is exceeded; however, if the duration of exiting becomes prolonged (more than 30 minutes), the Study Director or other researcher shall stop the monitoring and/or move the worker to a cooler environment until monitoring can be resumed. For example, a worker who exits an air conditioned cab to adjust the airblast sprayer (e.g., nozzles, deflectors, pressure, etc.) might spend only a few minutes doing so and monitoring would not need to be stopped. On the other hand, if a worker exits to make a repair of the equipment, and it takes more than a half-hour, researchers will stop the monitoring and/or require the worker to move into a cooler environment (e.g., back into the air conditioned cab or into a cooler building).

In addition to the procedures discussed above, it is possible that some monitoring will take place at night or early in the morning to avoid excessively hot and humid conditions. Discussions with orchard airblast applicators in Florida and Georgia (July, 2007) indicate this is often preferred by workers since winds tend to be lower than during the day and temperatures tend to be cooler. AHETF will encourage this practice when daytime conditions are expected to approach the heat index cutoff of 120º F (adjusted for direct sun, if applicable).

2.3.2 Risk of Exposure to Surrogate Chemicals

The short duration of study participation for a subject (generally only one day) limits the risk of toxicity from surrogate chemicals to acute toxic effects (i.e., the potential for chronic effects is negligible). The active ingredients proposed for use in this study have been reviewed to determine the relative acute toxicity risks and status of reregistration at EPA. This study could involve either of two active ingredients: carbaryl or malathion.

The pesticide products containing these active ingredients and potentially used in this study are currently registered for airblast applications to citrus crops. AHETF will only monitor workers making applications in accordance with all label and Worker Protection Standard (WPS) requirements. Margins of Exposure (MOEs) are presented below for the highest amount of active ingredient that will be handled in this scenario (100 lb ai/day). For each of the active ingredients that may be used in this scenario the calculated MOEs greatly exceeded the required MOE for both the individual dermal and inhalation routes of exposure, as well as for the combined exposure, and their use is acceptable for this scenario.

Margins of Exposure for Closed-cab Airblast Application:

	Carbaryl	Malathion
Max. Daily Amount Handled	100 lb ai/day	100 lb ai/A
Dermal MOE	**3,308**	**4,885**
Inhalation MOE	**1,719**	**40,313**
Combined MOE	**1,130**	**4,400**

Level of concern (LOC) dermal = 100
LOC inhalation = 100 (carbaryl) or 1000 (malathion)
LOC combined = 100

The potential surrogates are listed below. All include minimal PPE requirements, especially the need for only a single layer of clothing. A summary of the signs and symptoms of acute overexposure to these products is presented in the following table. Additional detailed information is presented in the Product Risk Statements for these products (attached to the Informed Consent Form).

Product	Signal Word	Acute Toxicity Summary
Sevin® brand 80WSP Carbaryl Insecticide	CAUTION	• Slight eye irritation • Low toxicity for oral, dermal, and inhalation routes • Cholinesterase inhibition
Sevin® brand XLR Plus Carbaryl Insecticide	CAUTION	
Sevin® brand 4F Carbaryl Insecticide	CAUTION	
Fyfanon® 8 lb. Emulsion	CAUTION	• Moderate skin irritation • Moderate eye irritation • Possible allergic skin reactions • Low toxicity for oral, dermal, and inhalation routes • Cholinesterase inhibition
Fyfanon®	CAUTION	
Malathion 8-E	CAUTION	• Moderate eye irritation • Slight skin irritation • Possible allergic skin reaction • Low toxicity for oral, dermal, and inhalation routes • Cholinesterase inhibition
Gowan Malathion 8 Flowable	CAUTION	

AHETF will make an effort to select growers who would normally be using one of these products regardless of their participation in the monitoring study. However, some growers might agree to use one of the listed surrogate products as a substitute for their usual product. In all cases, AHETF will ensure the workers are informed of the risks associated with the specific surrogate product during the informed consent process and prior to participation by reviewing the product label with the worker. In addition, attached to the informed consent form will be a Product Risk Statement that details the signs and symptoms of overexposure for the specific product that each worker will handle. This risk statement must be understood and signed by the subject during the consent process.

The risk of acute toxicity will be minimized by reminding workers of safe handling practices prior to participation in the study, ensuring that worker clothing meets WPS requirements prior to participation, and enforcing the use of label-specified PPE (especially the use of gloves outside the cab if contacting contaminated surfaces) during participation.

For this application study, participants will only be exposed to product that has been diluted in water. The closed cab will likely provide

significant protection from both dermal and inhalation exposure. In addition, dermal exposure potential will be reduced since the long underwear will intercept chemical that might otherwise reach the subject's skin. Therefore, the likelihood of acute overexposure to the test substance during this study is expected to be very low.

2.3.3 Risk Associated with Scripting of Field Activities

AHETF may script certain participant activities to achieve diversity in some factors that might have an impact on exposure potential for a scenario. In particular, for this closed cab airblast application study scripting may be needed to ensure that at least three loads are handled or that certain amounts of active ingredient are handled. However, workers will not be asked to use equipment they do not have recent experience with (i.e., within the past year).

In order to ensure all MUs involve handling at least three loads, AHETF may ask some workers to use a smaller tank size or a higher spray volume than they would normally select. This might lead to a slightly longer work period for those workers which may increase the risks of acute toxicity to the surrogate chemical and of heat-related illness. This type of scripting is only likely for MUs involving the lower amounts of active ingredient handled (AaiH) in the study, such as 5 to 9 or 10 to 17 pounds of AaiH (Section 7.8). If spray volume is increased, the worker's exposure would be to a more dilute spray solution. The increased work period might increase the risk of heat-related illness, but this scripting is likely to result in work periods of only about 4 hours. In summary, scripting to ensure at least three loads are handled involves MUs with relatively low chemical exposure and relatively short work days, so this type of scripting is not likely to result in increased risk.

In order to achieve diversity in AaiH at the high end, AHETF may ask some workers to use larger tank sizes or a lower spray volume per acre than they would normally select. These changes might result in longer work periods and greater chemical exposure than would otherwise occur and this may increase the risks of acute toxicity to the surrogate chemical or heat-related illness. With regard to the increased risk of heat-related illness, this will primarily depend on local environmental conditions. For these MUs, researchers must be extra vigilant in following the guidance discussed above for minimizing the risks of chemical exposure and heat-related illness. Therefore, AHETF believes the risk of chemical toxicity for this study is low relative to other approved label uses.

2.3.4 Psychological Risks

Participating in AHETF exposure monitoring studies involves activities that are unusual and might cause subjects psychological distress. These include:

- Performing an over-the-counter pregnancy test prior to participation (females only)
- Allowing a researcher to assist with removing long underwear

Minimizing the risk of psychological harm related to pregnancy tests involves providing a private place for women to take the test and following procedures outlined in SOP AHETF-11.D to ensure the confidentiality of a positive result. Minimizing the risk of embarrassment during undressing involves providing a private dressing area and ensuring a worker of the same gender will be available to assist in the process.

2.3.4 Risk of Exposure to Detergents During Face/Neck Wipe and Hand Wash Sampling

A very dilute detergent solution (0.01% v/v Aerosol® OT in water) is used as a surfactant for face/neck wipes and hand washes for all MUs. The only variation between MUs is in the duration of exposure since longer work periods or frequent eating breaks can lead to multiple hand washes and/or face/neck wipes. This surfactant is in a very dilute solution and its use represents a very short exposure period, but the undiluted surfactant causes mild to moderate skin and eye irritation in animals. This risk is minimized by making fresh solutions shortly before monitoring, being careful to avoid accidental exposure to the eyes during face/neck wipes, and having an eye rinse station on hand in case of an accidental exposure.

A long history of using this mild detergent solution in pesticide exposure monitoring studies indicates the likelihood of skin or eye irritation is negligible.

2.3.5 Background Risk of Injury Associated with Agricultural Work

Agriculture remains one of the country's most dangerous occupations (i.e., farm occupations, see Bureau of Labor Statistics). It perennially ranks in the top ten occupations measured by fatality rate (on-the-job deaths divided by total number of workers) or injury/illness rate. The most common risks for serious injury to farmers are vehicular accidents (especially tractor rollovers, but also accidents while driving machinery on roads) and entanglement with moving parts of farm

machinery. Farm workers are also commonly exposed to a variety of chemical products that present increased risks compared to the general public. These include pesticides, fertilizers, solvents, lubricants, fuels, etc.

For this closed cab airblast application study, the risk of injury will involve the use of mechanical equipment for all MUs (the tractor as well as the airblast sprayer) and for some MUs will likely involve the use of chemicals in addition to the AHETF surrogate chemical, such as spray adjuvants or other pesticide products. These risks are discussed below.

This study will require workers to utilize two pieces of equipment: a closed cab tractor and an airblast sprayer. AHETF will have very little input on the choice of equipment that workers utilize during exposure monitoring since it is generally dictated by the crop involved and the size of the farm or operation. However, AHETF will require that all participants have experience operating the particular equipment they will utilize in the study. Workers will operate their usual tractor unless researchers determine the closed cab is not intact. If that happens, the worker can use another suitable tractor with which he has experience. Workers will use their usual sprayer unless AHETF requests a different tank size. If that happens, the worker can use a more suitable sprayer with which he has experience, but if no such sprayer is available another worker will be selected who has the necessary experience with that equipment. These practices are designed to ensure the risk of injury from equipment is not increased by asking a worker to use equipment he is not familiar with.

Growers often choose to include chemicals other than the pesticide product in their tank mixes, such as anti-foam agents, spreaders, stickers, other pesticides, or fertilizers. This is likely to be the case during this study, but it is impossible to know in advance, since some decisions are made at the last moment depending on agronomic conditions. AHETF generally is not concerned by the use of such “tank mix partners” as long as they are legal uses, don’t interfere with chemical analysis of the AHETF surrogate pesticide being applied, and do not require the worker to wear any additional PPE. Prior to allowing the use of tank mix partners AHETF researchers will ensure that none of these situations exists. Since AHETF does not ask that additional products be added, participation in the study does not result in an increase in the chemical toxicity risk associated with tank mix chemicals above what would normally be experienced by the worker. Nevertheless, a researcher will review the label precautions for all tank mix products with the worker prior to their handling the products. This discussion will be documented by the researcher and ensures the

workers are informed of the risks associated with these tank mix products.

In summary, this study will likely involve a risk of physical injury based on the nature of the agricultural work involved and possibly an increased risk of heat illness. The following practices, designed to minimize these risks and respond to injuries, will be followed during this study:

- Selecting only experienced pesticide handlers
- Requiring experience operating the equipment to be used
- Reminding workers of safe chemical handling practices
- Identifying nearby hospitalization facilities in case of emergency
- Monitoring the heat index and stopping the study if conditions warrant
- Providing transportation to medical treatment and covering the costs of treatment
- Having a medical professional on site to observe the workers and provide urgent care
- Observing study participants throughout the monitoring period
- Ensuring that all tank mix products are used according to approved label (s) and that no additional PPE is required.

2.4 Benefits

The risks and benefits of the study described in this protocol will be reviewed with potential participants during the consenting process. There are no personal benefits to the study participants. Growers who allow the study to be conducted using their equipment, crops and facilities will be reimbursed for the pesticides used for the study. While this is beneficial to the grower, it is considered a minor benefit when compared to the costs of running their businesses. The AHETF member companies will accrue the advantage of fulfilling their regulatory data requirements and improving regulatory risk assessments, while substantially reducing the number of human subjects necessary to conduct similar studies by individual registrant companies.

Data from the AHETF exposure monitoring program has the potential to improve the ability of EPA and other regulatory agencies to accurately assess potential occupational risks associated with spraying pesticides using airblast equipment and closed cab tractors. The knowledge obtained from the monitoring program is generalizable and will be used to assess risks to new pesticides. Knowledge could also be used by EPA to impose stricter safety standards on currently used pesticides, when appropriate. Consequently, the farm community will be better protected and at the same time less likely to be

needlessly deprived of product benefits.

Since data suitable for use in a generic database do not exist for closed cab airblast application workers, society will benefit from data generated by this study from the improved risk assessments resulting from the use of the data by EPA and other regulatory agencies.

2.5 Risk/Benefit Balance

By monitoring exposure to professional agricultural handlers who follow their normal practices, but wear an additional layer of clothing (as an inner dosimeter which traps chemical that penetrates the work clothing), this study presents a greater than minimal risk to participants. The primary risk comes from their employment as an agricultural worker where accidents and chemicals contribute to injury and illness. In particular, this scenario involves the use of mechanical equipment that could cause physical injury and handling chemicals that could cause adverse health effects. However, workers will be experienced with the equipment they will be using and will follow their usual practices while handling pesticides approved for this use pattern.

Participating in this study increases the risk of heat-related illness, but this risk is mitigated by a medical management program which emphasizes prevention measures and guidelines for stopping participation when warranted based on environmental conditions.

In conclusion, the benefit to agricultural workers as a whole and to society in general, in the form of more accurate measurements of potential exposure to pesticides, must be weighed against the risks to participants. Airblast applications are common in both orchard and trellis crops across the country and a wide variety of experts indicated to AHETF that closed cabs are most common and are becoming more common. Therefore, a modern set of data for this scenario will provide a significant benefit to society. This study will contribute directly to that data set. Because AHETF has calculated MOEs which indicate that acute toxicity effects are unlikely, and because there are extensive procedures established to minimize all risks to participants, the likelihood of serious adverse effects is small. Therefore, AHETF believes the risks to study participants from this study are offset by the benefit to society.

2.6 Respect for Subjects

2.6.1 Subject Privacy

The AHETF engages many procedures designed to protect subject privacy during recruitment, consent, study conduct, and maintenance

of study records. The consent form also summarizes important confidentiality issues for subjects. These procedures, summarized below, will be followed during this study.

Initial contact with workers during recruitment will be made without the presence of their employer as described in detail in Sections 2.7 and 6.2 of this protocol. If workers are interested in participating, a private meeting with the Study Director or his/her designee will be used to obtain consent.

Pregnancy tests, required for female participants, must be conducted within 24 hours of the start of the monitoring period. These will be self-administered in a private restroom, but under the supervision of a female researcher. Positive results from pregnancy tests will not be documented or given to a woman's employers or co-workers. If a female volunteer has a positive pregnancy test result, she must withdraw from participation but can do so without stating a reason. Consent forms and all other records associated with the worker will be promptly shredded (SOP AHETF-11.D). Negative results must be confirmed by a female researcher and recorded in the study files.

Certain worker information will be collected during the course of this worker exposure monitoring study. The information collected, such as notes taken by study observers, will not be available to a participant's employer. Most information identifies subjects only by a unique worker identifier. Forms and paperwork that contain personal information (including a worker's name or address) will be kept confidential in a sealed envelope while in the field. After the study is completed, this confidential envelope will be sent to AHETF archives with the other raw data. Unrestricted access to this confidential information is allowed only to the AHETF Administrative Chair (SOP AHETF-6.B).

The information collected in this study may, under certain regulatory circumstances, be given to the U.S. Environmental Protection Agency (EPA) or to state governmental agencies and other countries. Participants in the study will be informed their names will not be disclosed, but that absolute confidentiality cannot be guaranteed because of the need to give information to these parties.

The results of this research study may be presented at meetings or in publications; however, only a unique worker identification number will identify each worker in reports or presentations.

2.6.2 Freedom to Withdraw

The absolute right for subjects to withdraw from the research is the

cornerstone of protection of human subjects. Prospective and enrolled subjects will be informed of their right to withdraw without consequence prior to and during the conduct of the research.

Any volunteer expressing a need or desire to withdraw from the research after exposure monitoring begins will be paid $80 and allowed to return to their normal work duties for their employer. If a participant withdraws while being monitored, the long underwear and air sampling pump will be removed, and the hand and face/neck samples will be collected with the worker's consent. The Study Director will decide whether these samples will be analyzed (SOP AHETF-8.K).

2.7 Informed Consent

The Study Director or designated member of the study team will obtain informed consent from all study volunteers prior to their participation in the study. The consenting process is conducted in a private meeting between the researcher and the volunteer (and possibly other individuals as described below). Depending on the circumstances, consenting may occur several days prior to the study up to the day of the study. In either case the volunteer will be given a copy of the consent form to review at least one day before the consent meeting. The volunteer may invite other persons to be present during the consent meeting. For example, the volunteer may feel more comfortable with a confidant or counselor in the consent meeting with him/her.

Study participation will be limited to English or Spanish speakers. When Spanish speakers are involved, a bilingual researcher will be utilized to translate verbal information presented by the Study Director or designee. Potential participants that have limited reading ability will have the consent form verbally explained in their preferred language (English or Spanish) with an impartial witness present. Witnesses must have no association with AHETF, its member companies, researchers, growers, or workers. Witnesses must have some familiarity with farming and will be recruited from any appropriate source such as a university, grower association, or other organization. The witness cannot serve as the interpreter or an advisor to the volunteer. The witness will sign the consent form to acknowledge that the study participant apparently understood the information presented to him/her.

During the private consent meeting the worker will be provided with a full explanation of the study, its requirements, any potential risks, and its likely benefits. Workers will be informed that the grower or their employer will be reimbursed for the product used in the conduct of the study on their farms. Workers will be advised of their right to withdraw from the study at any time and for any reason without jeopardizing their normal position with their employers. Each volunteer will be provided a copy of the supervisor's signed

Employer's Cooperation Statement (in the worker's preferred language) that states they will not suffer any consequence if they decide to participate or not and they will receive their usual pay for the day when the study is conducted. The volunteer will be informed that he/she will receive the $20 remuneration payment even if he/she decides not to participate.

The volunteer will be provided information about the risk of the particular product he/she will handle, including signs and symptoms of acute overexposure. The product and its risks will be identified in a Product Risk Statement that is an attachment to the consent form. The participant must read, understand, and sign and date the attachment. Appropriate sections of the product label and Material Safety Data Sheet will be discussed by the person conducting the consent meeting and made available for review by the volunteer. WPS requirements, especially proper use of clothing, personal protection equipment, and cleaning facilities will be discussed.

The Study Director or designated member of the study team will discuss the germane aspects of the AHETF medical management plan with the prospective participants. Information will be provided about the risk of heat stress, including signs and symptoms, and ways to prevent it.

The IRB-approved consent form will be presented in the preferred language (English or Spanish) of the volunteer. All sections of the consent form including the test substance Product Risk Statement will be discussed in detail.

During the discussions with potential participants, ample time will be provided for questions and any additional information or clarification that is requested will be provided. When the Study Director or designated member of the study team is satisfied that the volunteer understands the requirements and risks of the study, and if the worker still wants to participate, he/she will be asked to sign and date the informed consent form and the Product Risk Statement. The member of the study team conducting the interviews (and witness, if applicable) will also sign the consent form and provide a copy of the signed form (and signed attachments) to the worker. The worker will be informed of the impending date of the study and paid $20 for their participation in the private meeting.

When the pool of available worker volunteers at a site, or a particular citrus grove, exceeds the number of MUs required, a simple random selection of equivalent participants will be made. All potential participants will be informed of the possibility of not being selected for this reason. Volunteer workers who decide against participation or who are not selected will be paid $20 for meeting with the study team member and released to resume their normal activities.

In all situations, if the AHETF interviewer is not comfortable that the worker

fully understands the discussions and the contents of the consent form, the worker will be excluded from consideration to participate in the study. This will be ascertained by providing repeated opportunities to ask questions and by asking questions of the potential volunteers that would require a response that indicates understanding of key issues for all sections of the consent form. These responses will be documented and if necessary the person conducting the consent meeting will re-explain topics until the volunteer demonstrates an appropriate understanding.

2.8 Post-Exposure Follow-Up

During the consenting process each volunteer will be provided the opportunity to request a summary of their personal results from the study. This will require the worker to provide a name and address (mail or e-mail). The results will include the distribution of chemical exposure among the various body areas measured so the worker can be aware of where most dermal exposure occurs. Results are typically available six to nine months after monitoring occurs. The personal information related to this follow-up will be retained in the confidential envelope described above (SOP AHETF-6.B).

Just prior to the completion of the worker's participation in the study, a researcher will remind the participant he/she should bathe or shower as soon as practical and that they have received a copy of the signed consent form with phone numbers for reporting any health changes they think might be related to participation in the study. Post-study inquiries will be forwarded to the Study Director who will deal with the situation as appropriate and notify AHETF management (SOP AHETF-11.B).

3.0 SITE OF THE FIELD PHASE OF THE STUDY

The site for the field phase of the study will be commercial citrus groves in Polk and Hillsborough counties in Florida. These counties were selected because Polk is highest in orange production and Hillsborough is an adjacent county accessible to major transportation routes. In addition, AEHTF has already expended resources to discuss airblast applications with the handler community in Florida citrus (Bruce, et. al. 2007) and identified a suitable Local Site Coordinator. These counties are typical of citrus producing areas of Florida that utilize conventional closed cab airblast equipment to maintain the groves. The counties are also adjacent to citrus producing counties that can be contacted if suitable test conditions cannot be found in these two.

Exposure monitoring will be conducted in at least three citrus groves and require at least three citrus growers within the identified counties.

Researchers will identify eligible growers using a random method as described below.

The primary considerations for site selection will be the availability of citrus crops sprayed with airblast equipment, suitable growers that are willing to use the AHETF surrogate compounds and are willing to participate in the study, and the availability of a Local Site Coordinator with experience conducting similar studies and a familiarity with agricultural practices in the area. Full details of the site selection process and actual sites will be recorded in the study file.

4.0 ELIGIBLE GROWER POOL SELECTION

4.1 Use of Local Resources to Identify Potential Eligible Local Growers

AHETF researchers will contact local resources from each of the following categories in Polk and Hillsborough counties in Florida:

- Local Site Coordinator (LCS)
- Commercial Applicator Firms that service citrus groves
- University Agricultural Researchers / County Extension Agents
- Crop Consultants (e.g., pest control advisors or commercial applicators) that service citrus groves
- Chemical Dealers or Sales Representatives
- Citrus Grower Associations

The researchers will briefly explain the AHETF Exposure Monitoring Program to the local resources who are then asked for a list of growers in Polk and Hillsborough counties who are commercial citrus producers and might utilize airblast equipment in their operations. The list of growers from all of the resources will be compiled and duplicate names eliminated. All local resource contacts shall be documented in a detailed record that shall be maintained in the study file.

4.2 Random Selection of Eligible Growers

The compiled list of growers from local resources shall be placed in random order for further consideration. The randomization process will be documented and maintained in the study file.

The growers shall be contacted, one at a time, following the random order, to determine whether the grower is ‘eligible’ to participate in this study. Researchers making the contacts will briefly explain the AHETF Exposure Monitoring Program including the need for the proper equipment, potential worker volunteers, ethical aspects of the study, and reimbursement for the products they supply for the conduct of the study on their farms. Growers are considered eligible who:

- Are willing to cooperate with AHETF, including the ethical aspects of the research,
- Are commercial citrus producers,
- Spray their crop(s) with conventional airblast equipment with closed cabs,
- Have at least one worker with experience making closed cab airblast applications,
- Are willing to allow AHETF to recruit his/her worker(s) for the study
- Have sufficient acreage so the minimum AaiH stratum can reasonably be handled by a worker in one day, and
- Are willing to use at least one of the surrogate active ingredients listed in the study protocol and agree to be reimbursed only for the products utilized in the course of the study on their farm.

Growers who meet the criteria above but indicate they use commercial applicators to make airblast applications to their crop will tentatively be considered eligible. Those growers will be asked to identify their preferred commercial applicator(s) and researchers will contact them to screen them for willingness to cooperate by providing suitable equipment and workers to spray that specific grower's crop. This step in the procedure ensures that first the crop acreage is identified and then equipment and workers associated with that acreage are identified. The actual workers involved could be the grower himself, the grower's employee, or an employee of a commercial applicator that services that grower.

Each grower identified as eligible (sometimes with an associated commercial applicator) is placed into a working pool and the following information is assembled to allow construction of an efficient MU selection design:

- Crop(s) available, with acreage that might be treated
- Specific location of crop(s) that might be treated
- Description of equipment available (e.g., number, type, and size)
- Surrogate chemical(s) that might be utilized
- Approximate timing of surrogate applications
- Number of workers available
- AaiH those workers might be able to handle in a day

Screening of the growers (in the order of the random list) continues until the pool of eligible growers (and/or commercial applicators) contains at least 10 workers who may potentially volunteer for the study, and at least 2 workers are available for each of the AaiH strata. This pool will include more growers and more workers than are ultimately needed for the study.

This process results in a random sample of eligible growers and, by association, a random pool of potential workers associated with eligible growers. All grower contact discussions and decisions made during this eligibility screening will be documented in a detailed study notebook provided

by AHETF or kept in files bearing the study number.

5.0 EFFICIENT MU DESIGN

The Study Director and Local Site Coordinator will assemble the information obtained from the pool of eligible growers to construct a plan to efficiently assign all MUs in the study. Details of the potentially available MUs will be used to identify one configuration of MUs (i.e., growers, chemicals, workers, AaiH, timing) that will result in an efficient study. The efficient configuration will be comprised of a group of at least three growers that are near each other, can provide separate workers for all the five strata of AaiH, utilize some diversity in equipment, and plan to make applications within a narrow time frame. The growers and/or commercial applicators in the chosen configuration provide the pool of workers from which study participants will be recruited.

6.0 PARTICIPANT SELECTION

6.1 Site Inspection

The Study Director and/or Local Site Coordinator shall arrange to visit growers from the pool of eligible growers to confirm the suitability of their operation for the study. In accordance with SOP AHETF-11.B the individual growers will be asked to sign a non-coercion statement (Employer Cooperation Statement) affirming to their workers and AHETF that they will not coerce or unduly influence their workers to either participate or not participate in the study. Growers must also certify that alternate work will be provided on study days for workers who choose not to volunteer; and that the employee's decision to participate or not will have no impact on their employment. For grower/owners or grove operators/managers or commercial applicators that do not have a supervisor, but who are eligible handlers themselves, this form is not applicable and will not be used.

6.2 Initial Potential Participants Recruitment

AHETF will follow standard procedures (see SOP AHETF-11.B) to recruit potential participants for this closed cab airblast application study. Individual workers will be recruited during an initial site inspection or subsequent visit(s) to an eligible grower facility.

The Study Director or designated researcher will seek permission from the eligible grower to approach his/her employees to recruit volunteers for the study. Depending on the number of employees and size of the grower facility the Study Director or researcher may contact employees through the use of an informational recruitment flyer posted in a common work area. Such a flyer

will briefly describe the research study and provide contact information for employees who may have an interest in participation in the study. The flyer shall have been previously reviewed and approved by an IRB.

Alternatively, or subsequent to the use of a flyer, the Study Director or researcher will arrange a meeting with the grower's employees who express an interest in participation. Such meetings will always occur without the grower or supervisors being present (SOP AHETF-11.B). The Study Director or researcher shall make a presentation describing the AHETF Exposure Monitoring Program, the goals of the research study, the procedures used in exposure monitoring, and the risks and benefits to participants. Contact information will be provided, and individuals will be encouraged to contact AHETF if they desire additional information about the study or are interested in participating in the study. All presentation materials, such as handouts or visual aids, shall be reviewed and approved by an IRB prior to use in recruiting subjects.

The Study Director or researcher shall continue conducting site inspections and potential participant recruitment as described above until an adequate number of eligible growers and potential participants have been secured for an efficient configuration of all MUs in the study. During this process, the following restrictions will be maintained:

- At least 10 workers who may potentially volunteer for the study
- At least 2 workers available for each of the AaiH strata
- No more than 2 MUs from any one grower (this effectively requires at least 3 different growers since 5 MUs are desired)
- No workers may be used more than once
- No piece of equipment (tractor plus sprayer) may be used more than once

As indicated above, the efficient configuration must include a sufficiently large selection of eligible growers and potential participants to ensure there are adequate numbers to fill all MUs in the study, even in cases where growers or participants are not available at the last minute for the time interval scheduled for the field phase of the study.

6.3 Participant Selection and Consenting

The Study Director or designated researcher will establish a pool of eligible growers and workers (potential participants) from those in the efficient configuration who shall be contacted prior to initiating the field phase of the study to confirm their availability and interest in being in the study.

The Study Director or designated researcher will arrange a place and schedule to conduct consent meetings with individual volunteers from the eligible pool. Prior to such meetings, accommodations will have been made for interpreters,

witnesses, and ancillary personnel who must be present for the meeting. Consent meetings shall be conducted as described above in Section 2.7.

7.0 FIELD MATERIALS AND METHODS

7.1 Test System Identification - Workers

The test system for this study is the worker handling pesticides according to label directions. Workers may include farm owners, farm operators, farm employees, contract applicator employees, or employees of agricultural research facilities. Passive dermal dosimetry methods will be used to determine potential exposure of experienced workers handling the test substance. Inclusion/exclusion criteria have been enumerated in Section 2.1 of this protocol. The recruitment and consenting process will follow the procedures presented in Sections 2.7, 6.2, and 6.3 of this protocol. Details are provided in SOP AHETF-11.B. A total of five applicators are anticipated for this study.

7.2 Justification of the Test System and Test Substances

Experienced agricultural workers handling pesticide products using commercial product packaging and typical handling procedures will be monitored. Monitoring these workers provides the best estimate of potential dermal and inhalation exposure for handlers applying pesticides with conventional airblast equipment using closed cab equipment.

The test substances selected for this study are registered and approved for use in a wide variety of agricultural settings, including airblast application to citrus crops. The justification for their possible use in this study is that they have each been deemed suitable by the Sponsor as surrogate compounds for generating exposure data appropriate for a generic database. In addition, the analytical methods have been validated and these products have the requisite degree of stability under field, storage, and transit conditions.

7.3 Mixing/Loading Stations and Application Area

Field maps and/or sketches will be provided in the raw data showing the exact locations where mixing/loading and application occur. Relative distances between mix/load areas and application areas will be recorded. These will include area and local maps or sketches for all sites involved in the study.

7.4 Study Personnel – Field

The study team will be comprised of a sufficient number of people to conduct the following activities:

1. Monitoring the workers and environmental conditions to ensure safe working conditions
2. Assisting with the donning and collection of all dosimeters in a time-efficient manner to minimize the time from completion of the work cycle to sampling (requires a female researcher if there will be female participants)
3. Fortifying field recovery samples
4. Calibrating air sampling pumps and recording beginning and ending flow rates
5. Observing and recording all work practices, recording site details and treatment details
6. Taking a photographic record of representative study-related activities
7. Evaluating the working order and condition of application equipment
8. Monitoring by a Quality Assurance Officer of operations for compliance with the GLP regulations

7.5 Test Substances

7.5.1 Approved Test Substances

The test substances approved for use in this study are listed in Section 2.3.2 above and Table 1 below. The most appropriate test substance, based largely on the preference of the grower, will be used at each of the individual locations. A different test substance may be used at each location and by each worker within a location if appropriate.

Selection of the exact test substance is determined as the product selected by an eligible grower for his crop on the day of the study. As previously described, eligible growers are selected from an efficient configuration of MUs who plan to use or are willing to use one of the products approved by the AHETF. As the time approaches to conduct the field phase of the study, the grower will confirm the actual product he will be using on the day of the study. The researchers will insure a sufficient amount of the test substance product will be available at the grower site. The AHETF will reimburse the grower for the product used in the study at the completion of the study on his farm.

The product name, active ingredient and nominal concentration, EPA registration number, CAS number, lot number, formulation type, package type, and package size will be recorded for each product used by monitored workers.

Table 1. Approved Test Substances for AHE55

Test Substance	Active Ingredient	Type	Activity

Sevin® brand 80WSP	Carbaryl	Powder in water soluble bags	Insecticide
Sevin® brand XLR Plus	Carbaryl	Liquid flowable	Insecticide
Sevin® brand 4F	Carbaryl	Liquid flowable	Insecticide
Fyfanon® 8 Lb Emulsion	Malathion	Emulsifiable concentrate	Insecticide
Fyfanon®	Malathion	Emulsifiable concentrate	Insecticide
Malathion 8-E	Malathion	Emulsifiable concentrate	Insecticide
Gowan Malathion 8 Flowable	Malathion	Liquid flowable	Insecticide

7.5.2 Active Ingredient Stability

The stability of the test substances under recommended storage conditions will be documented before the start of the study. Generally, AHETF will rely on data supplied by the product registrant that were submitted to support the EPA registration of the test substance. Study researchers will record the storage conditions, including temperature, during the days of use of the products at the eligible grower's facility.

7.5.3 Purity Analysis

A sample of each lot of test substance used by each worker in the study at each location will be collected and sent to a designated laboratory for GLP purity analysis (content of active ingredient in the test substance). Purity analysis will be conducted concurrently with analytical phase of the study. Documentation of such analyses will be retained in the study raw data.

7.5.4 Retention Samples

Retained samples from each lot of the test substance(s) used in the study will be sent to the AHETF archive facility.

7.6 Application Parameters

Carrier: Water

Target application rate: Products will be applied at a rate specified on the label for the particular crop. Rates depend on target crop and field needs. Actual application rates will

	be documented in study raw data.
Target application volume:	Application volume will comply with the product label. Volumes depend on target crop and field needs. Actual application volumes will be documented in study raw data.
Route of application:	Applications will be made using available common airblast application equipment.

7.7 Equipment Accuracy Verification

Mixing/Loading equipment accuracy will be verified according to field testing facility SOPs prior to use in this study. This will include equipment used to pump or meter the carrier during the mixing/loading process.

Copies of relevant facility maintenance records (if available) for all mixing/loading and application equipment used for this study will be obtained and retained with the field raw data. The Study Director or designated member of the study team will assure equipment operation is acceptable according to SOP AHETF-10.D.

Workers will only be allowed to handle equipment for which they are familiar and have used recently. This will help ensure the safety of the worker when handling equipment and ensure that the procedures followed by the worker are normal and typical of their usual job function.

7.8 Amount of Material Handled

The amount of test substance that is mixed and loaded for each applicator worker will be determined and recorded in the raw data. Each worker will handle an amount of active ingredient designed to achieve a within-cluster diversification of AaiH following the standard approach of partitioning the practical AaiH range for the scenario into five strata. These strata are:

(1) 5 to 9 pounds ai handled
(2) 10 to 17 pounds ai handled
(3) 18 to 30 pounds ai handled
(4) 31 to 55 pounds ai handled
(5) 56 to 100 pounds ai handled

A single MU will be conducted in this study from each of the five strata.

The volume of spray mixture applied will be determined and recorded in the field raw data, along with other critical measurements including application

area and duration. Upon completion of spraying each load of diluted product, the amount of spray volume remaining in the tank(s) will be determined and recorded in the raw data. Disposal of excess spray mixture will occur in accordance with applicable regulations.

7.9 Rationale for the Route of Administration

The above handling procedures represent typical agricultural practices for each particular location and test substance.

8.0 DERMAL EXPOSURE SAMPLING

Full details of procedures for dermal and inhalation exposure sampling, and sample removal, are specified in the most recent versions of SOPs AHETF-8.A, 8.B, 8.C, and 8.D. At the completion of the monitoring period, exposure samples will be taken in the following order to minimize cross contamination: inhalation samples (discussed in the next section), then hand washes, then face/neck wipes, and finally inner dosimeters as described below and in SOP AHETF-10.E.

Workers will wear the clothing and PPE required by the product label. Depending on the particular product, this may include long pants, long-sleeved shirts, waterproof gloves, chemical resistant gloves, protective eyewear, shoes, and socks. The clothing can be provided by each worker as long as the Study Director agrees they are compliant with the WPS. All items worn must be compliant with the WPS, and the clothing must have been laundered since being worn while handling pesticides, or be new. Any clothing items deemed unacceptable by the Study Director will be replaced by alternate clothing (see SOP AHETF-8.F). Upon approval by the Study Director, workers may wear a hat or cap.

Workers will wear one layer of work clothing over the inner dosimeters. The inner dosimeter will consist of 100% white cotton long underwear, pre-washed and provided by the AHETF. The inner dosimeter is designed to represent the worker's skin and will act as a collection medium that will be analyzed. It will be worn throughout the period of monitoring and removed at the end of the work period, with the assistance of a member of the monitoring team.

Workers' hands will be washed just prior to the exposure monitoring period as described below. This assures that the worker hands are free of pesticide and provides an opportunity for researchers to ensure the worker understands how to assist with the hand washing procedure. The face and neck area will also be wiped just prior to the exposure monitoring period. All of the pre-monitoring hand wash and face/neck samples will be discarded.

At the end of the monitoring period (and after the inhalation exposure equipment is removed as described below), the worker will first remove his/her PPE (e.g. waterproof gloves) and shoes, then enter a clean, private area for collecting the

remaining samples. Once inside the private area, the worker will remove his/her outer clothing and socks. The outer layer of clothing and socks will not be collected or analyzed. To reduce the potential for cross contamination, each set of outer work garments will be used only once. Dermal exposure samples will be collected in the following order: final hand wash sample, final face/neck wipe sample, and the inner dosimeter.

Hand exposure will be measured by having the worker wash their hands in a 0.01% Aerosol OT solution according to a standardized washing procedure described in the most recent version of SOP AHETF-8.B. Interim hand wash samples will be collected whenever a worker would normally wash his/her hands (e.g., before using the toilet, etc.). These interim hand wash samples will be numbered sequentially, as described in SOP AHETF-8.F. After an MU is completed (i.e., at the end of the monitoring period) one final hand wash will be collected from each worker. The post-activity hand wash sample for each MU will be the final hand wash sample for the monitoring period and receive the final sequence number for the MU. This sample will be clearly marked as the post-activity hand wash. All hand washes collected during and at the end of the work period will be treated as separate samples. All hand wash samples will be poured into pre-labeled containers and placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will be maintained in frozen storage until analysis.

Face/neck exposure will be measured by wiping the entire face and neck areas (front and back of neck) with two gauze sponges, sequentially, that have been wetted with 0.01% Aerosol OT as described in the most recent version of SOP AHETF-8.C. Interim face/neck wipe samples (consisting of two gauze sponges) will be collected prior to eating. After each MU is completed, a final face/neck wipe sample will be collected from each worker after the hand wash sample is collected and before removal of the whole body dosimeters. Face/neck wipe samples will be wrapped in aluminum foil prior to placement in pre-labeled re-sealable plastic bags. All wipes collected during the study for a worker will be combined in the same container, resulting in a single sample for analysis. If more than two samples (4 sponges) are in a sample container, the laboratory must be notified as to the number in the container. All face/neck wipe samples will be placed in pre-labeled containers and placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will be maintained in frozen storage until analysis.

Finally, the inner layer of clothing (inner dosimeter) will be removed with the assistance of a member of the study team and sectioned into two sections for all MUs (upper body and lower body). The sections will be individually wrapped in aluminum foil, placed in pre-labeled containers and placed into temporary frozen storage as soon as possible for transport to the analytical facility. Samples will be maintained in frozen storage until analysis.

9.0 INHALATION EXPOSURE SAMPLING

Full details of the personal air-sampling method, attachment of pumps, monitoring of

workers, and pump calibration are given in the most recent versions of SOP AHETF-8.D and 10.A. Suitable low-volume personal air-sampling pumps and OVS tubes with a glass fiber filter and the appropriate sorbent for the test substance being used are required. Valid calibration equipment, specified in SOP AHETF-10.A, and Tygon® (or equivalent) tubing are also required. The pumps and calibration equipment will be uniquely labeled and this information recorded in the raw data records.

Before the work commences, the sampling pump will be attached to a belt around the waist of the worker to be monitored. Tygon® tubing (or equivalent) attached to the inlet valve of the pump will be placed over the shoulder of the worker and attached to the air-sampling tube. A clip will be used to attach the tube to the collar of the worker, thus positioning it in the breathing zone of the worker. The inlet of the air-sampling tube will be facing downward, similar to the nasal passage of a worker.

Each pump will be calibrated, as specified in SOP AHETF-10.A, to a nominal sample flow rate of approximately 2 L/min and will operate for the duration of the exposure monitoring period. Flow rates will be measured before and after each exposure monitoring period and detailed records of flow rates and sampling durations will be maintained in the raw data records.

The pumps will be turned on immediately prior to the start of the monitoring period and will operate continuously until the end of the period. Detailed time logs will be maintained to allow the length of the exposure period to be calculated.

Periodically throughout the monitoring period, the pumps will be inspected to ensure they are still running and the tubing checked to ensure that there are no kinks. Workers will be instructed to inform a study team member if the pump fails to operate or the tubing becomes kinked.

If a pump stops operating during the work cycle, it will be replaced with a pre-calibrated replacement pump or given fresh batteries as soon as possible. Only the pump or batteries will be changed, the same sampling tube and tubing will continue to be used. At the conclusion of each exposure monitoring period, after the final flow rate has been recorded, the OVS tube will be disconnected from the tubing leading to the pump. The OVS tube will be sealed at both ends, placed in a pre-labeled container, and placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will be maintained in frozen storage until analysis (SOP AHETF-8.A).

10.0 CONTROL OF BIAS

Sampling bias will be controlled by sampling multiple workers over a period representative of a typical work day, and by sampling over the entire body of each worker. Quality control samples in the field and in the laboratory also act as methods for controlling bias.

11.0 FIELD RECOVERY EVALUATION

11.1 Fortification Procedures

Full details regarding field recovery evaluation procedures for all sampling media are given in the most recent version of SOP AHETF-8.E. The SOP instructions for "spiking using vialed spikes" and analytical standard in solvent will be followed.

Sample matrix fortifications designed to assess the stability of the active ingredient during field, storage and transit conditions in or on the sampling materials (inner dosimeters, hand wash solutions, face/neck wipes, and air sampling matrices) will be conducted on a minimum of one day of exposure monitoring at each location, or more days as appropriate for environmental conditions.

Fortification vials with solutions of active ingredient in appropriate solvent will be shipped and stored under frozen conditions until used in the field. The entire contents of the fortification vials will be applied to the sampling media. The OVS tubes will be pre-spiked with the active ingredient (generally in an organic solvent) at the analytical laboratory and kept frozen until their use in the field.

Storage conditions of the individual vials used for fortifications, and of the fortified OVS tubes, will be specified by the analytical laboratory and the actual storage details will be recorded in the study file.

After fortification, the inner dosimeters and OVS tubes will be exposed to ambient conditions (i.e., weathered) for the longest expected exposure monitoring period in a location away from possible contamination (e.g., upwind of mixing/loading and application operations). Inner dosimeter samples will be covered with a single layer of shirt material during weathering. Segments representing any body area may be used for inner dosimeter fortification samples. An air sampling system will be set up in a manner similar to that of the workers, in which a pump will continuously draw air through the pre-fortified filter and OVS tube for the entire duration of the work period.

Hand wash and face/neck wipe samples will be fortified and immediately placed in frozen storage without exposure to ambient conditions. In addition, on each fortification day, duplicate samples of the inner dosimeters fortified in the field at the highest level, and duplicate OVS tubes fortified in the laboratory at the highest fortification level, will be processed for immediate frozen storage and used as travel spikes. These travel spikes will be analyzed only if deemed necessary by the Study Director, for example to help determine the cause of unusually low field fortification recovery results.

Finally, on each fortification day, two untreated control samples of each matrix will be processed similar to the field fortification samples (i.e., some are weathered). Packaging, storage and shipment of the field fortification samples will be the same as for the worker exposure samples.

11.2 Field Fortification Levels

Matrices will be fortified in triplicate at the following levels:

Matrix:	Fortification Levels (µg/sample):
Inner Dosimeters	5, 100, and 2,000
Face/neck Wipes	5, 100, and 2,000
Hand Wash	5, 100, and 2,000
OVS Tubes	0.05, 0.5, and 5.0

12.0 OBSERVATIONS

Observations will be recorded according to SOP AHETF-10.C throughout the monitoring period while the workers perform their tasks. Any specific occurrences that could affect exposure will be noted on the observation forms. Measurements will be made of the amount of test substance handled. A detailed time log will be maintained for all activities. A photographic record will be taken of representative study-related activities during exposure monitoring.

13.0 ENVIRONMENTAL MONITORING

Exposure monitoring will not be conducted under meteorological conditions inappropriate for the conduct of the activity (e.g., excessive precipitation, excessive wind speed or other adverse condition). Adequate protection from the elements will be provided for handling worker exposure samples and field fortifications in case of inclement weather.

Environmental conditions, including air temperature, relative humidity, wind speed, and wind direction will be recorded by means of an on-site, portable weather station during exposure monitoring. Measuring equipment will be calibrated as per the field contractor's SOP. Additionally, observations concerning pertinent weather conditions, such as amount of cloud cover, degree of sunshine, rainfall, relative humidity, etc. for each day of monitoring will be recorded in the field raw data.

Most importantly, environmental conditions will be monitored regularly by the Study Director or designated members of the study team to evaluate the risk to workers of heat-related illness according to SOP AHETF-11.G and Section 2.3.1 of this protocol. These temperature, relative humidity, and heat index values will be recorded in the field raw data.

14.0 SAMPLE IDENTIFICATION, SHIPPING AND STORAGE

14.1 Sample Identification

The sample identification process is described in the most recent version of SOP AHETF-8.F. Samples will be identified and tracked by unique sample numbers assigned by AHETF. During the analytical phase of the study, the laboratory may assign its own sample numbers as long as the AHETF number is cross-referenced and included in the documentation of the sample.

14.2 Shipping

Samples will be shipped frozen to the analytical laboratory designated for the specific active ingredient used at each location. Full chain of custody record will be available for all samples.

14.3 Storage

All samples will be placed into frozen storage as soon as possible after collection; the analytical laboratory will store samples under frozen conditions until analysis. Freezers will be monitored and the temperatures documented.

15.0 ANALYTICAL PROCEDURES

Experimental exposure and field recovery samples will be analyzed according to the analytical methods for the active ingredient in the specified test substance used in the field. The methodology will have been validated for use in the relevant matrices prior to the initiation of the sample analyses.

15.1 Reference Substance(s)

The reference substance for this study is the analytical standard used by the analytical laboratory to prepare analytical standard solutions.

The Study Director or an authorized representative will obtain analytical standard from the registrant or suitable commercial supplier. Receipt of the standard will be documented, including label identification, date of receipt, person receiving the standard, and the amount received. Preparation of all stock and serially diluted solutions will be documented.

The stability of the analytical standard (reference substance) will be documented before the start of the study. Generally, AHETF will rely on data supplied by the product registrant that were submitted to support the EPA registration of the technical grade active ingredient. An expiration date and recommended storage conditions will be based on the stability data to ensure the analytical standard strength does not change appreciably during conduct of the study. Analytical standards are to be stored under the recommended conditions.

GLP determination of the percent ai analysis (content of ai in the reference substance) will be performed for each lot of reference substance used in the study prior to the use of that substance for sample analyses. Documentation of such analyses will be retained in the study raw data file.

15.2 Analytical Methods

The latest revisions of the following validated analytical methods will be used:

Analytical Method No. ARTF-AM-005 entitled, "Determination of Diazinon and Malathion in Inner Dosimeters."

Analytical Method No. ARTF-AM-006 entitled, "Determination of Diazinon and Malathion in Hand Wash Solutions."

Analytical Method No. ARTF-AM-009 entitled, "Determination of Diazinon and Malathion in OVS Air Sampling Tubes."

Analytical Method No. ARTF-AM-010 entitled, "Determination of Diazinon and Malathion in Facial/Neck Wipes."

ARTF-AM-011, "Determination of Carbaryl in Dermal Dosimeters" by Gary Westberg, Revision 4, September 2003

ARTF -AM-012, "Determination of Carbaryl in Hand Wash Solutions" by Gary Westberg, Revision 2, June 1998

ARTF-AM-013, "Determination of Carbaryl in OVS Air Sampling Tubes" by Gary Westberg, February 1997

ARTF-AM-014, "Determination of Carbaryl in Cotton Facial/Neck Wipes" by Gary Westberg, Revision 2, April 1998

Equivalent instrumentation, apparatus, and reagents may be substituted for those specified in the method. All substitutions must be clearly documented in the raw data.

15.3 Analytical Design

All analytical procedures, techniques and matrices will be provided by the

AHETF. Procedures and techniques will be followed as rigidly as possible. No changes are permitted without the prior approval of the AHETF Analytical Monitor and the Study Director.

All data will be measured against a standard curve (five-point minimum) that brackets the levels of the matrix spikes. If necessary, a solvent blank for the standard solutions will be injected prior to the standard solutions for each run.

Analytical data sets for the study will be considered acceptable if the following criteria are met. If these criteria cannot be met, the analytical monitor must be contacted immediately.

1) The limit of determination, r^2, or the regression coefficient, r, must be reported for all curves to demonstrate sufficient linearity of detector response in the range of residues quantified. All r^2 values must be 0.90 or greater or all r values must be 0.94 or greater.

2) Back calculations of the standard to the calculated curve which is based on the standards run in a set of samples will be performed for all analytical sets. The back calculations of the standards to the curve will be around +/-15% for all standards but the lowest concentration standard may back calculate to around +/-20%. No standard will be discarded from a set unless there is a good reason for its being discarded and not without consultation with the analytical monitor.

A minimum of two laboratory spikes must be included in each analytical set. For large analytical sets, include approximately one spike for every ten field samples. The spiking concentrations will bracket the expected levels in the field samples. The LOQ is defined in each analytical method.

For all samples wrapped in aluminum foil, the inner surface of the foil wrapping will be rinsed with at least 50 mL of extraction solvent, which will be added to the total extract volume. The final volume of solvent used must be documented.

The filter, plus front and rear sorbent sections of the OVS tubes, (along with the retainer ring and sorbent section separators) will be analyzed together as one unit.

15.4 Analytical Statistical Methods

Chromatographic quantification (either GC or HPLC depending on the method) will be achieved using a standard curve obtained from peak heights or areas of injections of several concentrations of standards. The standard curve will be a least squares fit unless otherwise approved by the AHETF Analytical Subcommittee. Means and standard deviations (arithmetic and/or geometric), and coefficients of variation may be calculated on the limited data

set generated in this study.

16.0 STUDY RECORDS

16.1 Field Records

Raw data will be obtained to cover all aspects of the study, including but not limited to the following:

1. Test and reference substance lot numbers, receipt and storage location(s) use records
2. Crop description and growth stage, if applicable
3. Mixing/loading equipment details, if applicable
4. Application equipment details, if applicable
5. If available, application equipment maintenance records (retained in the study file)
6. Environmental conditions for the entire monitoring period, including data used for making determinations of potential heat stress indices
7. Approvals from the Institutional Review Board covering the protocol and the Informed Consent document, and all amendments to either document
8. All correspondence with the Institutional Review Board
9. Personal details of workers, including consent forms and documentation of consent process (which will be maintained under confidential conditions as per SOP AHETF-6.D)
10. Trial location maps, including description, dimensions, and exact locations of plots and mixing/loading stations
11. Pounds active ingredient handled, monitoring time, acres treated, and volume of liquid applied
12. Dermal exposure sampling information
13. Inhalation exposure sampling information, including pump identification, calibration, flow rates and times of sampling
14. Field recovery procedure information for all sampling media
15. Test and reference substance, and sample storage temperature records
16. Observations on work practices, including photographs
17. Sample information (including inventory and chain of custody)

Field raw data will be recorded directly into the study notebook provided by AHETF. All data generated during this study will be kept in files bearing the study number. All forms and paperwork that contain personal information (including a worker's name and address) will be kept confidential in a sealed envelope while in the field. After the study is completed, this confidential envelope will be sent to AHETF archives with the other raw data (SOP AHETF-6.B).

16.2 Analytical Records

All study-specific original documents and data generated in the course of this study, including but not limited to the following, will be maintained and turned over to the AHETF when requested, or at the completion of the study.

1. Analytical worksheets, chromatograms, methods, residue calculation sheets and other pertinent analytical data
2. Laboratory notebooks or bench sheets used to record details of the analyses
3. Chromatograms and/or machine-generated analysis reports and data
4. Spreadsheets and other calculated data
5. Chain of custody records

In addition to the above study-specific raw data, the following records must also be kept, and true copies submitted with the raw data:

a. Storage conditions for reference substances and samples
b. Reference substance use log
c. Balance and instrument log book pages
d. Communications logs or records

Following completion of the field or analytical portion of the study, copies of the relevant records will be indexed and sent to the Study Director for preparation of the final report. All original raw data will be transferred directly to the AHETF-designated GLP study archive at Quality Associates, Inc., 8161 Maple Lawn Boulevard, Suite 200, Fulton, MD 20759.

17.0 DATA HANDLING

17.1 Communication of Results

Results will be communicated from Principal Field and Analytical Investigators to the Study Director and the designated AHETF Study Monitor(s) on a regular and timely schedule. Volunteer subjects will have an opportunity to fill out a form to request their personal study results when they are available. Individual results requested by subjects will be communicated in accordance with SOP AHETF-11.B.

AHETF has an adverse effects reporting procedure in place and will submit reports to EPA, IIRB, and appropriate state authorities if potential adverse effects to workers are found (see SOP AHETF-1.F and AHETF-11.F). The Study Director has the primary responsibility for identifying potential adverse effects during study conduct and as exposure results are obtained.

17.2 Statistical Methods

Detailed statistical evaluations of exposure data from this study and any existing data will be conducted by AHETF for each use scenario in its generic

database.

18.0 QUALITY ASSURANCE

AHETF intends that all regulatory studies are conducted in accordance with the FIFRA GLP Standards (40 CFR part 160). Field and analytical aspects of this study will be monitored by the relevant quality assurance unit(s) (QAU) while this study is in progress to ensure compliance with the FIFRA GLP regulation and adherence to this protocol and relevant SOPs. The QAU(s) will submit copies of its/their inspection reports to the Study Director and AHETF Sponsor Representative (40 CFR part 160.35 [4]). The final report will be audited by the QAU specified in Section 1.15 to ensure that the contents of the report accurately describe the conduct and findings of the study.

The final report will contain a Quality Assurance Statement from the QAU of each contributing laboratory conducting QA audits, and from the QAU specified in Section 1.15.

19.0 WORKER SAMPLE RETENTION

All sample extracts, extracted sample matrices, unanalyzed fortification matrices, and analytical standards will be retained until the Study Director and Analytical Monitor determine they are no longer useful. These materials are the property of the AHETF and will be stored or disposed of in a safe and lawful manner by the appropriate authorized personnel with the approval of AHETF and with QA verification at the performing facility.

20.0 PHASE REPORTS

Separate final reports will be prepared for the field and analytical phases of the study.

20.1 Field Report

Upon completion of the field phase at each individual location, the field investigators will submit reports for individual locations to the AHETF and the Study Director in a format specified by the AHETF. Each field report will describe the procedures followed at that location and must contain, but is not limited to, the following:

1. Identification of the locations of the study, and the general environmental conditions during the exposure monitoring periods
2. A field laboratory QAU statement giving dates of inspections and dates that findings were reported to the Study Director and AHETF Management

3. A summary of the worker recruitment and consent process
4. A description of the workers and handling activities
5. A summary of worker observations identifying any specific occurrences that may contribute to unusual worker exposure
6. A detailed summary of the amount of test substance handled by each worker
7. A detailed summary of the length of time each worker was monitored
8. A complete description of the field recovery procedure with a summary of specific handling and weathering of all field samples
9. A complete description of collection, handling, storage, and shipping of field samples

20.2 Analytical Report

At the completion of the analytical phase, each analytical laboratory that analyzed samples for this study will submit a report to the AHETF and the Study Director in a format specified by the AHETF. Each analytical report will describe the procedures followed for analysis of sample matrices and must contain, but is not limited to, the following:

1. Results of analyses
2. An analytical laboratory QAU statement giving dates of inspections and dates that findings were reported to the Study Director and AHETF Management
3. A detailed description of the methods
4. Example calculations
5. A summary of the concurrent lab recovery data
6. Representative chromatograms of control, treated, fortified samples and calibration standards
7. A typical standard curve

21.0 FINAL STUDY SUMMARY REPORT

A final summary report will be prepared according to a standardized format provided by AHETF. The report will contain a description of the conduct of the studies that comprise this scenario as well as a statistical analysis of the exposure data for the scenario. The original signed copy of the summary report will be archived at the AHETF GLP study archive.

22.0 PROTOCOL CHANGES

22.1 Amendments

Amendments to this protocol during the course of the study are permissible and subject to review and approval by the Study Director, the Sponsor

representative and the IRB prior to implementation. Protocol amendments shall to be documented in accordance with SOP AHETF-2.C and reported in the Field Report, Analytical Report and Summary Reports.

22.2 Deviations

GLP deviations are to be documented on the "Statement of GLP Compliance" in the summary report. A description of any changes to the protocol must appear in the Field Report, Analytical Report and Summary Reports. Any deviations to the protocol, lab SOPs or GLPs, or situations that may affect the integrity of the study must be communicated to the Study Director in a timely manner. Any deviations affecting the safety or rights of the subjects must also be reported to the IRB. Protocol deviations are to be documented in accordance with SOP AHETF-2.C.

23.0 REFERENCES

Bruce, E., L. Smith and V. Standart. 2007. Report of workplace meetings with citrus and pecan growers and employees. With attached: AHETF exposure studies: input from the local workplace community. Georgia and Florida, July 2007. Prepared for the Agricultural Handlers Exposure Task Force, 8 August 2007.

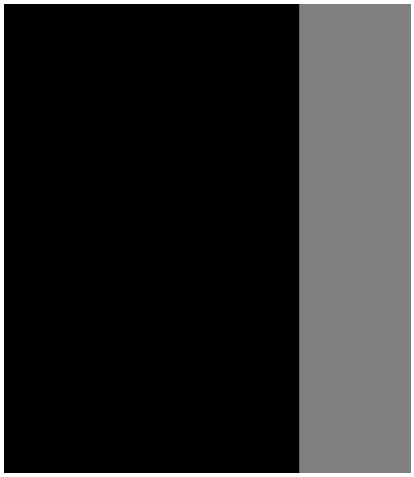
Research Study Volunteers

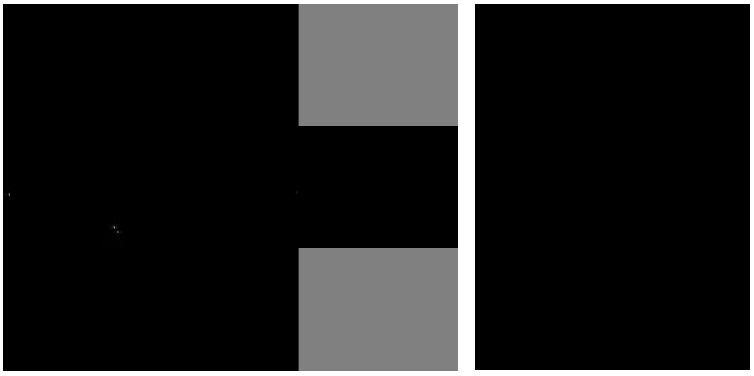
The Agricultural Handlers Exposure Task Force (AHETF) is a group of pesticide companies doing research to measure how much chemical gets on workers when they handle pesticides. They are looking for experienced airblast applicators to perform their usual work and let them collect exposure data.

To volunteer you must be:	You are not qualified if you:
• At least 18 years old with a government issued photo ID • Fluent in speaking English or Spanish • In good health • Not working for a pesticide manufacturer • Male or female (not pregnant or nursing) • Experienced and trained in handling pesticides	• Are less than 18 years of age • Do not have a government-issued photo identification card • Don't speak English or Spanish • Are not in good health • Work for a pesticide manufacturer • Are a pregnant or nursing female • Are cognitively impaired

You will be asked to do the following:

- Let us monitor you as you do your work for a day
- Sign a consent form before participating (in English or Spanish)
- Wear long underwear under your regular clothes
- Let us have the long underwear at the end of the day
- Let us wash your hands and wipe your face periodically with a mild soap solution





You should also know that:

- Participation is completely voluntary
- You can withdraw whenever you want
- Only non-invasive techniques are used, so you don't have to give urine or blood samples
- Information from the study will be used by EPA in assessing risks to agricultural workers.

If you are interested, please contact the Study Director:

Larry Smith
office phone 440-255-1954
cell phone 440-554-2812

He can answer any of your questions and give you more details.

Larry D. Smith, Ph.D.
LS Consulting Service, LLC

7919 Champaign Drive
Mentor, Ohio 44060
(440) 255-1954
lsconsulting@oh.rr.com

CAREER SUMMARY

Experienced scientist and manager providing technical planning and support to regulatory compliance, product development and manufacturing functions. Proven ability to attain technological objectives through management of innovative research programs. Strong leadership, motivational and training skills attained through academic and industry experience. Expertise includes:

- **Strategic Regulatory Evaluation and Product Defense**
- **FIFRA Regulatory Compliance**
- **Industry Task Force Representation**
- **Technical Program Planning and Review**
- **Agriculture and Industrial Biocides Product Development**
- **Human Exposure and Risk Assessment**
- **Project Management**
- **Data Interpretation**

PROFESSIONAL EXPERIENCE

LS CONSULTING SERVICE, LLC – Mentor, OH **1998-present**
Private consulting firm

Technical and Regulatory Consulting Scientist
As an independent consultant directly manages processes leading to registration and reregistration of proprietary products and regulatory defense through client representation and interaction with the U.S. Environmental Protection Agency. Provides leadership and expertise to a variety of projects and clients including basic manufacturers, industry-wide consortia, and industry task forces.

- Currently, Study Director and consultant for the Agricultural Handlers Exposure Task Force, a consortium of 18 manufacturers developing the Agricultural Handlers Exposure Database (AHED®). Planned and managed 11 worker exposure studies with diverse equipment, tasks and sites.
- Previously, consultant to Occupational and Residential Exposure Task Force, Agriculture Re-Entry Task Force, OP Case Study Group, and Methane Arsonic Acid Task Force III.
- Provides diverse experience in environmental and human exposure compliance issues. Recently completed active participation in a software development project to provide deterministic and stochastic modeling for residential exposure and risk assessment. The model (REX®) was evaluated by U.S. EPA for inclusion in its routine Tier I residential exposure assessments and incorporated in the CARES software.
- Provides strategic regulatory evaluation and product defense through technical data review and response to EPA assessments.
- Sponsor representative or study director for FIFRA GLP compliant regulatory studies.
- Provides technical guidance for U.S., OECD and JMAFF guideline study compliance.
- Technical planning and regulatory support for new product development.

ISK BIOSCIENCES CORPORATION - Mentor, OH **1989-1998**
(Formerly Diamond Shamrock Agricultural Chemical Division)
$300 million global manufacturer of agricultural and specialty chemicals.

Manager Technical Planning
Managed planning and implementation of domestic and international development programs to defend and expand existing product registrations and to introduce new products.

- Provided technical direction for reregistration of herbicide products and managed EPA guideline studies in environmental fate, human exposure, ground water studies, and technical defense in EPA negotiations.
- Directed AWPA compliant studies in support of wood preservation business.
- Completed non-occupational exposure assessment for proprietary compounds to comply with Food Quality Protection Act requirements.
- Provided technical leadership to Methanearsonic Acid (MAA) Research Task Force supporting registration of MSMA products and negotiated $2 million data compensation.
- Improved sales and marketing for proprietary products through planning and execution of field and laboratory programs resulting in label expansion.
- Completed a unique painter exposure study and greenhouse mixer, loader, applicator studies supporting chlorothalonil reregistration resulting in EPA approval.
- Managed product complaint resolution and directed investigations and analysis for products which resulted in a reduced settlement of crop injury claims in federal court.

PENWALT CORPORATION - Philadelphia, PA **1987-1989**
(Atochem, NA, subsidiary of Elf Atochem)
A $1.8 billion diversified chemical manufacturer of agricultural, petroleum, pharmaceutical and chemical industry products.

Manager, Field and Commercial Development - Agchem Division
Managed field and commercial development directing nationwide programs supporting fungicides, insecticides and aquatic herbicides. Supervised 7 field development representatives with $1.7 million budget.

- Supervised 330 residue projects providing database supporting registration standards, data call-ins, and special product reviews in response to EPA requirements.
- Developed field programs supporting reregistration of plant protection products, including herbicides, fungicides and insecticides.
- Provided leadership for new products committee evaluating new chemistry for product line inclusion.

CHEM LAWN SERVICES CORP. – Columbus, OH **1984-1987**
A residential and commercial lawn care and landscape service company.

Research Scientist
Managed Florida Regional Research Station and two research associates. Directed activities of associate scientist to provide conformational field studies.

- Developed non-phenoxy, warm season grass herbicide program by determining proper combinations, application rates, and application timing achieving maximum postemergence activity with minimum turf phytotoxcity.
- Supervised 240 research projects including disease control, weed control, fertility and insect control for turf and tropical ornamental plants.

TENNESSEE TECHNOLOGICAL UNIVERSITY **1978-1984**
An accredited state university.

Associate Professor, Plant & Soil Science Department
Provided technical support to the commercial nursery industry in Tennessee.

- Established University's Nursery Research and Service Center providing technical assistance to 350+ commercial nurseries in Tennessee.
- Conducted basic and applied research in disease, insect and weed control improving production of field, container and greenhouse ornamentals.
- Established and managed plant diagnostic laboratory and field plots supporting research efforts.
- Maintained cooperative projects with manufacturers providing efficacy and phytotoxicity data used in obtaining product registrations.

EDUCATION

Ph.D. - Plant Pathology, University of Illinois
M.S. - Plant Pathology, University of Arkansas
B.S. - Biology, Little Rock University

CITI Course in The Protection of Human Research Subjects

Thursday, February 10, 2005

CITI Course Completion Record
for Larry Smith

To whom it may concern:

On *2/10/2005*, *Larry Smith* (username=mildredfrances; Employee ID Number=000) completed all *CITI Program* requirements for the *Basic CITI* Course in The Protection of Human Research Subjects.

Learner Institution: *Ohio State University*

Learner Group: *IRB Reference Resource*

Learner Group Description: *Members of this group can preview all available CITI modules for demo purposes. You may complete additional modules and quizzes, but, you will not be able to download a transcript until you have completed the required modules for one of the groups listed above.*

Contact Information:

Department: Toxicology

Which course do you plan to take?: Social & Behavioral Investigator Course Only

Role in human subjects research: Study Coordinator

Mailing Address:

7919 Champaign Dr.
Mentor
Ohio
44060
USA

Email: lsconsulting@comcast.net

Office Phone: 4402551954

Home Phone: 4402550810

The Required Modules for *IRB Reference Resource* are:	**Date completed**
Introduction	02/09/05

Additional optional modules completed:	**Date completed**

History and Ethical Principles - SBR	02/09/05
Defining Research with Human Subjects - SBR	02/09/05
The Regulations and The Social and Behavioral Sciences - SBR	02/09/05
Assessing Risk in Social and Behavioral Sciences - SBR	02/09/05
Informed Consent - SBR	02/09/05
Privacy and Confidentiality - SBR	02/09/05
Research with Prisoners - SBR	02/09/05
Research with Children - SBR	02/10/05
Research in Public Elementary and Secondary Schools - SBR	02/10/05
International Research - SBR	02/10/05
Internet Research - SBR	02/10/05
History and Ethical Principles	02/10/05
Basic Institutional Review Board (IRB) Regulations and Review Process	02/10/05
Informed Consent	02/10/05
Social and Behavioral Research for Biomedical Researchers	02/10/05
Records-Based Research	02/09/05
Genetic Research in Human Populations	02/10/05
Research With Protected Populations - Vulnerable Subjects: An Overview	02/10/05
Vulnerable Subjects- Research With Prisoners	02/10/05
Vulnerable Subjects- Research Involving Minors	02/10/05
Vulnerable Subjects- Research Involving Pregnant Women and Fetuses in Utero	02/10/05
Group Harms:Research With Culturally or Medically Vulnerable Groups	02/10/05
FDA-Regulated Research.	02/10/05
Human Subjects Research at the VA	02/10/05
HIPAA and Human Subjects Research	02/10/05
Workers as Research Subjects-A Vulnerable Population	02/10/05
Hot Topics	02/10/05

Conflicts of Interest in Research Involving Human Subjects	02/10/05
Ohio State University	02/10/05

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

CITI Course in The Protection of Human Research Subjects

Print This Report

Tuesday, February 28, 2006

CITI Course Completion Record for Aaron Rotondaro

To whom it may concern:

On *2/28/2006*, *Aaron Rotondaro* (username=Aaron1R; Employee Number=) completed all *CITI Program* requirements for the *Basic CITI* Course in The Protection of Human Research Subjects.

Learner Institution: *Independent Users*

Learner Group: *Unaffiliated User Group*

Learner Group Description: ***This group is provided so that Unaffiliated MEMBERS may view all available CITI modules and complete the necessary requirements to obtain CME/CEU credit. All participants are required to pay $100.00 and submit proof of completion to the Office of Continuing Education.***

The CITI Developers

Contact Information:

Gender: Male
Department: None
Which course do you plan to take?: The Social And Behavioral AND Biomedical Courses
Role in human subjects research: Principal Investigator
Mailing Address:
332 W. Fountain Way
Fresno
CA
93705
Email: aaron1r@yahoo.com
Office Phone: 559-227-9225
Home Phone: 559-227-9225

The Required Modules for *Unaffiliated User Group* are:	**Date completed**
Introduction	02/26/06
Independent CITI-CME Users	02/26/06
Additional optional modules completed:	**Date completed**
History and Ethical Principles - SBR	02/27/06

Defining Research with Human Subjects - SBR	02/27/06
The Regulations and The Social and Behavioral Sciences - SBR	02/27/06
Assessing Risk in Social and Behavioral Sciences - SBR	02/28/06
Informed Consent - SBR	02/28/06
Privacy and Confidentiality - SBR	02/28/06
Internet Research - SBR	02/28/06
Informed Consent	02/28/06
Vulnerable Subjects - Research Involving Minors	02/28/06
Group Harms: Research With Culturally or Medically Vulnerable Groups	02/28/06
FDA-Regulated Research	02/28/06
Workers as Research Subjects-A Vulnerable Population	02/28/06
Hot Topics	02/28/06
Conflicts of Interest in Research Involving Human Subjects	02/28/06

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

CR# 243945

PARAGON Research Services
6773 Woodcliff Circle
Zionsville, IN 46077
Phone (317) 733-1243

Curriculum Vitae

Aaron Rotondaro

Paragon Research Services, Inc
Zionsville, IN 46077
317-733-1243

EXPERIENCE:

Feb. 93 to Present — Director of Research, Paragon Research Services, Inc., Zionsville, Indiana

Coordinate all activities necessary to conduct a study including site selection, test substance application, sample collection, sample shipment, and documentation. Responsible for client interaction, coordinating and training study personnel, and interacting with and coordinating Quality Assurance. Perform Principal Field Investigator and Study Director activities. Responsible for maintaining all equipment, logs, SOP's, and Master Schedule.

1987 - 1993 — Research Specialist, Pan-Agricultural Laboratories Inc., Madera, California

Responsible for the setup and sampling of efficacy, residue, environmental fate, worker exposure, field volatility, and drift studies. Coordinated various field research activities with growers. Responsible for protocol generation, study design, study conduct, and scheduling of worker exposure studies, drift studies, and field volatility studies throughout the United States and Canada. All studies were conducted in compliance with EPA Good Laboratory Practice Standards and Pesticide Assessment Guidelines. Also responsible for communications with personnel from major agricultural chemical companies and regulatory officials as well as evaluating, compiling, and analyzing data for reports submitted to various government and foreign agencies.

1984 - 1987 — Research Assistant, Wilbur-Ellis Company, Fresno, California

Responsible for agricultural chemical product research. Conducted and analyzed field and laboratory experiments for product registration and customer demonstration. Formulated pesticide, surfactant, and fertilizer compounds.

1982 - 1983 — Field Scout, Helena Chemical Company, Merced, California

Responsible for checking fields for pest and other problems and reporting findings to grower and pest control advisor. Utilized knowledge of insects, diseases, and weeds to prepare reports. Performed soil and tissue sampling.

EDUCATION:

1986 — Master of Science, California State University, Fresno

Major: Plant science with an emphasis in plant protection; Master Thesis: The Effects of Two Sterol-Inhibiting Fungicides on Wheat and Barley Seedling Emergence.

PARAGON Research Services
332 W. Fountain Way
Fresno, California 93705-3530
Phone (559) 227-9225

Curriculum Vitae for Aaron Rotondaro Continued

1984 Bachelor of Science, California State University, Fresno

Major: Agricultural Science; Awarded certificate of academic excellence from the University.

TRAINING:

Attend several meetings to maintain PCA and QAL Licenses. 20 hours per year. 1985-2007

Application of GLP's to Field Studies, West Coast Quality Training Institiute, Fresno, CA, February 2001

American Chemical Society, New Orleans LA, March 1996

Beltwide Cotton Conference, January 1996

Beltwide Cotton Conference, January 1995

Society of Environmental Toxicologists and Chemists Meeting, November 1994

Pacific Region Society of Quality Assurance, March 1994. Fresno, CA.

Society of Environmental Toxicologists and Chemists, November 1990, Washington DC

Introduction to Radiation Safety, Roger J. Kloepping, C.H.P., Radiation Officer, San Jose State University - 1989 - Certificate Awarded

LICENSES:

California Pest Control Advisor License - 1985 to Present
California Qualified Applicators License - 1985 to Present

For purposes of GLP compliance, I acknowledge this to be true and correct

_____ _____
Aaron Rotondaro Date

CITI Collaborative Institutional Training Initiative

Course In The Protection of Human Subjects Curriculum Completion Report
Printed on Wednesday, February 27, 2008

Learner: Tami Belcher (username: tbelcher)
Institution: Independent Investigational Review Board, Inc.(IIRBI)
Contact Information
P.O. Box 706
211 N. Main Street
Creedmoor, NC 27522 USA
Phone: 9195285508
Email: tbelcher@graysonresearch.com

IIRB Project Leader:

Stage 1. IIRB Project Basic Passed on 02/09/08 (Ref # 1594310)

Required Modules	Date Completed	Score
Belmont Report and CITI Course Introduction	02/09/08	3/3 (100%)
History and Ethical Principles	02/09/08	5/5 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process	02/09/08	5/5 (100%)
Informed Consent	02/09/08	4/4 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	02/09/08	4/4 (100%)
International Research	02/09/08	no quiz
FDA-Regulated Research	02/09/08	5/5 (100%)
HIPAA and Human Subjects Research	02/09/08	2/2 (100%)
Hot Topics	02/09/08	no quiz
Conflicts of Interest in Research Involving Human Subjects	02/09/08	2/2 (100%)
Independent Investigational Review Board, Inc. (IIRBI)	02/09/08	no quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

Return

Human Participant Protections Education for Research T

Completion Certificate

This is to certify that

Brian Lange

has completed the **Human Participants Protection Education for Research Teams** online course, sponsored by the National Institutes of Health (NIH), on 08/09/2006.

This course included the following:

- key historical events and current issues that impact guidelines and legislation on human participant protection in research.
- ethical principles and guidelines that should assist in resolving the ethical issues inherent in the conduct of research with human participants.
- the use of key ethical principles and federal regulations to protect human participants at various stages in the research process.
- a description of guidelines for the protection of special populations in research.
- a definition of informed consent and components necessary for a valid consent.
- a description of the role of the IRB in the research process.
- the roles, responsibilities, and interactions of federal agencies, institutions, and researchers in conducting research with human participants.

National Institutes of Health
http://www.nih.gov

Access Research and Consulting, Inc.

Curriculum Vitae

Brian D. Lange
Director of Research

Education

California State University, Fresno — May 1988, B.A. Biological Sciences

Current Position

Research Specialist — Access Research and Consulting, Inc.

Brian Lange has 19 years experience in the agricultural research industry. He founded Access Research and Consulting, Inc. in January 2003, and is its sole owner. He assumes roles of Project Manager, Principal Investigator, and/or Study Director in a wide variety of field research studies, and is responsible for operation of the business.

Summary of Training and Experience Related to Current Position

Acted as Project Manager, Principal Investigator, and/or Study Director in numerous studies throughout the United States, Canada, and Australia. Study types are identified below:

- Radiolabeled Studies: Design and setup of plots, calibration and application using various sprayers, plant, soil and water sampling, plot remediation, personnel and facility contamination control and monitoring.
- Dissipation Studies: Design and setup of plots, calibration and application using various sprayers, mechanical and hand soil and water sampling, and field fortification preparation and collection.
- Dislodgeable Studies: Design and setup of plots, calibration and application using various sprayers, leaf punch and dust collection, leaf disc dislodging, and field fortification preparation and collection.
- Worker Exposure Studies: Design and setup of plots, preparation of dosimetry, calibration and application using various sprayers, monitoring participants, sample collection, and field fortification preparation and collection.
- Transferable Turf Residue: Design and setup of plots, calibration and application using various sprayers, sample collection, and field fortification preparation and collection.
- Magnitude of the Residue: Design and setup of plots, calibration and application using various sprayers, mechanical and hand soil and water sampling.
- Drift Studies: setup of sampling stations, sampling drift study media.
- Efficacy Studies: Plot setup, calibration and application using various sprayers, evaluation of efficacy to insect, fungal, and weed populations.
- All studies previously listed: Protocol development, logbook and label preparation, and field and EPA submission reports.

Professional Meetings and Training Related to Current Position

IR-4 Project National Education Conference	February 2006
NAICC Annual Meeting, Tuscon, AZ	January 2006
California Weed Science Society Annual Meeting, Ventura, CA	January 2006
GLP Training, J.J.'s Technical Services, Syntech Research, Sanger, CA	December 2005
GLP Training, Perspective Consulting, Universal City, CA	January 2005
NAICC Annual Meeting, Universal City, CA	January 2005
California Weed Science Society Annual Meeting, Monterey, CA	January 2005
NAICC Annual Meeting, New Orleans, LA	January 2004
NAICC Annual Meeting, Washington, DC	January 2003
Astrix-Fieldnotes Software Training, Washington, DC	January 2003
Syngenta Crop Protection, GLP's For the Field, Albuquerque, NM	January 2002
American Agricultural Services, Inc., Advantage Training, Albuquerque, NM	January 2002
NAICC Annual Meeting, Albuquerque, NM	January 2002
DOT HazMat Basic Training, Fresno, CA	January 2002
PRCSQA Meeting, Fresno, CA	February 2001
NAICC Annual Meeting, Orlando, FL	January 2001
Biotechnology Field Trial Compliance-Monsanto, Orlando, FL	January 2001
Astrix-Fieldnotes Software Training, Orlando, FL	January 2001
California Weed Science Society Annual Meeting, Sacramento, CA	January 2000
PRCSQA Meeting, Las Vegas, NV	January 1999
GLP Field Research Training Seminar, Northwest Quality Training Institute	February 1998
NAICC Annual Meeting, Washington, D.C.	January 1998
Transferable Turf Residue Sampling Tech., ORETF/NAICC, Wash., D.C.	January 1998
California Weed Science Society Annual Meeting, Monterey, CA	January 1998
GLP Field Research Training Seminar, WCQTI, Hood River, OR	December 1997
Advanced GLP Training Seminar, WCQTI Northwest, Hood River, OR	February 1996
NAICC Annual Meeting, Orlando, FL	January 1996
PRCSQA Meeting, Dublin, CA	December 1995
GLP Training Seminar, M.K. Consulting, Fresno, CA	April 1995
PRCSQA Meeting	March 1995
NAICC Annual Meeting, San Diego, CA	January 1995
CAPCA Meeting	January 1995
California Weed Science Society Annual Meeting, Santa Barbara, CA	January 1995
Low Level Radioactive Waste Minimization Workshop, Berkeley, CA	October 1994
Low Level Radioactive Waste Interim Storage Workshop, Oakland, CA	April 1994
PRCSQA Meeting	December 1993
SQA Annual Meeting, San Francisco, CA	September 1993
GLP Training Seminar, Pacific Rim Consulting, Fresno, CA	March 1993
California Weed Conference Annual Meeting, Santa Barbara, CA	January 1990
Radiation Safety Training Seminar, San Jose State University, San Jose, CA	October 1989

Past Positions

Research Specialist, Excel Research Services, Inc.
November 1992 to December 2002
One of four founders and co-owners. Assumed the responsibilities of Principal Field Investigator and/or Study Director in radiolabeled field and environmental fate studies. Responsible for day-to-day management activities of the company, including planning, invoicing, purchasing, hiring, and supervising employees.

Team Leader, Pan-Agricultural Laboratories, Inc.
February 1992 to November 1992
Responsible for personnel and operations in the environmental fate and radiolabeled field studies divisions, and the hiring and training of personnel.

Research Biologist, Pan-Agricultural Laboratories, Inc.
August 1988 to February 1992
Acted as Principal Investigator for radiolabeled, environmental fate, and other types of studies.

Research Technician, Pan-Agricultural Laboratories, Inc.
April 1988 to August 1988
Assisted with field studies including soil and plant sampling, planting of crops, irrigation, and data collection.

Signature Confirmation

The following sample of signature, initials, and date format will be used for GLP data entries:

Signature	Initial	Date	Format (eg. dd/mm/yy)
	bdl	26 Jun 06	dd Mmm yy

Certification

I certify that the above information is accurate.

Brian D. Lange — 26 Jun 06
Research Specialist — Date
Access Research and Consulting, Inc.

Reviewed 13 Nov 07. bdl 13 Nov 07

Grayson Research, LLC

Name: **Tami I. Belcher**

Title: **Senior Project Manager**

Functions: Responsible for planning, directing and reporting a wide variety of occupational exposure, environmental fate, and crop residue studies.

Background Summary

Over twenty-five years experience as Principal Field Investigator, Project Manager and Study Director at various contract research organizations. Study Director and/or Principal Field Investigator for over 60 worker exposure studies, including passive dosimetry and biological monitoring of workers entering treated crop, and Mixer/Loader/Applicator studies with typical ground, air and fumigant application systems. Worker exposure studies have been conducted throughout the Unites States, Canada, and Australia. Assumed the role of Study Director, Project Manager, or Principal Field Investigator on numerous transferable turf residue, dislodgeable foliar and soil residue, flux and air monitoring, magnitude of the residue, and terrestrial dissipation studies.

Professional Experience

Senior Project Manager *06/04 through present*
Grayson Research, LLC, Creedmoor, NC

(see functions above)

President/Research Specialist *01/03 through 06/04*
Access Research and Consulting, Inc.

Formed company in 2003 and was cooperatively responsible for operation of the business. Served as Study Director or Principal Field Investigator on a variety of research programs, including worker exposure, flux and air monitoring, transferable turf residue, dislodgeable foliar and soil residue, magnitude of the residue, and terrestrial dissipation studies. Developed protocols, directed in-life activities, and interacted with analytical investigators regarding laboratory activities. Prepared field and final submission reports for various regulatory agencies.

Research Specialist *01/98 through 12/02*
Excel Research Services, Inc.

Assumed the role of Principal Field Investigator and/or Study Director in worker exposure, dislodgeable foliar and soil residue, transferable turf residue, air monitoring, and other related studies. Acted as Project Manager on field residue and environmental fate programs.

Scientist/Project Manager *11/93 through 12/97*
ABC Laboratories California

Duties included project management of field residue and environmental fate programs and acted as Principal Field Investigator and/or Study Director in worker exposure and related studies.

Project Specialist *04/92 to 11/93*
Pan-Agricultural Laboratories, Inc.

Assisted the Project Managers with GLP research programs and report preparation. Developed and maintained client relations, prepared and executed marketing plans, and conducted in-life phase quality assurance audits.

Manager, Product Registration and Quality Assurance *08/82 to 04/92*
Siemer and Associates, Inc.

Acted on the behalf of clients in the registration of new and established pesticides at the State and Federal levels, and was responsible for GLP compliance of the facility. Assisted with efficacy studies.

Education

California State University, Fresno, B.S., Marketing, 1988

Professional Memberships

National Alliance of Independent Crop Consultants, 2000 to Present
Pacific Regional Chapter of the Society of Quality Assurance, 2001 to 2004

Training/Continuing Education

CITI Course "The Protection of Human Research Subjects", IIRB, February 2008
CITI Course "The Protection of Human Research Subjects", WIRB, February 2008
NAICC Annual Meeting, Atlanta, February 2007
CITI Course "The Protection of Human Research Subjects", WIRB, February 2006
Global Transport Training Services, USA, Ltd., IATA/ICAO Dangerous Goods by Air, Los Angeles, CA, January 2005
Global Transport Training Services, USA, Ltd., US DOT 49CFR Parts 172 to 180, Los Angeles, CA, January 2005
NAICC Annual Meeting, Los Angeles, CA, January 2005
NAICC Annual Meeting, New Orleans, LA, January 2004
NAICC Annual Meeting, Washington, DC, January 2003
Astrix-Fieldnotes Software Training, Washington, DC, January 2003
NAICC Annual Meeting, Albuquerque, NM, January 2002
Syngenta Crop Protection, GLPs for the Field, Albuquerque, NM, January 2002
American Agricultural Services, Inc., Advantage Training, Albuquerque, NM, January 2002
PRCSQA Meeting, Fresno, CA, February 2001
NAICC Annual Meeting, Orlando, FL, January 2001
Pacific Rim Consulting, Advanced GLP Training, St. Louis, MO, February 1998
NAICC Annual Meeting, Washington, DC, January 1998
Outdoor Residential Exposure Task Force, TTR Sampling, Washington, DC, January 1998
NAICC Annual Meeting, San Antonio, TX, January 1997
NAICC Annual Meeting, San Diego, CA, January 1995
SQA Annual Meeting, San Francisco, CA, October 1993
PRCSQA Meeting, Madera, CA, March 1993
ACS Meeting, Washington, DC, August 1992

CITI Collaborative Institutional Training Initiative

Additional Groups in the Course for The Protection of Human Subjects Curriculum Completion Report
Printed on Wednesday, February 27, 2008

Learner: Tami Belcher (username: tbelcher)
Institution: Independent Investigational Review Board, Inc.(IIRBI)
Contact Information
P.O. Box 706
211 N. Main Street
Creedmoor, NC 27522 USA
Phone: 9195285508
Email: tbelcher@graysonresearch.com

Investigators (Biomedical):

Stage 1. Investigators - Biomed Passed on 02/09/08 (Ref # 1594311)

Required Modules	Date Completed	Score
Belmont Report and CITI Course Introduction	02/09/08	3/3 (100%)
History and Ethical Principles	02/09/08	5/5 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process	02/09/08	5/5 (100%)
Informed Consent	02/09/08	4/4 (100%)
Genetic Research in Human Populations	02/09/08	2/2 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	02/09/08	4/4 (100%)
Vulnerable Subjects - Research Involving Minors	02/09/08	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero	02/09/08	3/3 (100%)
International Research	02/09/08	no quiz
Group Harms: Research With Culturally or Medically Vulnerable Groups	02/09/08	3/3 (100%)
FDA-Regulated Research	02/09/08	5/5 (100%)
HIPAA and Human Subjects Research	02/09/08	2/2 (100%)
Hot Topics	02/09/08	no quiz
Conflicts of Interest in Research Involving Human Subjects	02/09/08	2/2 (100%)
Independent Investigational Review Board, Inc. (IIRBI)	02/09/08	no quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

Return

AHETF Study No. AHE55

Product-Specific Risk Statement
(Must be attached to the Informed Consent Form)

The product you will handle is identified as follows:

Name: Sevin® Brand 80WSP Carbaryl Insecticide (EPA Registration No. 264-526)

Active Ingredient (AI): Carbaryl (insecticide, CAS No. 63-25-2)

Formulation and Packaging: 80% AI dry powder in a 1.25 lb water soluble pack

You may handle up to: 100 water soluble packs

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear waterproof gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This carbaryl product is classified as moderate toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye irritation, minimal skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 9/23/04
MSDS date: 12/26/02 (number 000000001825; Version 1.1)

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

Bayer CropScience

SEVIN® brand 80WSP Carbaryl Insecticide

FOR AGRICULTURAL OR COMMERCIAL USE ONLY

ACTIVE INGREDIENT:

Carbaryl (1-naphthyl N-methylcarbamate) ..... **80% by wt.**

INERT INGREDIENTS: ..... **20% by wt.**

E.P.A. Reg. No. 264-526 **E.P.A. Est. No.**

KEEP OUT OF REACH OF CHILDREN

WARNING AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577

For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

Carbaryl is an N-Methyl Carbamate Insecticide.

IF SWALLOWED:	• Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything by mouth to an unconscious person.
IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577. **Have the product container or label with you when calling a poison control center or doctor or going for treatment.**	

GENERAL

Contact a physician immediately in all cases of suspected poisoning. Transport to a physician or hospital immediately and SHOW A COPY OF THIS LABEL TO THE PHYSICIAN. If poisoning is suspected in animals, contact a veterinarian.

ANTIDOTE STATEMENT

ATROPINE SULFATE IS HIGHLY EFFECTIVE AS AN ANTIDOTE. Narcotics and other sedatives should not be used. Further, drugs like 2-PAM (pyridine-2-aldoxime methiodide) are not recommended. See NOTE TO PHYSICIAN .

NOTE TO PHYSICIAN

Treat symptomatically. Overexposure to materials other than this product may have occurred.

Carbaryl is an N-methyl carbamate insecticide, which is a cholinesterase inhibitor. Overexposure to this substance may cause toxic signs and symptoms due to stimulation of the cholinergic nervous system. These effects of overexposure are spontaneously and rapidly reversible. Gastric lavage may be used if this product has been swallowed. Carbaryl poisoning may occur rapidly after ingestion and prompt removal of stomach contents is indicated.

Specific treatment consists of parenteral atropine sulfate. Caution should be maintained to prevent overatropinization. Improve tissue oxygenation as much as possible before administering atropine to minimize the risk of ventricular fibrillation. Mild cases may be given 1 to 2 mg intramuscularly every 10 minutes until full atropinization has been achieved and repeated thereafter whenever symptoms reappear. Severe cases should be given 2 to 4 mg intravenously every 10 minutes until fully atropinized, then intramuscularly every 30 to 60 minutes as needed to maintain the effect for at least 12 hours. Dosages for children should be appropriately reduced. Complete recovery from overexposure is to be expected within 24 hours.

Narcotics and other sedatives should not be used. Further, drugs like 2-PAM (pyridine-2-aldoxime methiodide) are NOT recommended.

To aid in confirmation of a diagnosis, urine samples should be obtained within 24 hours of exposure and immediately frozen. Analysis will be arranged by Bayer CropScience.

Consultation on therapy can be obtained at all hours by calling the Bayer CropScience emergency number 1-800-334-7577.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS (& DOMESTIC ANIMALS)

WARNING

MAY BE FATAL IF SWALLOWED. HARMFUL IF ABSORBED THROUGH THE SKIN, OR INHALED, OR IF IN EYES.
Do not breathe vapors, dust or spray mist. Do not get in eyes, on skin or on clothing. Keep out of reach of children and domestic animals.

OVEREXPOSURE MAY CAUSE: Salivation, watery eyes, pinpoint eye pupils, blurred vision, muscle tremors, difficult breathing, excessive sweating, abdominal cramps, nausea, vomiting, diarrhea, weakness, headache. IN SEVERE CASES CONVULSION, UNCONSCIOUSNESS AND RESPIRATORY FAILURE MAY OCCUR. SIGNS AND SYMPTOMS OCCUR RAPIDLY FOLLOWING OVEREXPOSURE TO THIS PRODUCT.

PERSONAL PROTECTIVE EQUIPMENT:

Applicators and other handlers must wear long-sleeved shirt and long pants, waterproof gloves, shoes plus socks and chemical-resistant headgear for overhead exposure.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning and maintaining Personal Protective Equipment (PPE). If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

User Safety Recommendations
Users should wash hands before eating, drinking chewing gum, using tobacco, or using the toilet.
Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to aquatic and estuarine invertebrates. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Discharge from rice fields may kill aquatic and estaurine invertebrates. Do not apply when weather conditions favor drift from area treated. Do not contaminate water by cleaning equipment or disposal of wastes. Do not contaminate water when disposing of equipment washwaters.

BEE CAUTION: MAY KILL HONEYBEES IN SUBSTANTIAL NUMBERS.
This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area. Contact your Cooperative Agricultural Extension Service or your local Bayer CropScience representative for further information.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Read the entire label before using this product.

Strictly observe label directions and cautions. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is coveralls, waterproof gloves, shoes plus socks and chemical-resistant headgear for overhead exposure.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

The area being treated must be vacated by unprotected persons.

Keep unprotected persons out of treated areas until sprays have dried.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE

Store unused SEVIN® brand 80WSP Carbaryl Insecticide in original container only, in cool, dry area out of reach of children and animals. Do not store in areas where temperatures frequently exceed 100° F.

If container is damaged, before cleaning up, put on Personal Protective Equipment.

PESTICIDE DISPOSAL

Open dumping is prohibited. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

Do not reuse outer bag. Dispose of outer bag in the trash, or, if allowed by State and local authorities, by burning. If outer bag is burned, stay out of smoke.

GENERAL CAUTIONS AND RESTRICTIONS

SEVIN® brand 80WSP Carbaryl Insecticide is a dry powder formulation of SEVIN® brand carbaryl insecticide and is packaged in water soluble paks. Each pak contains 1.25 lbs of formulated product. Do not sell individual water soluble paks. Do not handle inner bag with wet hands or gloves. Do not allow paks to become wet prior to adding to the spray tank. Handle outer container (over wrap bag) carefully to avoid breakage of inner soluble paks. Always reseal outer (over wrap bag) in a manner that protects remaining paks from moisture. Do not remove the WSPs from the container except for immediate use. Use the entire contents of a WSP, do not break open to use partial contents of a WSP.

This product readily disperses in water to form a spray which may be applied by air or ground equipment.

PLANT RESPONSE PRECAUTIONS

Application to wet foliage or during periods of high humidity may cause injury to tender foliage.

Do not use on Boston Ivy, Virginia creeper and maidenhair fern as injury may result. Carbaryl may also injure Virginia and sand pines.

The use of adjuvants may increase the potential for crop injury to sensitive crops.

PREHARVEST AND GRAZING RESTRICTIONS AND LIMITATIONS

Tolerances established under the Federal Food, Drug and Cosmetic Act permit the sale of labeled crops bearing probable carbaryl residues when this product is used in accordance with the label directions. If used as directed, treated forage may be grazed or used as feed for dairy and meat animals without causing illegal residues in meat or milk. Do not apply at greater rates or at more frequent intervals than stated on the label. To do so may result in illegal residues in crops, meat, and milk.

Do not use reclaimed irrigation water from crops treated with carbaryl on crops for which carbaryl tolerances are not established.

Do not plant rotational food and feed crops not listed on this or other carbaryl labels in carbaryl treated soil.

APPLICATION STATEMENTS

Calibrate and adjust application equipment to insure proper rate and accurate placement. To clean spray system after use, drain and flush with a water and detergent mixture. Rinse thoroughly with clean water. Refer to the Storage and Disposal section for disposal instructions.

NOTE: **Staining may occur on certain surfaces such as stucco, brick, cinder block, and wood. Spray deposits on painted or stained surfaces or finishes (i.e., cars, houses, trailers, boats, etc.) should be immediately removed by washing to prevent discoloration. Avoid applications to surfaces where visible spray residues are objectionable.**

RESISTANT SPECIES NOTICE

All references to armyworm on the crops listed below refer to the species, *Pseudaletia unipuncta*, often called the "true armyworm". Except where indicated otherwise, this product is not registered for the control of other armyworm species. Regional differences have been noted in the susceptibility of certain strains of fall armyworm, diamondback moth, Colorado potato beetle and Southern green stink bug to carbaryl. If local experience indicates inadequate control, use an alternative pesticide.

MIXING, LOADING AND HANDLING INSTRUCTIONS

Remove oil, rust, scale, pesticide residues and other foreign matter from mix tanks and entire spray system. Flush with clean water. Consult the Specific Use Directions section of this label to determine the number of paks and spray volume required. Fill the mixing tank partially (1/2 to 3/4) with water. With the agitator on, slowly add the required number of unopened paks of SEVIN® brand 80WSP Carbaryl Insecticide into the mixing tank. Allow all the water soluble paks to dissolve and completely disperse. Depending upon the water temperature and the degree of agitation, the water soluble paks should be completely dissolved within 3 – 5 minutes. Continue agitation while adding the remainder of the water. Do not put water soluble paks close to the recirculating inlet and outlet, as they may block the line before completely dissolved. Prepare only as much spray mixture as can be applied on the day of mixing. Do not use partial water soluble paks. MAINTAIN CONTINUOUS AGITATION DURING MIXING AND APPLICATION TO ASSURE A UNIFORM SUSPENSION. DO NOT STORE SPRAY MIXTURE FOR PROLONGED PERIODS OR DEGRADATION OF CARBARYL MAY OCCUR. Local water conditions may also accelerate the degradation of spray mixtures containing carbaryl. See COMPATIBILITY STATEMENT below.

TANK MIXING INSTRUCTIONS

Once the water soluble paks have completely dissolved, add other products in the following order: wettable powder, dry flowable (wettable granules), liquid flowable, liquids, and EC's. Always allow each tank mix partner to disperse fully before adding the next product.

COMPATIBILITY INFORMATION

SEVIN® brand 80WSP Carbaryl Insecticide, when diluted with at least an equal volume of water, is compatible with a wide range of pesticides. It is not compatible with diesel fuel, kerosene, fuel oil or aromatic solvents. If compatibility with another product and the resulting crop response is unknown, the mixture should be tested on a small scale. Curdling, precipitation, greasing, layer formation or increased viscosity are symptoms of incompatibility. Incompatibility will reduce insect control and may cause application and handling difficulties or plant injury. Observe all cautions and limitations on labeling of all products used in mixtures. WHEN PREPARING COMBINATION SPRAYS, FIRST ADD SEVIN® BRAND 80WSP CARBARYL INSECTICIDE TO AT LEAST AN EQUAL VOLUME OF WATER, MIX THOROUGHLY, AND THEN ADD COMBINATION PRODUCTS TO THE MIXTURE. DO NOT APPLY TANK MIX COMBINATIONS UNLESS YOUR PREVIOUS EXPERIENCE INDICATES THE MIXTURE IS EFFECTIVE AND WILL NOT RESULT IN APPLICATION PROBLEMS OR PLANT INJURY.

Carbaryl is unstable under highly alkaline conditions and mixtures with strong bases, such as Bordeaux, lime-sulfur and casein-lime spreaders, will result in chemical degradation of the insecticide. Do not use this product in water with pH values above 8.0 unless a buffer is added. If necessary, water should be buffered to neutral (pH = 7.0) before adding this product to the spray tank. Overhead irrigation with alkaline or muddy water after application will also accelerate chemical degradation and may result in reduced insect control.

APPLICATION PROCEDURES AND PRECAUTIONS

On all crops use sufficient gallonage to obtain thorough and uniform coverage. Observe crop label instructions for specific directions regarding spray volume where they occur. Calibrate spray equipment to deliver the required volume. Use of 50 mesh slotted strainers in spray system and 25 mesh slotted strainers behind nozzles is recommended.

GROUND APPLICATION

Apply in sufficient volume for adequate coverage on all crops and sites.

AERIAL APPLICATION

For adequate distribution, use at least 10 gallons of spray mixture per acre for application for tree and orchard crops or at least 2 gallons of spray mixture per acre for application to other crops.

SPRINKLER IRRIGATION SYSTEMS

Apply this product only through sprinkler irrigation systems including center pivot and solid set. Do not apply this product through any other type of irrigation system.

SPRAY PREPARATION: First prepare a suspension of SEVIN® brand 80WSP Carbaryl Insecticide in a mix tank. Fill tank with 1/2 to 3/4 the desired amount of water. Start mechanical or hydraulic agitation. Add the required amount of SEVIN® brand 80WSP, and then the remaining volume of water. (Suspension concentrations using the appropriate dosage per acre recommended on this label of

SEVIN® brand 80WSP, per 1 to 4 gallons of water are recommended). Then set sprinkler to deliver 0.1 to 0.3 inch of water per acre. Start sprinkler and uniformly inject the suspension of SEVIN® brand 80WSP into the irrigation water line so as to deliver the desired rate per acre. The suspension of SEVIN® brand 80WSP should be injected with a positive displacement pump into the main line ahead of a right angle turn to insure adequate mixing. If you should have any other questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts.

NOTE: When treatment with SEVIN® brand 80WSP has been completed, further field irrigation over the treated area should be avoided for 24 to 48 hours to prevent washing the chemical off the crop.

GENERAL PRECAUTIONS FOR APPLICATIONS THROUGH SPRINKLER IRRIGATION SYSTEMS

Maintain continuous agitation in mix tank during mixing and application to assure a uniform suspension.

Greater accuracy in calibration and distribution will be achieved by injecting a larger volume of a more dilute solution per unit time.

The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump. The pesticide injection pipeline must also contain a functional, normally closed solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shutdown. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock. Do not apply when wind speed favors drift beyond the area intended for treatment.

Do not apply when wind speed favors drift, when system connection or fittings leak, when nozzles do not provide uniform distribution or when lines containing the product must be dismantled and drained.

Crop injury, lack of effectiveness, or illegal pesticide residues in the crop may result from nonuniform distribution of treated water.

Allow sufficient time for pesticide to be flushed through all lines and all nozzles before turning off irrigation water. A person knowledgeable of the chemigation system and responsible for its operation shall shut the system down and make necessary adjustments should the need arise.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the label-prescribed safety devices for public water supplies are in place.

SPECIFIC USE DIRECTIONS

CROP/SITE GROUPINGS:

Asparagus

Brassica Leafy Vegetable Crops

Cereal Grain Crops (Field and Pop Corn; Grain Sorghum; Rice; Sweet Corn; Wheat and Proso Millet)

Cucurbit Vegetables

Flax

Forage Crops (Alfalfa, Clovers, Birdsfoot Trefoil; Pasture and Grasses Grown for Seed; Rangeland)

Fruiting Vegetables

Leafy Vegetables

Legume Vegetables

Noncropland (Conservation Reserve Program; Wasteland; Rights-of-Way; Hedgerows; Ditchbanks; Roadsides)

Okra

Peanuts

Prickly Pear Cactus

Root and Tuber Crops (Root and Tuber Crops except Sugar Beets and Sweet Potatoes; Sugar Beets; Sweet Potatoes)

Small Fruits and Berries

Sunflower

Tobacco

Tree Fruit Crops (Citrus Fruits; Olives; Pome Fruits; Stone Fruits)

Tree Nut Crops (Pistachios; Tree Nuts)

Forested Areas and Rangeland Trees

Control of Specific Pests Across Multiple Sites

- Grasshoppers
- Ticks which Vector Lyme Disease

Imported Fire Ants
Adult Mosquito Control

INSECT CONTROL

Begin application when insect populations reach recognized economic threshold levels. Consult the Cooperative Extension Service, Consultants, or other qualified authorities to determine appropriate threshold levels for treatment and specific use information in your area. Where a dosage range is indicated, use the lower rate on light to moderate infestations, young plants and early instars and use the higher rate on heavy infestations, mature plants, advanced instars and adults. Thorough and uniform spray coverage is essential for effective control.

ASPARAGUS

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Asparagus	Apache cicada Asparagus beetle Cutworms	1 1/4 to 2 1/2	1.0 to 0.5	Repeat applications as necessary up to a total of 3 times prior to harvest or a total of 5 times per crop but not more often than once every 3 days. For cutworm control, this product is most effective against species which feed on the upper portions of the plant.
		2 1/2 to 5	0.5 to 0.25	**Application to ferns or brush growth following harvest of spears**: Repeat applications as necessary but not more often than once every 7 days. Do not make more than a total of 5 applications per year to spears and ferns combined.

RESTRICTIONS AND PRECAUTIONS: ASPARAGUS

- Do not apply within 1 day of harvest.
- Do not apply more than a total of 7 1/2 pounds per acre before harvest of spears.
- Do not apply more than a total of 12 1/2 pounds per acre per year.

BRASSICA LEAFY VEGETABLES CROPS

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Broccoli Brussel Sprouts Cauliflower	Flea beetles Harlequin bug Leafhoppers	2/3 to 1 1/4	1.8 to 1.0	Repeat applications as needed up to a total of 4 times but not more often than once every 7 days.
Cabbage Chinese Cabbage Collards Kale Kohlrabi Mustard Greens	Armyworm Aster leafhopper Corn earworm Diamondback moth Fall armyworm Imported cabbageworm Lygus bugs Spittle bugs Stink bugs Tarnished plant bug	1 1/4 to 2 1/2	1.0 to 0.5	

RESTRICTIONS AND PRECAUTIONS: BRASSICA LEAFY VEGETABLES

- For Broccoli, Brussel Sprouts, Cabbage Cauliflower, and Kohlrabi, do not apply within 3 days of harvest.
- For Chinese Cabbage, Collards, Kale, and Mustard Greens, do not apply within 14 days of harvest.
- Do not apply more than a total of 7 1/2 pounds per acre per crop.

CEREAL GRAIN CROPS

FIELD CORN AND POPCORN

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Field corn and Popcorn	Armyworm, Chinch bugs, Corn earworm, Corn rootworm adults, Fall armyworm, Flea beetles, Japanese beetle, Sap beetles, Southwestern corn borer, Leafhoppers	1 1/4 to 2 1/2	1.0 to 0.5	OBSERVE BEE CAUTION. Repeat applications as needed up to a total of 4 times but not more often than once every 14 days. Optimum timing and good coverage are essential for effective control.
	European corn borer	1 7/8 to 2 1/2	0.67 to 0.5	For optimum chinch bug control, use ground equipment to apply at least 20 gallons of water per acre and direct spray toward stalk to provide thorough coverage. For optimum European corn borer control, do not apply in less than 3 gallons of water per acre by air and 15 gallons of water by ground. For western bean cutworm, treat when infestation averages 15% and at 90 to 100% tassel emergence. Treatment after 100% silk emergence will reduce effectiveness. For optimum cutworm control, apply in a 12-inch band, over the row, using sufficient volume of water to obtain thorough coverage. For broadcast application, use at least 20 gallons by ground or 5 gallons by air per acre. For cutworm control, this product is most effective against species which feed on the upper portions of the plant.
	Western bean cutworm, Cutworms	2 1/2	0.5	

RESTRICTIONS AND PRECAUTIONS: FIELD AND POP CORN

- Do not apply within 48 days of harvest of grain and fodder or within 14 days of harvest or grazing of forage or silage.
- Do not apply more than a total of 10 pounds per acre per crop.

GRAIN SORGHUM

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Grain Sorghum	Armyworm, Fall armyworm, Chinch bugs, Stink bugs, Corn earworm, Webworms	1 1/4 to 2 1/2	1.0 to 0.5	Repeat applications as necessary up to a total of 4 times but not more often than once every 7 days.
	Southwestern corn borer	1 7/8	0.67	Direct spray into forming heads for optimum control of insects attacking heads.
	Cutworms	2 1/2	0.5	For optimum chinch bug control, use high gallonage ground application at the base of plants. For cutworm control, this product is most effective against species which feed on the upper portions of the plant.

RESTRICTIONS AND PRECAUTIONS: GRAIN SORGHUM

- Do not apply within 21 days of harvest for grain or fodder or within 14 days of harvest or grazing of forage or silage.
- Do not apply more than a total of 7 1/2 pounds per acre per crop.

RICE

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Rice	Armyworm, Leafhoppers, Chinch bugs, Stink bugs, Fall armyworm	1 1/4 to 1 7/8	1.0 to 0.67	Up to 2 applications per crop may be made but not more often than once every 7 days.
	Tadpole shrimp	1 7/8	0.67	**California only** For optimum tadpole shrimp control, apply to water when pest first appears.

RESTRICTIONS AND PRECAUTIONS: RICE

- Do not apply within 14 days of harvest for grain or straw.
- Do not apply more than a total of 5 pounds per acre per crop.
- CAUTION: May kill shrimp, crabs, and crayfish.
- Do not apply propanil herbicides within 15 days before or after application of this product or plant injury will result.

SWEET CORN

CROP	PEST		POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Sweet Corn	Armyworm Chinch bugs Corn earworm Corn rootworm adults Fall armyworm Flea beetles	Japanese beetle Sap beetles Southwestern corn borer Leafhoppers	1 1/4 to 2 1/2	1.0 to 0.5	OBSERVE BEE CAUTION Repeat applications as necessary up to a total of 8 times but not more often than once every 3 days. Optimum timing and good coverage are essential for effective control.
	European corn borer		1 7/8 to 2 1/2	0.67 to 0.5	For insects attacking silks and ears,
	Western bean cutworm	Cutworms	2 1/2	0.5	insecticide sprays should be applied starting when first silks appear and continuing until silks begin to dry. During silking, the minimum retreatment interval (3 days) may not provide adequate levels of protection under conditions of rapid growth or severe pest pressure. The use of an alternative product should be considered in conjunction with this product. For optimum chinch bug control, use ground equipment to apply at least 20 gallons of water per acre and direct spray toward stalk to provide thorough coverage. For optimum European corn borer control, do not apply in less than 3 gallons of water per acre by air and 15 gallons of water by ground. For western bean cutworm, treat when infestation average 15% and at 90 to 100% tassel emergence. Treatment after 100% silk emergence will reduce effectiveness. For optimum cutworm control, apply in a 12-inch band, over the row, using sufficient volume of water to obtain thorough coverage. For broadcast application, use at least 20 gallons by ground or 5 gallons by air per acre. For cutworm control, this product is most effective against species which feed on the upper portions of the plant.

RESTRICTIONS AND PRECAUTIONS: SWEET CORN

- Do not apply within 2 days of harvest of ears, within 14 days of harvest or grazing of forage, or within 48 days of harvest of fodder.
- Do not apply more than a total of 20 pounds per acre per crop.

WHEAT AND PROSO MILLET

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Wheat Proso Millet	Flea beetles	2/3 to 1 1/4	1.8 to 1.0	Up to 2 applications per crop may be made but not more often than once every 14 days.
	Cereal leaf beetle	1 1/4	1.0	
DO NOT USE ON WHEAT AND PROSO MILLET IN CALIFORNIA	Armyworm Fall armyworm	1 1/4 to 1 7/8	1.0 to 0.67	Application is effective against eggs, larvae, and adults of the cereal leaf beetle. Application for armyworm control should be made when armyworms are actively feeding on the upper foliage and night temperatures and not expected to drop below 55°F. If applying by air to lush growth, use a minimum spray volume of 5 gallons per acre to optimize coverage.

RESTRICTIONS AND PRECAUTIONS: WHEAT AND PROSO MILLET

- Do not apply within 21 days of harvest for grain or straw or within 7 days of harvest or grazing of forage.
- Do not apply more than a total of 3 3/4 pounds per acre per crop.

CUCURBIT VEGETABLES

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Cucurbit Vegetables: Cucumbers Melons Pumpkins Squash	Pickleworm Melonworm	2/3 to 1 1/4	1.8 to 1.0	Repeat applications as necessary up to a total of 6 times but not more often than once every 7 days. For optimum control of squash bugs, apply sufficient spray volume for thorough coverage and time sprays for early morning or late afternoon.
	Cucumber beetles Flea beetles Leafhoppers Squash bugs	1 1/4	1.0	

RESTRICTIONS AND PRECAUTIONS: CUCURBIT VEGETABLES

- Do not apply within 3 days of harvest.
- Do not apply more than a total of 7 1/2 pounds per acre per crop.
- Observe plant response precautions.

FLAX

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Flax **DO NOT USE ON FLAX IN CALIFORNIA**	Armyworm	1 1/4 to 1 7/8	1.0 to 0.67	Up to 2 applications per crop may be made but not more often than once every 14 days.

RESTRICTIONS AND PRECAUTIONS: FLAX

- Do not apply within 42 days of harvest for seed or straw.
- Do not apply more than a total of 3 3/4 pounds per acre per crop.

FORAGE CROPS
ALFALFA, CLOVERS, AND BIRDSFOOT TREFOIL

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Alfalfa, Clovers, and Birdsfoot Trefoil	Blister beetles Mexican bean beetle	2/3 to 1 1/4	1.8 to 1.0	OBSERVE BEE CAUTION. Observe plant response precautions.
	Alfalfa caterpillar Bean leaf beetle Cucumber beetles Green cloverworm Japanese beetle Leafhoppers Potato leafhopper Three cornered alfalfa hopper Thrips Velvetbean caterpillar	1 1/4	1.0	On dense growth, use 25 to 40 gallons of water per acre with ground equipment to ensure adequate coverage.
	Alfalfa blotch leafminer Armyworm Cloverhead weevil Corn earworm Cutworms Egyptian alfalfa weevil larvae Essex skipper European alfalfa beetle Fall armyworm Lygus bugs Stink bugs Webworms Yellow striped armyworm	1 1/4 to 1 7/8	1.0 to 0.67	For alfalfa weevil larvae, if pretreatment damage is extensive, cut alfalfa and treat the stubble. This product is not effective against **adult** alfalfa weevils. For cutworm control, this product is most effective against species which feed on the upper portions of the plant.
	Alfalfa weevil larvae (west of the Rocky Mountains)	1 1/4 to 1 7/8	1.0 to 0.67	
	Alfalfa weevil larvae (east of the Rocky Mountains)	1 7/8	0.67	

RESTRICTIONS AND PRECAUTIONS: FORAGE CROPS

- Do not apply more than once per cutting.
- Do not apply within 7 days of harvest or grazing.
- Do not exceed 1 7/8 pounds per acre per cutting.
- Carbaryl may cause a temporary bleaching of tender alfalfa foliage.

PASTURE AND GRASSES GROWN FOR SEED

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Pasture and Grasses Grown for Seed	Armyworm Chinch bugs Essex skipper Fall armyworm Striped grass looper Thrips Range caterpillar Range crane fly Ticks	1 1/4 to 1 7/8	1.0 to 0.67	Up to 2 applications per year may be made but not more often than once every 14 days. To control thrips in grasses grown for seed, use high spray pressure to improve penetration into boot. Carefully mark swaths to avoid over-application.

RESTRICTIONS AND PRECAUTIONS: PASTURE AND GRASSES GROWN FOR SEED

- Do not apply within 14 days of harvest or grazing.
- Do not exceed a total of 3 3/4 pounds per acre per year.

RANGELAND

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Rangeland	Black grass bug Grasshoppers Mormon cricket Range caterpillar Range crane fly	2/3 to 1 1/4	1.8 to 1.0	Do not make more than 1 application per year. Carefully mark swaths to avoid over-application.
	Ticks	1 1/4	1.0	

RESTRICTIONS AND PRECAUTIONS: RANGELAND

- May be harvested or grazed the same day as treatment.
- Do not apply more than 1 1/4 pounds per acre per year.

FRUITING VEGETABLES

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Fruiting Vegetables: Tomatoes, Peppers, Eggplant	Colorado potato beetle European corn borer Fall armyworm Lace bugs Stink bugs (suppression) Tarnished plant bug Thrips (suppression) Tomato fruitworm Tomato hornworm Tomato pinworm	1 1/4 to 2 1/2	1.0 to 0.5	Repeat applications as necessary up to a total of 7 times but not more often than once every 7 days. Thorough coverage is essential to effectively suppress stink bugs. When disease transmission is suspected, monitor fields following application and retreat if reinfestation occurs but not more often than once every 7 days.
	Flea beetles Leafhoppers	2/3 to 1 1/4	1.8 to 1.0	
	Cutworms	2 1/2	0.5	For cutworm control, this product is most effective against species which feed on the upper portions of the plant.

RESTRICTIONS AND PRECAUTIONS: FRUITING VEGETABLES

- Do not apply within 3 days of harvest.
- Do not apply more than a total of 10 pounds per crop.

LEAFY VEGETABLES

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Leafy vegetables:	Flea beetles Harlequin bug Leafhoppers	2/3 to 1 1/4	1.8 to 1.0	Repeat applications as necessary up to a total of 5 times but not more often than once every 7 days.
Celery, Dandelion, Endive, Lettuce (head and leaf), Parsley, Spinach, Swiss Chard	Armyworm Aster leafhopper Corn earworm Fall armyworm Imported cabbageworm Lygus bugs Spittlebugs Stink bugs Tarnished plant bug	1 1/4 to 2 1/2	1.0 to 0.5	

RESTRICTIONS AND PRECAUTIONS: LEAFY VEGETABLES

- Do not apply within 14 days of harvest.
- Do not apply more than a total of 7 1/2 pounds per acre per crop.

LEGUME VEGETABLES

CROP	PEST		POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Legume Vegetables: Soybeans, Fresh and Dried Beans (*Phaseolus* species including snap, navy and kidney), Fresh and Dried Peas (*Pisum* species), Lentils, Cowpeas, Southern Peas **DO NOT USE ON LENTILS IN CALIFORNIA**	Bean leaf beetle Blister beetle Cucumber beetles Grape colapsis	Green cloverworm Japanese beetle Mexican bean beetle Velvetbean caterpillar	2/3 to 1 1/4	1.8 to 1.0	Repeat applications as necessary up to a total of 4 times but not more often than once every 7 days. For cutworm control, this product is most effective against species which feed on the upper portions of the plant. Use lower rates for light to moderate populations and smaller instars and to provide maximum survival of beneficial insects and spiders. Use the higher rates for heavy populations and larger instars.
	Corn earworm		2/3 to 1 7/8	1.8 to 0.67	
	Alfalfa caterpillar Colorado potato beetle Flea beetles Leafhoppers	Three cornered alfalfa hopper Thrips Western bean cutworm	1 1/4	1.0	
	Armyworm Cutworms European corn borer Fall armyworm	Stink bugs Tarnished plant bug Webworms	1 1/4 to 1 7/8	1.0 to 0.67	
	Alfalfa looper (suppression) Cowpea curculio (suppression) Painted lady (Thistle caterpillar) Pea leaf weevil	Pea weevil Saltmarsh caterpillar Woollybean caterpillar Yellowstriped armyworm	1 7/8	0.67	
	California only: Corn earworm (suppression) Limabean podborer (suppression)	Lygus bugs (suppression) Stink bugs (suppression)	1 7/8	0.67	

RESTRICTIONS AND PRECAUTIONS: LEGUME VEGETABLES

- Do not apply within 14 days of grazing or harvest for forage or within 3 days of harvest of fresh beans or peas or within 21 days of harvest of dried beans or peas, seed, or hay.
- Do not apply more than a total of 7 1/2 pounds per acre per crop.
- Do not apply a combination of this product and 2,4-DB herbicides to soybeans as crop injury may result.
- Observe plant response precautions.

NON CROPLAND

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Conservation Reserve Program Acreage	Black grass bug	1/3 to 2/3	3.7 to 1.8	Up to 2 applications per year may be made but not more often than once every 14 days.
Set-Aside Program Acreage Wasteland Rights-of-Way Hedgerows Ditchbanks Roadsides	Mormon cricket Range caterpillar Range crane fly	2/3 to 1 1/4	1.8 to 1.0	Carefully mark swaths to avoid over-application.
	Ticks	1 1/4 to 1 7/8	1.0 to 0.67	

RESTRICTIONS AND PRECAUTIONS: NONCROPLAND

- Do not apply within 14 days of grazing or harvest for forage or hay.
- Do not apply more than a total of 3 3/4 pounds per acre per year.

OKRA

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Okra **DO NOT USE ON OKRA IN CALIFORNIA.**	Corn earworm Stink bugs	1 1/4 to 1 7/8	1.0 to 0.67	Apply using ground equipment in sufficient volume to insure good coverage. Apply as needed on 6 to 8 day intervals. For grasshopper control, refer to the general Grasshopper Section.

RESTRICTIONS AND PRECAUTIONS: OKRA

- Do not apply within 3 days of harvest.
- Do not apply more than a total of 7 1/2 pounds per acre per season.

PEANUTS

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Peanuts	Blister beetles Mexican bean beetle	2/3 to 1 1/4	1.8 to 1.0	Repeat applications as necessary up to a total of 5 times but not more often than once every 7 days.
	Alfalfa caterpillar Bean leaf beetle Cucumber beetle Green cloverworm Japanese beetle Leafhoppers Rednecked peanutworm Three cornered alfalfa hopper Thrips Velvetbean caterpillar	1 1/4	1.0	For optimum control of thrips, use directed or banded sprays with hollow cone spray nozzles. Ensure adequate coverage for the underside of leaves.
	Armyworm Corn earworm Fall armyworm Stink bugs Webworms	1 1/4 to 1 7/8	1.0 to 0.67	For cutworm control, this product is most effective against species which feed on the upper portions of the plant.
	Whitefringed beetle adults Cutworms	2 1/2	0.5	

RESTRICTIONS AND PRECAUTIONS: PEANUTS

- Do not apply within 14 days of harvest.
- Do not apply more than a total of 10 pounds per acre per crop.
- Observe plant response precautions.

PRICKLY PEAR CACTUS

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Prickly Pear Cactus **DO NOT USE ON PRICKLY PEAR CACTUS IN CALIFORNIA**	Cochineal scale (crawlers)	2 1/2	0.5	Apply using ground equipment in sufficient volume to insure good coverage. Apply as needed on 7 to 10 day intervals. For grasshopper control, refer to the general Grasshopper Section.

RESTRICTIONS AND PRECAUTIONS: PRICKLY PEAR CACTUS

- Do not apply within 3 days of harvest.
- Do not apply more than a total of 7 1/2 pounds per acre per season.

ROOT AND TUBER CROPS

ROOT AND TUBER CROPS EXCEPT SUGAR BEETS AND SWEET POTATOES

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Root and Tuber Crops:	Flea beetles Leafhoppers	2/3 to 1 1/4	1.8 to 1.0	Repeat applications as necessary up to a total of 6 times but not more often than once every 7 days. For cutworm control, this product is most effective against species which feed on the upper portions of the plant.
Garden Beets, Carrots, Horseradish, Parsnips, Radishes, Rutabagas, Salsify, Potatoes	Armyworm Aster leafhopper Colorado potato beetle Corn earworm Cutworms European corn borer Fall armyworm Lace bugs Lygus bugs Spittlebugs Stink bugs Tarnished plant bug	1 1/4 to 2 1/2	1.0 to 0.5	

RESTRICTIONS AND PRECAUTIONS: ROOT AND TUBER CROPS EXCEPT SUGAR BEETS AND SWEET POTATOES

- Do not apply within 7 days of harvest.
- Do not apply more than a total of 7 1/2 pounds per acre per crop.

SUGAR BEETS

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Sugar beets	Armyworm Beet leaf beetle Fall armyworm Flea beetles Leafhoppers Webworms	1 1/2 to 1 7/8	1.0 to 0.67	Repeat applications as necessary up to a total of 2 times but not more often than once every 14 days. For cutworm control, this product is most effective against species which feed on the upper portions of the plant.
	Cutworms	1 7/8	0.67	

RESTRICTIONS AND PRECAUTIONS: SUGAR BEETS

- Do not apply within 28 days of harvest for roots or forage.
- Do not apply more than a total of 5 pounds per acre per crop.

SWEET POTATOES

CROP	PEST		POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Sweet Potatoes	Corn earworm Cucumber beetles Flea beetles Sweet potato hornworm	Sweet potato weevil Tortoise beetles Whitefringed beetle	1 1/4 to 2 1/2	1.0 to 0.5	**Preplant dip for control of sweet potato weevil**: Just prior to planting, dip sweet potato cuttings in a suspension containing 10 pounds of this product in 100 gallons of water (1.6 ounces of this product per gallon of water)
	Yellowstriped armyworm		2 1/2	0.5	For foliar sprays, repeat applications as necessary up to a total of 8 times but not more often than once every 7 days.

RESTRICTIONS AND PRECAUTIONS: SWEET POTATOES

- Do not apply within 7 days of harvest.
- Do not apply more than a total of 10 pounds per acre per crop with in-season sprays.
- Do not apply more than a total of 1 1/2 pounds per acre as a preplant dip treatment.

SMALL FRUITS AND BERRIES

CROP	PEST		POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Small Fruits and Berries: Caneberries, Blueberries, Cranberries, Grapes, Strawberries	European fruit lecanium European raspberry aphid Flea beetles Grape leaffolder Grape leafroller Japanese beetle Leafhoppers Leafrollers Meadow spittlebug Omnivorous leaftier	Rose chafer Snowy tree cricket Strawberry bud weevil Strawberry clipper Strawberry fruitworm Strawberry leafroller Strawberry weevil Western grapeleaf skeletonizer Western yellowstriped armyworm	1 1/4 to 2 1/2	1.0 to 0.5	OBSERVE BEE CAUTION. Repeat applications as necessary up to a total of 5 times but not more often than once every 7 days. For cutworm control, this product is most effective against species which feed on the upper portions of the plant. In grapes for grape leaffolder control, apply before first brood larvae emerge from rolls. In grapes, do not concentrate spray on the bunch or visible residues may result.
	Blueberry maggot Cherry fruitworm Cranberry fireworm Cranberry fruitworms Cranberry twig girdler	Elm spanworm Gypsy moth Spaganothus worm Tarnished plant bug	1 7/8 to 2 1/2	0.67 to 0.5	
	Eight-spotted forester Cutworms Grape berry moth June beetles Omnivorous leafroller	Orange tortrix Raspberry fruitworm Raspberry sawfly Redbanded leafroller Saltmarsh caterpillar	2 1/2	0.5	

RESTRICTIONS AND PRECAUTIONS: SMALL FRUITS AND BERRIES

- Do not apply within 7 days of harvest.
- Do not apply more than a total of 12 1/2 pounds per acre per crop.
- CAUTION: Use in cranberries may kill shrimp and crabs. Do not use in areas where these are important resources.
- Carbaryl may injure Early Dawn and Sunrise varieties of strawberries.

SUNFLOWERS

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Sunflowers	Stem weevil Sunflower beetle	1 1/4 to 1 7/8	1.0 to 0.67	Up to 2 applications may be made but not more often than once every 7 days.
DO NOT USE ON SUNFLOWERS IN CALIFORNIA	Armyworm Cutworms Fall armyworm Sunflower moth	1 7/8	0.67	For cutworm control, this product is most effective against species which feed on the upper portions of the plant.

RESTRICTIONS AND PRECAUTIONS: SUNFLOWERS

- Do not apply within 30 days of grazing or harvest for forage or within 60 days of harvest for seed.
- Do not apply more than a total of 3 3/4 pounds per acre per crop.

TOBACCO

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Tobacco	Budworms Fall armyworm Tobacco flea beetles Hornworms Japanese beetle June beetle Suckfly	1 1/4 to 2 1/2	1.0 to 0.67	**Plant bed and Field Treatment** Repeat treatments as necessary up to a total of 4 times per crop but not more often than once every 7 days. Use lower rate on young plants (up to knee height). Use at least 10 gallons of prepared spray per acre. Begin treatments when worms are small.

RESTRICTIONS AND PRECAUTIONS: TOBACCO

- Tobacco may be harvested on the day of treatment.
- Do not apply more than a total of 10 pounds per acre per crop.
- Observe plant response precautions.

TREE FRUIT CROPS

On all tree fruit crops, apply in sufficient volume for adequate coverage. This will vary depending on the pest and its severity, the tree condition, size, and density, and other factors.

CITRUS FRUITS

CROP	PEST		POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Citrus Fruits	Avocado leafroller California orangedog Citrus cutworm Fruittree leafroller	Orange Tortrix Western tussock moth	2 1/2 to 3 3/4	0.5 to 0.3	OBSERVE BEE CAUTION. Repeat applications as necessary up to a total of 8 times but not more often than once every 14 days.
	Citrus rust mite Eriophyid mites Plant bugs	Scale insects [Black scale, brown soft scale, California red scale (except in California), citrus snow scale, yellow scale (except in California)]	3 3/4 to 6 1/4	0.3 to 0.2	For scale control, apply when crawlers are present. For best control of Eriophyid mites including citrus rust mite, apply when pest populations are low.
	Apopka weevil (adult) Citrus root weevils (adults)	Fuller Rose Beetle Little leaf notcher (adult)	6 1/4 to 9 3/8	0.2 to 0.13	
	California only: California red scale	Yellow scale	6 1/4 to 20	0.2 to 0.05	Do not make more than 1 application per season for California red scale. Apply when crawlers are present.

RESTRICTIONS AND PRECAUTIONS: CITRUS FRUITS

- Do not apply within 5 days of harvest.
- Do not apply more than a total of 25 pounds per acre per crop.

OLIVES

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Olives	Scale insects (olive scale, black scale)	6 1/4 to 9 3/8	0.2 to 0.13	Up to 2 applications per crop may be made but not more often than once every 14 days.

RESTRICTIONS AND PRECAUTIONS: OLIVES

- Do not apply within 14 days of harvest.
- Do not apply more than a total of 18 3/4 pounds per acre per crop.

POME FRUITS

CROP	PEST		POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Pome Fruits: apples, pears, loquats, crabapples, oriental pears	White apple leafhopper		5/8 to 1 7/8	1.8 to 0.67	OBSERVE BEE CAUTION On apples, avoid use during the period from full bloom until 30 days after full bloom unless fruit thinning is desired. Use for pest control during this period also may result in fruit removal.
	Apple aphid	Codling moth	1 1/4 to 3 3/4	1.0 to 0.3	
	Apple aphid Apple maggot Apple mealybug Apple rust mite Bagworms California pearslug (pear sawfly) European apple sawfly Eyespotted bud moth Fruittree leafroller Gypsy moth Japanese beetle Lesser appleworm Lygus bugs Orange tortrix	Pearleaf blister mite Pear psylla Pear rust mite Periodical cicada Plum curculio Redbanded leafroller Rosy apply aphid Scale insects (Forbes scale, Lecanium scale, San Jose scale) Tarnished plant bug Tentiform leafminers Woolly apple aphid Yellowheaded fireworm	1 7/8 to 3 3/4	0.67 to 0.3	Repeat applications as necessary up to a total of 8 times per crop (including thinning sprays on apples) but not more often than once every 14 days. For psylla control, apply when eggs hatch or young nymphs are present. For scale control, apply when crawlers are present.

POME FRUITS
(continued)

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Apples Only, for Fruit Thinning		1 1/4 to 3 3/4	1.0 to 0.3	OBSERVE BEE CAUTION. For easily thinned varieties: apply 1/3 to 2/3 pounds per 100 gal. of spray mixture. For difficult to thin varieties: apply 2/3 to 1 1/4 pounds per 100 gal. of spray mixture. Apply between 10 and 25 days after full bloom. Factors such as tree age, variety, nutrition, previous crop, pruning, bloom and degree of set favor excessive fruit thinning with this product. Exercise caution to avoid possible yield reduction. **Rates may vary depending on variety and local orchard conditions. Consult with your County Extension Service or other experts for advice on the proper use of this product.** **CAUTION:** The use of SEVIN® 80WSP may result in fruit deformity under certain environmental conditions. Before using on any variety of apples, the user must weigh the risk versus benefits when using this product, particularly when using between **80% petal fall and 6 mm fruit size**. Red Delicious are more sensitive to this phenomenon and in particular, the varieties Bisbee, Red Chief and Vallee Spur are very susceptible to conditions causing fruit deformity. Precipitation and temperatures below 65° F increases the possibility of fruit deformity. The use with summer spray oils and wetting agents may increase the risk of fruit deformity and injury.

RESTRICTIONS AND PRECAUTIONS: POME FRUITS

- Do not apply to quince.
- Do not use on pears between the tight flower cluster up to the 20 mm fruit size. Use during this period may result in undesirable fruit thinning and/or deformed fruit.
- Do not apply within 3 days of harvest.
- Do not apply more than a total of 18 3/4 pounds per acre per crop.
- Do not make more than a total of 8 applications per crop.

FOR PROTECTION OF HONEY BEES:

- Remove all bee hives from orchard to be treated prior to application.
- Do not apply this product if bees are actively foraging in orchard.
- If weed bloom is present, mow the cover crop on the orchard floor prior to applying this product.

STONE FRUITS

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Stone Fruits: Apricots, Cherries, Nectarines, Peaches, Plums, and Prunes	Apple pandemis Black cherry aphid Cherry fruitworm Cherry maggot (Cherry fruit fly) Codling moth Cucumber beetles Eastern tent caterpillar Eyespotted bud moth European earwig Fruittree leafroller Green fruitworm Gypsy moth Japanese beetle June beetle Lesser peachtree borer Mealy plum aphid Orange tortrix Oriental fruit moth Peach twig borer Periodical cicada Plum curculio Prune leafhopper Redbanded leafroller Rose chafer Scale insects (Brown soft scale, Forbes scale, Lecanium scale, Olive scale, Oystershell scale, San Jose scale) Tarnished plant bug Tussock moth Variegated leafroller	2 1/2 to 3 3/4	0.5 to 0.3	OBSERVE BEE CAUTION. Repeat applications as necessary up to a total of 3 times per crop but not more often than once every 7 days. An additional application at the dormant or delayed dormant timing may be made. For optimum scale control, apply when crawlers are present. For lesser peachtree borer, best results have been found by thoroughly spraying limbs and tree trunks at weekly intervals during moth flight.
	California Only: Black cherry aphid Cherry fruitworm Cherry maggot (Cherry fruit fly) Codling moth Cucumber beetles Eyespotted bud moth European earwig Fruittree leafroller Green fruitworm Mealy plum aphid Orange tortrix Oriental fruit moth Peach twig borer Scale insects (Brown soft scale, Forbes scale, Lecanium scale, Olive scale, Oystershell scale, San Jose scale) Tarnished plant bug Tussock moth	3 3/4 to 5	0.3 to 0.25	OBSERVE BEE CAUTION. Repeat applications as necessary up to a total of 3 times per crop but not more often than once every 14 days. An additional application at the dormant or delayed dormant timing may be made. For optimum scale control, apply when crawlers are present.
	Peach twig borer Scale insects (Brown soft scale, Forbes scale, Lecanium scale, Olive scale, Oystershell scale, San Jose scale)	5 to 6 1/4	0.25 to 0.2	**For dormant or delayed dormant timing,** apply in combination with a recommended dormant oil. Refer to the dormant oil product label for additional use directions and restrictions.

RESTRICTIONS AND PRECAUTIONS: STONE FRUITS

- Do not apply within 3 days of harvest, except in California. In California, do not apply within 1 day of harvest.
- Do not apply more than a total of 17 1/2 pounds per acre per crop.
- Do not apply more than a total of 6 1/4 pounds per acre at the dormant or delayed dormant timing.
- Do not apply more than a total of 11 1/4 pounds per acre during the production season.

TREE NUT CROPS

On all tree nut crops, apply in sufficient volume for adequate coverage. This will vary depending on the pest and its severity, the tree condition, size, and density, and other factors.

PISTACHIOS

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Pistachios	Brown soft scale Lecanium scale Navel orangeworm	3 3/4 to 6 1/4	0.3 to 0.2	Repeat applications as necessary up to a total of 4 times per crop (including any applications at the dormant or delayed dormant timing) but not more often than once every 7 days. For scale control, apply when crawlers are present.
	Scale insects	5 to 6 1/4	0.25 to 0.2	**For dormant or delayed dormant timing**, apply in combination with a recommended dormant oil. Refer to the dormant oil product label for additional use directions and restrictions.

RESTRICTIONS AND PRECAUTIONS: PISTACHIOS

- Do not apply within 14 days of harvest.
- Do not apply more than a total of 18 3/4 pounds per acre per crop, including any application at the dormant or delayed dormant timing.

TREE NUTS

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Tree Nuts: Almonds, Chestnuts, Filberts, Pecans, Walnuts	Black margined aphid Calico scale Codling moth European fruit lecanium Fall webworm Filbert aphid Filbert leafroller Filbertworm Frosted scale Fruittree leafroller Hickory shuckworm Lesser webworm Navel orangeworm Peach twig borer Pecan leaf phylloxera Pecan stem phylloxera Pecan nut casebearer Pecan spittlebug Pecan weevil San Jose scale Twig girdler Walnut caterpillar	2 1/2 to 6 1/4	0.5 to 0.2	OBSERVE BEE CAUTION Repeat applications as necessary up to a total of 4 times per crop (including any applications at the dormant or delayed dormant timing) but not more often than once every 7 days. Use lower rates for pests attacking leaves. Use higher rates for pests attacking fruit and for higher infestations. For scale control, apply when crawlers are present. For peach twig borer, best results with foliar applications have been found by making applications in "popcorn" or petal fall stages when the May brood begins to hatch. For navel orangeworm in almonds and walnuts, best results have been found by timing early and midseason applications to correspond with moth flight peaks. For filbert leafroller, best results have been found by making applications when eggs are hatching, repeating application on first appearance of moths and again 3 to 4 weeks later. For codling moth in walnuts, best results have been found by making applications when average cross-sectional diameters of developing nuts are 0.5 to 0.75 inches and again during middle or late June as needed.
	Chestnut weevil European earwig	5 to 6 1/4	0.25 to 0.2	For chestnut weevil, best results have been found with 4 applications at weekly intervals beginning in late July. The last application should be made prior to shuck split. For European earwig, thorough coverage of trunks, branches, and nuts is needed for best results.
Almonds only	Peach twig borer Scale insects	5 to 6 1/4	0.25 to 0.2	**For dormant or delayed dormant timing**, apply in combination with a recommended dormant oil. Refer to the dormant oil product label for additional use directions and restrictions.

RESTRICTIONS AND PRECAUTIONS: TREE NUTS

- Do not apply within 14 days of harvest.
- Do not apply more than a total of 18 3/4 pounds per acre per crop, including any application at the dormant or delayed dormant timing.

FORESTED AREAS AND RANGELAND TREES

Apply in sufficient volume for adequate coverage. This will vary depending on the tree size, density and stage of growth.

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Forested areas: Non-urban Forests, Tree Plantations, Planted Christmas Trees, Parks, Rural Shelter Belts Rangeland Trees	Ants Apple aphid Armyworm Ash whitefly Azalea leafminer Bagworms Balsam twig aphid Birch leafminer Blister beetle Boxelder bug Boxwood leafminer Brown tail moth Cankerworms Catalpa sphinx Chiggers Cooley spruce gall adelgid Cutworms Cypress tip moth Douglas-fir tussock moth Eastern spruce gall adelgid Elm leaf aphid Elm leaf beetle Elm spanworm Eriophyid mites European pine shoot moth Fall armyworm Flea beetle Fuschia gall mite Fuller rose beetle Gall midges Gall wasps Greenstriped mapleworm Grasshoppers Hackberry nipplegall maker Holly bud moth Holly leafminer Jackpine budworm Japanese beetle Jeffrey pine needleminer June beetles Lace bugs Leafhoppers Leafrollers Locust borer Maple leafcutter Mealy bugs Mimosa webworm Nantucket pine tip moth Oak leafminers Oak moth Oak skeletonizer Oakworm complex Oleander caterpillar Olive ash borer Orange-striped oakworm Periodical cicada Pine looper Pine sawfly Pine spittlebug Pitch pine tip moth Spruce budworm Plant bugs Poinsettia hornworm Psyllids Puss caterpillar Redhumped oakworm Rose aphid Rose chafer Rose slug Saddled prominent Sawflies (exposed) Scale insects (crawlers) Sowbugs Spiney elm caterpillar Springtails Spruce needleminer Subtropical pine tip moth Tent caterpillars Thorn bug Thrips (exposed) Ticks Walnut caterpillar Webworms Western hemlock looper Western spruce budworm Willow leaf beetles Wooly gall aphid Yellow poplar weevil	1 1/4	1.0	Observe plant response precautions. Obtain thorough coverage of upper and lower leaf surfaces. The addition of a sticker may improve residual control. To control scale insects, treat trunks, stems and twigs in addition to plant foliage. For optimum worm control, treat when pests are small. Do not use on syrup-producing sugar maples where sap is harvested. Applications for control of maple leafcutter on sugar maple should be made when larvae are in 2nd instar after mining and as cases are being formed. Repeat treatments as necessary up to a total of 2 times per year but not more often than once every 7 days. For gypsy moth control, use the higher rate for heavy infestations.
	Gypsy Moth	9/10 to 1 1/4	1.3 to 1.0	

FORESTED AREAS AND RANGELAND TREES, CONTINUED

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Forested areas: Non-urban Forests, Tree Plantations, Planted Christmas Trees, Parks, Rural Shelter Belts Rangeland Trees	Elm bark beetle Ips engraver beetles Mountain pine beetle Roundheaded pine beetle Spruce beetle Western pine beetle	2% solution (1 pak per 6.67 gallons)	See Specific Directions	**Direct Trunk Treatment**: Effective as a preventative treatment only. Repeat annually as required to prevent beetle attacks. Apply 1 gallon of spray per 50 square feet of bark prior to beetle flight or host-tree attack. Treat tree trunk from ground level up, until trunk diameter is less than 5 inches. For elm bark beetle: apply approximately 20-30 gallons of spray mixture for each 50 feet of elm tree for thorough coverage of all bark surfaces on trunks, limbs and twigs. Do not make more than 2 applications per year or repeat applications more often than once every six months.

RESTRICTIONS AND PRECAUTIONS: FORESTED AREAS AND RANGELAND TREES

- Do not make more than 2 applications per year.
- DO NOT ALLOW PUBLIC USE OF TREATED AREAS DURING APPLICATIONS OR UNTIL SPRAYS HAVE DRIED.

CONTROL OF SPECIFIC PESTS ACROSS MULTIPLE SITES

GRASSHOPPERS

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
All crops on this label	Grasshoppers	2/3 to 1 7/8*	1.8 to 0.67	Apply 2/3 to 9/10 pounds per acre of this product for nymphs on small plants or sparse vegetation. Apply 1 1/4 to 1 7/8 pounds per acre for mature grasshoppers or applications to dense foliage or if extended residual control is desired. Be certain spray volumes are appropriate to assure adequate coverage.

RESTRICTIONS AND PRECAUTIONS: GRASSHOPPER CONTROL

- ***NOTE**: Refer to individual site listings elsewhere on this label for use limitations and restrictions. Do not use rates higher than listed for the site or exceed other use restrictions.

CONTROL OF TICKS WHICH VECTOR LYME DISEASE

For control of juvenile and adult ticks which vector Lyme Disease, apply the recommended amount in sufficient volume for thorough coverage.

CROP/SITE	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
All crops on this label Pastures Forested Areas Wasteland, Rights-of-Way, Hedgerows, Ditchbanks, Roadsides, Set-Aside and Conservation Reserve Program Acreage	*Ixodes* spp. (Deer tick, Bear tick, Black legged tick) *Amblyomma* spp. (Lone star tick)	1 1/4 to 2 1/2*	1.0 to 0.5	Use the high rate for heavy tick infestations.* Use higher spray volumes for dense ground cover or heavy leaf litter. Target applications for nymphal control in late spring or early summer. Control of adult tick can be obtained with late summer and fall applications. Do not use spot treatments. Treat entire area and perimeter areas where exposure to ticks may occur. Ticks may be reintroduced from surrounding areas on host animals. Retreat as necessary to maintain adequate control levels*.

RESTRICTIONS AND PRECAUTIONS: CONTROL OF TICKS WHICH VECTOR LYME DISEASE

- ***NOTE**: Refer to individual site listings elsewhere on this label for use limitations and restrictions. Do not use rates higher than listed for the site or exceed other use restrictions.
- DO NOT ALLOW PUBLIC USE OF TREATED AREAS DURING APPLICATION OR UNTIL SPRAYS HAVE DRIED.

IMPORTED FIRE ANTS

CROP/SITE	PEST	POUNDS OF SEVIN® 80WSP PER VOLUME OF WATER	AREA TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Pastures Rangeland Forested Areas Trees and Ornamentals Turfgrass Wasteland	Imported fire ants	1 pak per 67.6 gallons	See Specific Directions	**DRENCH APPLICATION:** Apply a total of 2 gallons of the diluted solution over the surface of each mound or at least 1 quart per 6 inches of mound diameter using a bucket, can or other appropriate equipment. Thoroughly wet mound and surrounding areas to a 4 ft diameter (12 sq.ft.). Do not disturb mound prior to treatment. Pour solution from a height of about three feet to give sufficient force to break mound apex and flow into ant tunnels. For best results apply in cool weather (65-80°F) or in early morning or late evening hours. Repeat application if mound activity resumes after 7 days. Treat new mounds as they appear. Pressurized sprays may disturb the ants and cause migration, reducing product effectiveness.
Nursery Stock, Vegetable Transplants*, Foliage Plants, Bedding Plants **(Outdoor Use Only)**	Imported fire ants	1 pak per 67.6 gallons	See Specific Directions	Avoid contact with foliage and treat only the growing media when using on bedding plants. Do not make more than one application, either as a root dip or drench treatments (applied to the point of saturation).

RESTRICTIONS AND PRECAUTIONS: IMPORTED FIRE ANT CONTROL

- DO NOT ALLOW PUBLIC USE OF TREATED AREAS DURING APPLICATIONS OR UNTIL DRENCH HAS DRIED.
- DO NOT USE IN GREENHOUSES.
- ***NOTE**: DO NOT USE ON ANY FOOD CROP NOT LISTED ON THIS LABEL. Refer to the specific crop section for additional restrictions and precautions.

ADULT MOSQUITO CONTROL

Apply in sufficient gallonage for thorough coverage.

CROP	PEST	POUNDS OF SEVIN® 80WSP PER ACRE	ACRES TREATED per PAK SEVIN® 80WSP	SPECIFIC DIRECTIONS
Pastures Rangeland Forested Lands Trees and Ornamentals Turfgrass Wastelands	Mosquitoes (adults)	1/3 to 1 1/4*	1.0	OBSERVE BEE CAUTION. Treat shrubbery and areas where adult mosquitoes congregate. Treat when adult mosquitoes are active in early mornings or late evenings. Repeat applications as necessary*. Use 1/3 to 2/3 pounds per 100 gallons in mistblowers, 2/3 to 1 1/4 pounds per acre in aerial sprays, and 1 1/4 pounds per acre in low pressure ground sprayers.

RESTRICTIONS AND PRECAUTIONS: ADULT MOSQUITO CONTROL.

- DO NOT ALLOW PUBLIC USE OF TREATED AREAS DURING APPLICATION OR UNTIL SPRAYS HAVE DRIED.
- CAUTION: May kill shrimp and crabs. Do not use in areas where these are important resources.
- ***NOTE**: Refer to individual site listings elsewhere on this label for use limitations and restrictions. Do not use rates higher than listed for the site or exceed other use restrictions.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and should be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

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LIMITATIONS OF LIABILITY: THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

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1-866-99BAYER (1-866-992-2937)

09/23/04.

SEVIN® 80WSP CARBARYL INSECTICIDE

SECTION 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Product Name: SEVIN® 80WSP CARBARYL INSECTICIDE
Chemical Name: Carbaryl
Synonym
MSDS Number: 1825
Chemical Family
Chemical Formulation: C12H11NO2
EPA Registration No.: 264-526
Canadian Registrat. No.
Bayer CropScience
2 T.W. Alexander Drive
Research Triangle PK, NC 27709
USA
For Product Use Information: (866)-992-2937 Monday through Friday (CRLF) 8:00AM-4:30PM (CRLF)
For Medical Emergency contact DART: 1-800-334-7577 24 Hours/Day (CRLF)
For Transportation Emergency CHEMTREC: 1-800-424-9300 24 Hours/Day
Product Use Description: FIFRA regulated use only.
MSDS Number: 000000001825
MSDS Version 1.1

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

Component Name	CAS No.	Concentration % by Weight	
		Minimum	Maximum
CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE)	63-25-2	80.0000	
CALCIUM SILICATE	1344-95-2		
QUARTZ	14808-60-7	0.1100	
DIATOMACEOUS EARTH	61790-53-2		
Other ingredients (Trade secret)			

SECTION 3. HAZARDS IDENTIFICATION

NOTE: Please refer to Section 11 for detailed toxicological information.
Emergency Overview: Warning! May be fatal if swallowed.
Physical State: solid powder
Odor: phenolic
Appearance: off-white to pale yellow
Immediate Effects
Eye: Do not get in eyes. Causes redness, irritation, tearing.
Skin: Harmful if absorbed through the skin. May produce symptoms similar to those from ingestion.
Ingestion: May be fatal if swallowed. This product causes reversible cholinesterase inhibition. Repeated overexposure may cause more severe cholinesterase inhibition with more pronounced signs and symptoms. May lead to rapid onset of nausea, vomiting, diarrhea, abdominal pain, involuntary shaking, excess salivation, pinpoint pupils, blurred vision, profuse sweating, temporary paralysis, respiratory depression, and convulsions.
Inhalation: Harmful if inhaled. May produce symptoms similar to those from ingestion.
Chronic or Delayed Long-Term: This product contains ingredients that are considered to be probable or suspected human carcinogens (See Section 11 - Chronic).
Medical Conditions Aggravated by Exposure: Inhalation of product may aggravate existing chronic respiratory problems such as asthma, emphysema or bronchitis. Skin contact may aggravate existing skin disease.

SECTION 4. FIRST AID MEASURES

Eye: Hold eyelids open and flush with a steady, gentle stream of water for at least 15 minutes. Seek medical attention.
Skin: In case of contact, immediately wash with plenty of soap and water for at least 5 minutes. Seek medical attention if irritation develops or persists. Remove contaminated clothing and shoes. Clean contaminated clothing and shoes before re-use.
Ingestion: If victim is conscious and alert, give 2-3 glasses of water to drink and induce vomiting by touching back of throat with a finger. Do not induce vomiting or give anything by mouth to an unconscious person. Seek immediate medical attention. Do not leave victim unattended. Vomiting may occur spontaneously. To prevent aspiration of swallowed product, lay victim on side with head lower than waist. If vomiting occurs and the victim is conscious, give water to further dilute the chemical.
Inhalation: Remove victim from immediate source of exposure and assure that the victim is breathing. If breathing is difficult, administer oxygen, if available. If victim is not breathing, administer CPR (cardio-pulmonary resuscitation). Seek medical attention.
Note to Physician
All treatment should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.
This product contains a methyl carbamate insecticide, which is a chloinesterase inhibitor. Overexposure to this substance may cause toxic signs and symptoms due to stimulation of the cholinergic nervous system. These effects of overexposure are spontaneously and rapidly reversible.
Specific treatment consists of parenteral atropine sulfate. Caution should be maintained to prevent overatropinization. Improve tissue oxygenation as much as possible before administering atropine to minimize the risk of ventricular fibrillation. Mild cases may be given 1 to 2 mg intramuscularly every 10 minutes until full atropinization has been achieved and repeated thereafter whenever symptoms reappear. Severe cases should be given 2 to 4 mg intravenously every 10 minutes until fully atropinized, then intramuscularly every 30 to 60 minutes as needed to maintain the effect for at least 12 hours. Dosages for children should be appropriately reduced. Complete recovery from overexposure is to be expected within 24 hours.
To aid in confirmation of a diagnosis, urine samples should be obtained within 24 hours of exposure and immediately frozen. Call 1-800-334-7577 before sending samples. Analysis will be arranged by Bayer.
Persons regularly exposed in manufacturing and handling this product should have a preexposure and periodic red blood cell cholinesterase level checks. Narcotics and other sedatives should not be used. Further, drugs like 2-PAM (pyridine-2-aldoxime methiodide) are NOT recommended.

SECTION 5. FIRE FIGHTING MEASURES

Flash Point: Not applicable
Fire and Explosion: Hazards Like all organic and most dry chemicals, as a powder or dust, this product (when mixed with air in critical proportions and in the presence of an ignition source) may present an explosion hazard.
Suitable Extinguishing Media
Small Fires: carbon dioxide (CO_2), dry chemical
Large Fires: alcohol foam, polymer foam, water spray
Fire Fighting Instructions: Firefighters should wear NIOSH/MSHA approved self-contained breathing apparatus and full protective clothing. Keep unnecessary people away, isolate hazard area and deny entry. Evacuate residents who are downwind of fire. Dike area to prevent runoff and contamination of water sources. Dispose of fire control water later. Persons who may have been exposed to contaminated smoke should be immediately examined by a physician and checked for symptoms of poisoning. The symptoms should not be mistaken for heat exhaustion or smoke inhalation.

SECTION 6. ACCIDENTAL RELEASE MEASURES

General and Disposal
Evacuation Procedures and Safety: Wear appropriate gear for the situation. See Personal Protection information in Section 8.
Cleanup and Disposal of Spill: Shovel up into an appropriate closed container (see Section 7: Handling and Storage). Clean up residual material by washing area with water. Decontaminate tools and equipment following cleanup. Avoid creation of dusty conditions.
Land Spill or Leaks
Containment of Spill: Follow procedure under Cleanup and Disposal of Spill.
Environmental and Regulatory Reporting: If spilled on the ground, the affected area should be scraped clean and placed in an appropriate container for disposal. Runoff from fire control or dilution water may cause pollution. Prevent material from entering public sewer system or any waterway. Spills may be reportable to the National Response Center (800-424-8802) and to state and/or local agencies.

SECTION 7. HANDLING AND STORAGE

Handling Procedures: Avoid direct or prolonged contact with skin and eyes. Avoid breathing dusts. Do not ingest.
Storing Procedures: Store in original container. Keep in a dry, cool place. Store in an area that is away from foodstuffs or animal feed, out of reach of children and animals. Handle bag carefully when stored at temperatures below 50°F (10°C) to avoid breakage.
Work/Hygienic Procedures
Personal hygiene is an important work practice exposure control measure and the following general measures should be taken when working with or handling this material:
Do not store, use, and/or consume foods, beverages, tobacco products, or cosmetics in areas where this material is stored.
Wash hands and face carefully before eating, drinking, using tobacco, applying cosmetics, or using the toilet.
Wash exposed skin promptly to remove accidental splashes of contact with this material.
In addition, based upon the specific hazard of this product: Do not take clothing/objects contaminated by this material off the work site. Shower and change into street clothes before leaving the work site.
Min/Max Storage Temperatures: 0°C / 38°C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Where engineering controls are indicated by use conditions of a potential for excessive exposure exists, the following traditional exposure control techniques may be used to effectively minimize employee exposures: general area dilution/exhaust ventilation
Eye/Face Protection
Eye and face protection requirements will vary dependent upon work environment conditions and material handling practices. Appropriate ANSI Z87 approved equipment should be selected for the particular use intended for this material.
Eye contact should be prevented through use of chemical safety glasses with side shields or splash proof goggles. An emergency eye wash must be readily accessible to the work area.
Body Protection: Skin contact should be prevented through use of suitable protective clothing, gloves and footwear, selected with regard of use conditions and exposure potential. Consideration must be given both to durability as well as permeation resistance.
Respiratory Protection
When respirators are required, select NIOSH/MSHA approved equipment based on actual or potential airborne concentrations and in accordance with the appropriate regulatory standards and/or industrial recommendations.
Under normal conditions, in the absence of other airborne contaminants, the following should provide protection from this material up to the conditions specified by the appropriate OSHA, WHMIS or ANSI

standard(s): Air-purifying (half-mask/full-face) respirator with cartridge/canister approved for use against pesticides.
Under conditions immediately dangerous to life or health, or emergency conditions with unknown concentrations, use a full-face positive pressure air-supplied respirator equipped with an emergency escape *air supply unit or use a self-contained breathing* apparatus unit.

General Protection

These recommendations provide general guidance for handling this product. Because specific work environments and material handling practices vary, safety procedures should be developed for each intended application. While developing safe handling procedures, do not overlook the need to clean equipment and piping systems for maintenance and repairs. *Waste resulting from these procedures should* be handled in accordance with Section 13: Disposal Considerations.
Assistance with selection, use and maintenance of worker protection equipment is generally available from equipment manufacturers.

Exposure Limits

CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE) 63-25-2

ACGIH	TWA	5 mg/m3
NIOSH	REL	5 mg/m3
OSHA Z1	PEL	5 mg/m3
OSHA Z1A	TWA	5 mg/m3
US CA OEL	TWA PEL	5 mg/m3

CALCIUM SILICATE 1344-95-2

ACGIH	TWA	10 mg/m3
Remarks		The value is for particulate matter containing no asbestos and <1% crystalline silica.
NIOSH	REL	5 mg/m3
Form of Exposure		Respirable.
NIOSH	REL	10 mg/m3
Form of Exposure		Total
OSHA Z1	PEL	5 mg/m3
Form of Exposure		Respirable fraction.
OSHA Z1	PEL	15 mg/m3
Form of Exposure		Total dust.
OSHA Z1A	TWA	5 mg/m3
Form of Exposure		Respirable fraction.
OSHA Z1A	TWA	15 mg/m3
Form of Exposure		Total dust.
US CA OEL	TWA PEL	5 mg/m3
Form of Exposure		Respirable fraction.
US CA OEL	TWA PEL	10 mg/m3
Form of Exposure		Total dust.

QUARTZ 14808-60-7

NIOSH	REL	0.05 mg/m3
Form of Exposure		Respirable dust.
OSHA Z1A	TWA	0.1 mg/m3
Form of Exposure		Respirable dust.
US CA OEL	TWA PEL	0.1 mg/m3
Form of Exposure		Respirable dust.
US CA OEL	TWA PEL	0.3 mg/m3
Form of Exposure		Total dust.
ACGIH	TWA	0.05 mg/m3

DIATOMACEOUS EARTH 61790-53-2

OSHA Z1A	TWA	6 mg/m3
US CA OEL	TWA PEL	3 mg/m3
Form of Exposure		Respirable dust.
US CA OEL	TWA PEL	6 mg/m3
Form of Exposure		Total dust.
US CA OEL	TWA PEL	6 mg/m3
ACGIH	TWA	10 mg/m3
Remarks		The value is for particulate matter containing no asbestos and <1% crystalline silica.
ACGIH	TWA	3 mg/m3
Remarks		The value is for particulate matter containing no asbestos and <1% crystalline silica.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: off-white to pale yellow
Physical State: solid powder
Odor: phenolic
pH: 4 - 6.5 at 10 wt/wt%.
Vapor Pressure: Not available
Vapor Density (air = 1): Not available
Specific Gravity: Not Available
Boiling Point: Not available
Melting/Freezing Point: Not available
Solubility (in water): *dispersible*
Molecular Weight: 201.2 g/mol
Decomposition Temperature: 140°C
Other Information: Physical and Chemical properties here represent typical properties of this product. Contact the business area using the Product Information phone number in Section 1 for its exact specifications.

SECTION 10. STABILITY AND REACTIVITY

Chemical Stability: This material is stable under normal handling and storage conditions described in Section 7.
Conditions to Avoid
extreme heat
open flame
extreme humidity
moisture
Incompatibility
strong acids
bases
Hazardous Products of Decomposition
Decomposition Type: thermal
oxides of nitrogen
carbon oxides
methyl isocyanate (trace; no adverse effects expected)
Hazardous Polymerization (Conditions to avoid): not applicable

SECTION 11. TOXICOLOGICAL INFORMATION

Acute Oral Toxicity: Rat: LD50: 281 mg/kg
Acute Dermal Toxicity: Rabbit: LD50: > 2,000 mg/kg
Acute Inhalation Toxicity
No test data found for product.
Acute Respiratory Irritation: No test data found for product.
Skin Irritation: Rabbit: Minimally Irritating
Eye Irritation: Rabbit: Slightly irritating.
Chronic Toxicity: Carbaryl has been shown to cause tumors in laboratory animals in lifetime feeding studies. Carbaryl, when administered by various routes, at doses toxic to the maternal animals, has been shown to produce developmental toxicity in a number of species. Carbaryl produces no teratogenic effect in the absence of maternal toxicity.
Assessment Carcinogenicity
ACGIH
CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE) 63-25-2: Group A4
CALCIUM SILICATE 1344-95-2: Group A4
QUARTZ 14808-60-7: Group A2
NTP
QUARTZ 14808-60-7
IARC
CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE) 63-25-2: 3
OSHA
None

SECTION 12. ECOLOGICAL INFORMATION

Acute and Prolonged Toxicity to Fish
The following data is based on the technical grade active ingredient(s) (TGAI).
Rainbow trout
LC50: 1950 ug/l
Exposure Time: 96 h
The following data is based on the technical grade active ingredient(s) (TGAI).
Bluegill sunfish
LC50: 6760 ug/l
Exposure Time: 96 h
Toxicity Other Non Mammal Terr. Species
The following data is based on the technical grade active ingredient(s) (TGAI).
Mallard duck
LC50: > 5,000 mg/kg
Exposure Time: 8 d
Dietary concentrations.
The following data is based on the technical grade active ingredient(s) (TGAI).
Bobwhite quail
LC50: > 5,000 mg/kg
Exposure Time: 8 d
Dietary concentrations.
Environmental Fate: For chemical fate data call the product information phone number listed in Section 1.

SECTION 13. DISPOSAL CONSIDERATIONS

General Disposal Guidance: Chemical additions, processing or otherwise altering this material may make the waste management information presented in this MSDS incomplete, inaccurate or otherwise inappropriate. *Please be advised that state and local* requirements for waste disposal may be more restrictive or otherwise different from federal laws and regulations. Consult state and local regulations regarding the proper disposal of this material.
Container Disposal: EPA Hazardous Waste - Yes
RCRA Classification
63-25-2 CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE)
US. EPA Resource Conservation and Recovery Act *(RCRA) U List of Hazardous Wastes (40 CFR* 261.33(f) and 40 CFR 302 [CERCLA]): U279

SECTION 14. TRANSPORT INFORMATION

Transportation Status:
The listed Transportation Classification does not address regulatory variations due to changes in package size, mode of shipment or other regulatory descriptors.
US Department of Transportation
Shipping Name: NOT REGULATED

SECTION 15. REGULATORY INFORMATION

US Federal
EPA Registration No.: 264-526
TSCA list
CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE) 63-25-2
CALCIUM SILICATE 1344-95-2
QUARTZ 14808-60-7
DIATOMACEOUS EARTH 61790-53-2
TSCA 12b export notification
None
SARA Title III - section 302 - notification and information
None
SARA Title III - section 313 - toxic chemical release reporting
CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE) 63-25-2: 1.0%
US States Regulatory
CA Prop65
This product contains a chemical known to the state of California to cause cancer.
QUARTZ 14808-60-7
US State right-to-know ingredients
CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE) 63-25-2: CA, CT, IL, MA, MN, NJ, PA, RI
CALCIUM SILICATE 1344-95-2: IL, MN, PA, RI
QUARTZ 14808-60-7: IL, MA, MN, PA
DIATOMACEOUS EARTH 61790-53-2: IL
Canadian Regulations
Canadian Registrat. No.
Canadian Domestic Substance List
CALCIUM SILICATE 1344-95-2
QUARTZ 14808-60-7
Environmental
CERCLA
CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE) 63-25-2: 100 lbs
Clean Water Section 307 Priority Pollutants
None
Safe Drinking Water Act Maximum Contaminant Levels
None
International Regulations
EU Classification

None
European Inventory of Existing Commercial Substances (EINECS)
CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE) 63-25-2
CALCIUM SILICATE 1344-95-2
QUARTZ 14808-60-7

SECTION 16. OTHER INFORMATION

	Health	Flammability	Reactivity	Others
HMIS	2	1	1	
NFPA	3	1	1	

Reason for Revisions:
MSDS REVISION INDICATOR: Company name change.
Print Date: 12/26/2002
Supersedes MSDS, which is older than: 12/19/2002
This information is provided in good faith but without express or implied warranty. Buyer assumes all responsibility for safety and use not in accordance with label instructions. The product names are registered trademarks of Bayer AG. Bayer CropScience VID 5.8.03

AHETF Study No. AHE55

Product-Specific Risk Statement
(Must be attached to the Informed Consent Form)

The product you will handle is identified as follows:

Name: Sevin® Brand 4F Carbaryl Insecticide (EPA Registration No. 264-349)

Active Ingredient (AI): Carbaryl (insecticide, CAS No. 63-25-2)

Formulation and Packaging: 4 lb AI/gallon Flowable liquid in 2.5 gallon [redacted]

You may handle up to: 25 gallons of product

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This carbaryl product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye irritation, minimal skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 9/27/04
MSDS date: 12/18/02 (No. 000000000194, Version 2.1)

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

Bayer CropScience

SEVIN® brand 4F Carbaryl Insecticide

FOR AGRICULTURAL OR COMMERCIAL USE ONLY

ACTIVE INGREDIENTS:

Carbaryl (1-naphthyl N-methylcarbamate).....**43.0% by Wt.**

INERT INGREDIENTS:.....**57.0% by Wt.**

(Contains 4 pounds Carbaryl per Gallon)

E.P.A Reg No. 264-349 **E.P.A. Est. No. 264-MO-02**

KEEP OUT OF REACH OF CHILDREN

CAUTION

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577

For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

Carbaryl is an N-Methyl Carbamate Insecticide.

IF SWALLOWED:	• Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything by mouth to an unconscious person.
IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577. **Have the product container or label with you when calling a poison control center or doctor or going for treatment.**	

GENERAL

Contact a physician immediately in all cases of suspected poisoning. Transport to a physician or hospital immediately and SHOW A COPY OF THIS LABEL TO THE PHYSICIAN. If poisoning is suspected in animals, contact a veterinarian.

ANTIDOTE STATEMENT

ATROPINE SULFATE IS HIGHLY EFFECTIVE AS AN ANTIDOTE. Narcotics and other sedatives should not be used. Further, drugs like 2-PAM (pyridine-2-aldoxime methiodide) are NOT recommended. See NOTE TO PHYSICIAN.

NOTE TO PHYSICIAN

Treat symptomatically. Overexposure to materials other than this product may have occurred.

Carbaryl is an N-methyl carbamate insecticide, which is a cholinesterase inhibitor. Overexposure to this substance may cause toxic signs and symptoms due to stimulation of the cholinergic nervous system. These effects of overexposure are spontaneously and rapidly reversible. Gastric lavage may be used if this product has been swallowed. Carbaryl poisoning may occur rapidly after ingestion and prompt removal of stomach contents is indicated.

Specific treatment consists of parenteral atropine sulfate. Caution should be maintained to prevent over atropinization. Improve tissue oxygenation as much as possible before administering atropine to minimize the risk of ventricular fibrillation. Mild cases may be given 1

to 2 mg intramuscularly every 10 minutes until full atropinization has been achieved and repeated thereafter whenever symptoms reappear. Severe cases should be given 2 to 4 mg intravenously every 10 minutes until fully atropinized, then intramuscularly every 30 to 60 minutes as needed to maintain the effect for at least 12 hours. Dosages for children should be appropriately reduced. Complete recovery from overexposure is to be expected within 24 hours.

Narcotics and other sedatives should not be used. Further, drugs like 2-PAM (pyridine-2-aldoxime methiodide) are NOT recommended.

To aid in confirmation of a diagnosis, urine samples should be obtained within 24 hours of exposure and immediately frozen. Analysis will be arranged by Bayer CropScience.

Consultation on therapy can be obtained at all hours by calling the Bayer CropScience emergency number 1-800-334-7577.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS (& DOMESTIC ANIMALS)

CAUTION

HARMFUL IF SWALLOWED, ABSORBED THROUGH THE SKIN, INHALED, OR IF IN EYES.
Avoid breathing vapors or spray mist. Avoid contact with eyes, skin or clothing. Keep out of reach of children and domestic animals.

OVEREXPOSURE MAY CAUSE: Salivation, watery eyes, pinpoint eye pupils, blurred vision, muscle tremors, difficult breathing, excessive sweating, abdominal cramps, nausea, vomiting, diarrhea, weakness, headache. IN SEVERE CASES CONVULSION, UNCONSCIOUSNESS AND RESPIRATORY FAILURE MAY OCCUR. SIGNS AND SYMPTOMS OCCUR RAPIDLY FOLLOWING OVEREXPOSURE TO THIS PRODUCT.

PERSONAL PROTECTIVE EQUIPMENT:

Applicators and other handlers must wear long-sleeved shirt and long pants, chemical resistant gloves such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride (PVC), or viton, shoes plus socks and chemical-resistant headgear for overhead exposure.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning and maintaining Personal Protective Equipment (PPE). If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

User Safety Recommendations

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to aquatic and estuarine invertebrates. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Discharge from rice fields may kill aquatic and estuarine invertebrates. Do not apply when weather conditions favor drift from area treated. Do not contaminate water by cleaning equipment or disposal of wastes. Do not contaminate water when disposing of equipment washwaters.

BEE CAUTION: MAY KILL HONEYBEES IN SUBSTANTIAL NUMBERS.
This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area. Contact your Cooperative Agricultural Extension Service or your local Bayer CropScience representative for further information.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Read the entire label before using this product.

Strictly observe label directions and cautions. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is coveralls, chemical resistant gloves such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride (PVC), or viton, shoes plus socks and chemical-resistant headgear for overhead exposure.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

The area being treated must be vacated by unprotected persons.

Keep unprotected persons out of treated areas until sprays have dried.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE

Store unused SEVIN® brand 4F Carbaryl Insecticide in original container only, in cool, dry area out of reach of children and animals. Do not store in areas where temperatures frequently exceed 100° F.

If container is damaged, before cleaning up, put on Personal Protective Equipment.

PESTICIDE DISPOSAL

Open dumping is prohibited. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

Triple rinse (or equivalent). Then offer container for recycling or reconditioning or puncture and dispose of container in a sanitary landfill, by incineration, or, if allowed by state and local authorities, by burning. If container is burned, stay out of smoke.

GENERAL CAUTIONS AND RESTRICTIONS

SEVIN® brand 4F Carbaryl Insecticide is a suspension of microfine SEVIN® brand carbaryl insecticide in an aqueous medium. It readily disperses in water to form a spray which may be applied by air or ground.

PLANT RESPONSE PRECAUTIONS

Application to wet foliage or during periods of high humidity may cause injury to tender foliage.

Do not use on Boston Ivy, Virginia creeper and maidenhair fern as injury may result. Carbaryl may also injure Virginia and sand pines.

The use of adjuvants may increase the potential for crop injury to sensitive crops.

PREHARVEST AND GRAZING RESTRICTIONS AND LIMITATIONS

Tolerances established under the Federal Food, Drug and Cosmetic Act permit the sale of labeled crops bearing probable carbaryl residues when this product is used in accordance with the label directions. If used as directed, treated forage may be grazed or used as feed for dairy and meat animals without causing illegal residues in meat or milk. Do not apply at greater rates or at more frequent intervals than stated on the label. To do so may result in illegal residues in crops, meat, and milk.

Do not use reclaimed irrigation water from crops treated with carbaryl on crops for which carbaryl tolerances are not established.

Do not plant rotational food and feed crops not listed on this or other carbaryl labels in carbaryl treated soil.

APPLICATION STATEMENTS

Calibrate and adjust application equipment to insure proper rate and accurate placement. To clean spray system after use, drain and flush with a water and detergent mixture. Rinse thoroughly with clean water. Refer to the Storage and Disposal section for disposal instructions.

NOTE: Staining may occur on certain surfaces such as stucco, brick, cinder block, and wood. Spray deposits on painted or stained surfaces or finishes (i.e., cars, houses, trailers, boats, etc.) should be immediately removed by washing to prevent discoloration. Avoid applications to surfaces where visible spray residues are objectionable.

RESISTANT SPECIES NOTICE

All references to armyworm on the crops listed below refer to the species, *Pseudaletia unipuncta*, often called the "true armyworm". Except where indicated otherwise, this product is not registered for the control of other armyworm species. Regional differences have been noted in the susceptibility of certain strains of fall armyworm, diamondback moth, Colorado potato beetle and Southern green stink bug to carbaryl. If local experience indicates inadequate control, use an alternative pesticide.

MIXING, LOADING AND HANDLING INSTRUCTIONS

TO ASSURE A UNIFORM SUSPENSION, AGITATE, STIR OR RECIRCULATE ALL CONTAINERS OF THIS PRODUCT PRIOR TO USE. Remove oil, rust, scale, pesticide residues and other foreign matter from mix tanks and entire spray system. Flush with clean water. Fill spray or mix tank with 1/2 to 3/4 the desired amount of water. Start mechanical or hydraulic agitation. Slowly add the required amount of SEVIN® brand 4F Carbaryl Insecticide, and then the remaining volume of water. Include rinse water from container. Prepare only as much spray mixture as can be applied on the day of mixing. MAINTAIN CONTINUOUS AGITATION DURING MIXING AND APPLICATION TO ASSURE A UNIFORM SUSPENSION. DO NOT STORE SPRAY MIXTURE FOR PROLONGED PERIODS OR DEGRADATION OF CARBARYL MAY OCCUR. Local water conditions may also accelerate the degradation of spray mixtures containing carbaryl. See COMPATIBILITY STATEMENT below.

COMPATIBILITY INFORMATION

SEVIN® brand 4F Carbaryl Insecticide, when diluted with at least an equal volume of water, is compatible with a wide range of pesticides. It is not compatible with diesel fuel, kerosene, fuel oil or aromatic solvents. If compatibility with another product and the resulting crop response is unknown, the mixture should be tested on a small scale. Curdling, precipitation, greasing, layer formation or increased viscosity are symptoms of incompatibility. Incompatibility will reduce insect control and may cause application and handling difficulties or plant injury. Observe all cautions and limitations on labeling of all products used in mixtures. WHEN PREPARING COMBINATION SPRAYS, FIRST ADD SEVIN® BRAND 4F CARBARYL INSECTICIDE TO AT LEAST AN EQUAL VOLUME OF WATER, MIX THOROUGHLY, AND THEN ADD COMBINATION PRODUCTS TO THE MIXTURE. DO NOT APPLY TANK MIX COMBINATIONS UNLESS YOUR PREVIOUS EXPERIENCE INDICATES THE MIXTURE IS EFFECTIVE AND WILL NOT RESULT IN APPLICATION PROBLEMS OR PLANT INJURY.

Carbaryl is unstable under highly alkaline conditions and mixtures with strong bases, such as Bordeaux, lime-sulfur and casein-lime spreaders, will result in chemical degradation of the insecticide. Do not use this product in water with pH values above 8.0 unless a buffer is added. If necessary, water should be buffered to neutral (pH = 7.0) before adding this product to the spray tank. Overhead irrigation with alkaline or muddy water after application will also accelerate chemical degradation and may result in reduced insect control.

APPLICATION PROCEDURES AND PRECAUTIONS

On all crops use sufficient gallonage to obtain thorough and uniform coverage. Observe crop label instructions for specific directions regarding spray volume where they occur. Calibrate spray equipment to deliver the required volume. The flow rate of this product diluted 1:1 with water is similar to water. Use of 50 mesh slotted strainers in spray system and 25 mesh slotted strainers behind nozzles is recommended.

GROUND APPLICATION

Apply in sufficient volume for adequate coverage on all crops and sites. To prepare small volumes of spray mixture, use 1/3 fl. oz. (approximately 2 teaspoons) of this product in an adequate amount of water and apply to 500 sq.ft. where rates of 1 quart per acre are indicated.

AERIAL APPLICATION

For adequate distribution, use at least 10 gallons of spray mixture per acre for application for tree and orchard crops or at least 2 gallons of spray mixture per acre for application to other crops.

SPRINKLER IRRIGATION SYSTEMS

Apply this product only through sprinkler irrigation systems including center pivot and solid set. Do not apply this product through any other type of irrigation system.

SPRAY PREPARATION: First prepare a suspension of SEVIN® brand 4F Carbaryl Insecticide in a mix tank. Fill tank with 1/2 to 3/4 the desired amount of water. Start mechanical or hydraulic agitation. Add the required amount of SEVIN® brand 4F, and then the remaining volume of water. (Suspension concentrations using the appropriate dosage per acre recommended on this label of SEVIN® brand 4F, per 1 to 4 gallons of water are recommended). Then set sprinkler to deliver 0.1 to 0.3 inch of water per acre. Start sprinkler and uniformly inject the suspension of SEVIN® brand 4F into the irrigation water line so as to deliver the desired rate per acre. The suspension of SEVIN® brand 4F should be injected with a positive displacement pump into the main line ahead of a right angle turn to insure adequate mixing. If you should have any other questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts.

NOTE: When treatment with SEVIN® brand 4F has been completed, further field irrigation over the treated area should be avoided for 24 to 48 hours to prevent washing the chemical off the crop.

GENERAL PRECAUTIONS FOR APPLICATIONS THROUGH SPRINKLER IRRIGATION SYSTEMS

Maintain continuous agitation in mix tank during mixing and application to assure a uniform suspension.

Greater accuracy in calibration and distribution will be achieved by injecting a larger volume of a more dilute solution per unit time.

The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump. The pesticide injection pipeline must also contain a functional, normally closed solenoid-operated valve located on the intake side of the injection pump and connected to the system

interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shutdown. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock. Do not apply when wind speed favors drift beyond the area intended for treatment.

Do not apply when wind speed favors drift, when system connection or fittings leak, when nozzles do not provide uniform distribution or when lines containing the product must be dismantled and drained.

Crop injury, lack of effectiveness, or illegal pesticide residues in the crop may result from nonuniform distribution of treated water.

Allow sufficient time for pesticide to be flushed through all lines and all nozzles before turning off irrigation water. A person knowledgeable of the chemigation system and responsible for its operation shall shut the system down and make necessary adjustments should the need arise.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the label-prescribed safety devices for public water supplies are in place.

SPECIFIC USE DIRECTIONS

CROP/SITE GROUPINGS:

Asparagus
Brassica Leafy Vegetable Crops
Cereal Grain Crops (Field and Pop Corn; Grain Sorghum; Rice; Sweet Corn; Wheat and Proso Millet)
Cucurbit Vegetables
Flax
Forage Crops (Alfalfa, Clovers, Birdsfoot Trefoil; Pasture and Grasses Grown for Seed; Rangeland)
Fruiting Vegetables
Leafy Vegetables
Legume Vegetables
Noncropland (Conservation Reserve Program; Wasteland; Rights-of-Way; Hedgerows; Ditchbanks; Roadsides)
Okra
Peanuts
Prickly Pear Cactus
Root and Tuber Crops (Root and Tuber Crops except Sugar Beets and Sweet Potatoes; Sugar Beets; Sweet Potatoes)
Small Fruits and Berries
Sunflower
Tobacco
Tree Fruit Crops (Citrus Fruits; Olives; Pome Fruits; Stone Fruits)
Tree Nut Crops (Pistachios; Tree Nuts)
Forested Areas and Rangeland Trees
Control of Specific Pests Across Multiple Sites
- Grasshoppers
- Ticks which Vector Lyme Disease
- Imported Fire Ants
- Adult Mosquito Control

INSECT CONTROL

Begin application when insect populations reach recognized economic threshold levels. Consult the Cooperative Extension Service, Consultants, or other qualified authorities to determine appropriate threshold levels for treatment and specific use information in your area. Where a dosage range is indicated, use the lower rate on light to moderate infestations, young plants and early instars and use the higher rate on heavy infestations, mature plants, advanced instars and adults. Thorough and uniform spray coverage is essential for effective control.

ASPARAGUS

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Asparagus	Apache cicada Asparagus beetle Cutworms	1 to 2	Repeat applications as necessary up to a total of 3 times prior to harvest or a total of 5 times per crop but not more often than once every 3 days. For cutworm control, this product is most effective against species which feed on the upper portions of the plant.
		2 to 4	**Application to ferns or brush growth following harvest of spears**: Repeat applications as necessary but not more often than every 7 days. Do not make more than a total of 5 applications per year to spears and ferns combined.

RESTRICTIONS AND PRECAUTIONS: ASPARAGUS

- Do not apply within 1 day of harvest.
- Do not apply more than a total of 6 quarts per acre before harvest of spears.
- Do not apply more than a total of 10 quarts per acre per year.

BRASSICA LEAFY VEGETABLES CROPS

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Broccoli Brussel Sprouts Cauliflower Cabbage Chinese Cabbage Collards Kale Kohlrabi Mustard Greens	Flea beetles Harlequin bug Leafhoppers	1/2 to 1	Repeat applications as needed up to a total of 4 times but not more often than once every 7 days.
	Armyworm Aster leafhopper Corn earworm Diamondback moth Fall armyworm Imported cabbageworm Lygus bugs Spittle bugs Stink bugs Tarnished plant bug	1 to 2	

RESTRICTIONS AND PRECAUTIONS: BRASSICA LEAFY VEGETABLES

- For Broccoli, Brussel Sprouts, Cabbage Cauliflower, and Kohlrabi, do not apply within 3 days of harvest.
- For Chinese Cabbage, Collards, Kale, and Mustard Greens, do not apply within 14 days of harvest.
- Do not apply more than a total of 6 quarts per acre per crop.

CEREAL GRAIN CROPS

FIELD CORN AND POPCORN

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Field corn and Popcorn	Armyworm, Chinch bugs, Corn earworm, Corn rootworm adults, Fall armyworm, Flea beetles, Japanese beetle, Sap beetles, Southwestern corn borer, Leafhoppers	1 to 2	OBSERVE BEE CAUTION. Repeat applications as needed up to a total of 4 times but not more often than once every 14 days. Optimum timing and good coverage are essential for effective control.
	European corn borer	1 1/2 to 2	For optimum chinch bug control, use ground equipment to apply at least 20 gallons of water per acre and direct spray toward stalk to provide thorough coverage. For optimum European corn borer control, do not apply in less than 3 gallons of water per acre by air and 15 gallons of water by ground. For western bean cutworm, treat when infestation averages 15% and at 90 to 100% tassel emergence. Treatment after 100% silk emergence will reduce effectiveness. For optimum cutworm control, apply in a 12-inch band, over the row, using sufficient volume of water to obtain thorough coverage. For broadcast application, use at least 20 gallons by ground or 5 gallons by air per acre. For cutworm control, this product is most effective against species which feed on the upper portions of the plant.
	Western bean cutworm, Cutworms	2	

RESTRICTIONS AND PRECAUTIONS: FIELD AND POP CORN

- Do not apply within 48 days of harvest of grain and fodder or within 14 days of harvest or grazing of forage or silage.
- Do not apply more than a total of 8 quarts per acre per crop.

GRAIN SORGHUM

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Grain Sorghum	Armyworm, Chinch bugs, Corn earworm, Fall armyworm, Stink bugs, Webworms	1 to 2	Repeat applications as necessary up to a total of 4 times but not more often than once every 7 days.
	Southwestern corn borer	1 1/2	Direct spray into forming heads for optimum control of insects attacking heads.
	Cutworms	2	For optimum chinch bug control, use high gallonage ground application at the base of plants. For cutworm control, this product is most effective against species which feed on the upper portions of the plant.

RESTRICTIONS AND PRECAUTIONS: GRAIN SORGHUM

- Do not apply within 21 days of harvest for grain or fodder or within 14 days of harvest or grazing of forage or silage.
- Do not apply more than a total of 6 quarts per acre per crop.

RICE

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Rice	Armyworm Chinch bugs Fall armyworm Leafhoppers Stink bugs	1 to 1 1/2	Up to 2 applications per crop may be made but not more often than once every 7 days.
	Tadpole shrimp	1 1/2	**California only** For optimum tadpole shrimp control, apply to water when pest first appears.

RESTRICTIONS AND PRECAUTIONS: RICE

- Do not apply within 14 days of harvest for grain or straw.
- Do not apply more than a total of 4 quarts per acre per crop.
- CAUTION: May kill shrimp, crabs, and crayfish.
- Do not apply propanil herbicides within 15 days before or after application of this product or plant injury will result.

SWEET CORN

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Sweet Corn	Armyworm, Chinch bugs, Corn earworm, Corn rootworm adults, Fall armyworm, Flea beetles, Japanese beetle, Sap beetles, Southwestern corn borer, Leafhoppers	1 to 2	OBSERVE BEE CAUTION Repeat applications as necessary up to a total of 8 times but not more often than once every 3 days. Optimum timing and good coverage are essential for effective control
	European corn borer	1 1/2 to 2	For insects attacking silks and ears, insecticide sprays should be applied starting when first silks appear and continuing until silks begin to dry. During silking, the minimum retreatment interval (3 days) may not provide adequate levels of protection under conditions of rapid growth or severe pest pressure. The use of an alternative product should be considered in conjunction with this product. For optimum chinch bug control, use ground equipment to apply at least 20 gallons of water per acre and direct spray toward stalk to provide thorough coverage. For optimum European corn borer control, do not apply in less than 3 gallons of water per acre by air and 15 gallons of water by ground. For western bean cutworm, treat when infestation average 15% and at 90 to 100% tassel emergence. Treatment after 100% silk emergence will reduce effectiveness. For optimum cutworm control, apply in a 12-inch band, over the row, using sufficient volume of water to obtain thorough coverage. For broadcast application, use at least 20 gallons by ground or 5 gallons by air per acre. For cutworm control, this product is most effective against species which feed on the upper portions of the plant.
	Western bean cutworm, Cutworms	2	

RESTRICTIONS AND PRECAUTIONS: SWEET CORN

- Do not apply within 2 days of harvest of ears, within 14 days of harvest or grazing of forage, or within 48 days of harvest of forage.
- Do not apply more than a total of 16 quarts per acre per crop.

WHEAT AND PROSO MILLET

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Wheat Proso Millet **DO NOT USE IN CALIFORNIA**	Flea beetles	1/2 to 1	Up to 2 applications per crop may be made but not more often than once every 14 days. Application is effective against eggs, larvae, and adults of the cereal leaf beetle. Application for armyworm control should be made when armyworms are actively feeding on the upper foliage and night temperatures and not expected to drop below 55°F. If applying by air to lush growth, use a minimum spray volume of 5 gallons per acre to optimize coverage.
	Cereal leaf beetle	1	
	Armyworm Fall armyworm	1 to 1 1/2	

RESTRICTIONS AND PRECAUTIONS: WHEAT AND PROSO MILLET

- Do not apply within 21 days of harvest for grain or straw or within 7 days of harvest or grazing of forage.
- Do not apply more than a total of 3 quarts per acre per crop.

CUCURBIT VEGETABLES

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Cucurbit Vegetables: Cucumbers Melons Pumpkins Squash	Pickleworm Melonworm	1/2 to 1	Repeat applications as necessary up to a total of 6 times but not more often than once every 7 days
	Cucumber beetles Flea beetles Leafhoppers Squash bugs	1	For optimum control of squash bugs, apply sufficient spray volume for thorough coverage and time sprays for early morning or late afternoon.

RESTRICTIONS AND PRECAUTIONS: CUCURBIT VEGETABLES

- Do not apply within 3 days of harvest.
- Do not apply more than a total of 6 quarts per acre per crop.
- Observe plant response precautions.

FLAX

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Flax **DO NOT USE IN CALIFORNIA**	Armyworm	1 to 1 1/2	Up to 2 applications per crop may be made but not more often than once every 14 days.

RESTRICTIONS AND PRECAUTIONS: FLAX

- Do not apply within 42 days of harvest for seed or straw.
- Do not apply more than a total of 3 quarts per acre per crop.

FORAGE CROPS

ALFALFA, CLOVERS, AND BIRDSFOOT TREFOIL

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Alfalfa, Clovers, and Birdsfoot Trefoil	Blister beetles Mexican bean beetle	1/2 to 1	OBSERVE BEE CAUTION. Observe plant response precautions.
	Alfalfa caterpillar Bean leaf beetle Cucumber beetles Green cloverworm Japanese beetle Leafhoppers Potato leafhopper Three cornered alfalfa hopper Thrips Velvetbean caterpillar	1	On dense growth, use 25 to 40 gallons of water per acre with ground equipment to ensure adequate coverage.
	Alfalfa blotch leafminer Armyworm Cloverhead weevil Corn earworm Cutworms Egyptian alfalfa weevil larvae Essex skipper European alfalfa beetle Fall armyworm Lygus bugs Stink bugs Webworms Yellow striped armyworm	1 to 1 1/2	For alfalfa weevil larvae, if pretreatment damage is extensive, cut alfalfa and treat the stubble. This product is not effective against **adult** alfalfa weevils. For cutworm control, this product is most effective against species which feed on the upper portions of the plant.
	Alfalfa weevil larvae (west of the Rocky Mountains)	1 to 1 1/2	
	Alfalfa weevil larvae (east of the Rocky Mountains)	1 1/2	

RESTRICTIONS AND PRECAUTIONS: FORAGE CROPS

- Do not apply more than once per cutting.
- Do not apply within 7 days of harvest or grazing.
- Do not exceed 1 1/2 quarts per acre per cutting.
- Carbaryl may cause a temporary bleaching of tender alfalfa foliage.

PASTURE AND GRASSES GROWN FOR SEED

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Pasture and Grasses Grown for Seed	Armyworm Chinch bugs Essex skipper Fall armyworm Striped grass looper Thrips Range caterpillar Range crane fly Ticks	1 to 1 1/2	Up to 2 applications per year may be made but not more often than once every 14 days. To control thrips in grasses grown for seed, use high spray pressure to improve penetration into boot. Carefully mark swaths to avoid over-application.

RESTRICTIONS AND PRECAUTIONS: PASTURE AND GRASSES GROWN FOR SEED

- Do not apply within 14 days of harvest or grazing.
- Do not exceed a total of 3 quarts per acre per year.

RANGELAND

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Rangeland	Black grass bug Grasshoppers Mormon cricket Range caterpillar Range crane fly	1/2 to 1	Do not make more than 1 application per year. Carefully mark swaths to avoid over-application.
	Ticks	1	

RESTRICTIONS AND PRECAUTIONS: RANGELAND

- May be harvested or grazed the same day as treatment.
- Do not apply more than 1 quart per acre per year.

FRUITING VEGETABLES

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Fruiting Vegetables: Tomatoes, Peppers, Eggplant	Colorado potato beetle European corn borer Fall armyworm Lace bugs Stink bugs (suppression) Tarnished plant bug Thrips (suppression) Tomato fruitworm Tomato hornworm Tomato pinworm	1 to 2	Repeat applications as necessary up to a total of 7 times but not more often than once every 7 days. Thorough coverage is essential to effectively suppress stink bugs. When disease transmission is suspected, monitor fields following application and retreat if reinfestation occurs but not more often than once every 7 days.
	Flea beetles Leafhoppers	1/2 to 1	
	Cutworms	2	For cutworm control, this product is most effective against species which feed on the upper portions of the plant.

RESTRICTIONS AND PRECAUTIONS: FRUITING VEGETABLES

- Do not apply within 3 days of harvest.
- Do not apply more than a total of 8 quarts per crop.

LEAFY VEGETABLES

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Leafy vegetables: Celery, Dandelion, Endive, Lettuce (head and leaf), Parsley, Spinach, Swiss Chard	Flea beetles Harlequin bug Leafhoppers	1/2 to 1	Repeat applications as necessary up to a total of 5 times but not more often than once every 7 days.
	Armyworm Aster leafhopper Corn earworm Fall armyworm Imported cabbageworm Lygus bugs Spittlebugs Stink bugs Tarnished plant bug	1 to 2	

RESTRICTIONS AND PRECAUTIONS: LEAFY VEGETABLES

- Do not apply within 14 days of harvest.
- Do not apply more than a total of 6 quarts per acre per crop.

LEGUME VEGETABLES

CROP	PEST		QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Legume Vegetables: Soybeans, Fresh and Dried Beans (*Phaseolus* species including snap, navy and kidney), Fresh and Dried Peas (*Pisum* species), Lentils, Cowpeas, Southern Peas **DO NOT USE ON LENTILS IN CALIFORNIA**	Bean leaf beetle Blister beetle Cucumber beetles Grape colapsis	Green cloverworm Japanese beetle Mexican bean beetle Velvetbean caterpillar	1/2 to 1	Repeat applications as necessary up to a total of 4 times but not more often than once every 7 days. For cutworm control, this product is most effective against species which feed on the upper portions of the plant. Use lower rates for light to moderate populations and smaller instars and to provide maximum survival of beneficial insects and spiders. Use the higher rates for heavy populations and larger instars.
	Corn earworm		1/2 to 1 1/2	
	Alfalfa caterpillar Colorado potato beetle Flea beetles Leafhoppers	Three cornered alfalfa hopper Thrips Western bean cutworm	1	
	Armyworm Cutworms European corn borer Fall armyworm	Stink bugs Tarnished plant bug Webworms	1 to 1 1/2	
	Alfalfa looper (suppression) Cowpea curculio (suppression) Painted lady (Thistle caterpillar) Pea leaf weevil	Pea weevil Saltmarsh caterpillar Woollybean caterpillar Yellowstriped armyworm	1 1/2	
	California only: Corn earworm (suppression) Limabean podborer (suppression)	Lygus bugs (suppression) Stink bugs (suppression)	1 1/2	

RESTRICTIONS AND PRECAUTIONS: LEGUME VEGETABLES

- Do not apply within 14 days of grazing or harvest for forage or within 3 days of harvest of fresh beans or peas or within 21 days of harvest of dried beans or peas, seed, or hay.
- Do not apply more than a total of 6 quarts per acre per crop.
- Do not apply a combination of this product and 2,4-DB herbicides to soybeans as crop injury may result.
- Observe plant response precautions.

NONCROPLAND

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Conservation Reserve Program Acreage Set-Aside Program Acreage Wasteland Rights-of-Way Hedgerows Ditchbanks Roadsides	Black grass bug	1/4 to 1/2	Up to 2 applications per year may be made but not more often than once every 14 days. Carefully mark swaths to avoid over-application.
	Mormon cricket Range caterpillar Range crane fly	1/2 to 1	
	Ticks	1 to 1 1/2	

RESTRICTIONS AND PRECAUTIONS: NONCROPLAND

- Do not apply within 14 days of grazing or harvest for forage or hay.
- Do not apply more than a total of 3 quarts per acre per year.

OKRA*

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Okra	Corn earworm Stink bugs	1 to 1 1/2	Apply using ground equipment in sufficient volume to insure good coverage. Apply as needed on 6 to 8 day intervals. For grasshopper control, refer to the general Grasshopper Section.

RESTRICTIONS AND PRECAUTIONS: OKRA

- Do not apply within 3 days of harvest.
- Do not apply more than a total of 6 quarts per acre per season.

*** Use not permitted in CA unless otherwise directed by supplemental labeling.**

PEANUTS

CROP	PEST		QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Peanuts	Blister beetles Mexican bean beetle		1/2 to 1	Repeat applications as necessary up to a total of 5 times but not more often than once every 7 days.
	Alfalfa caterpillar Bean leaf beetle Cucumber beetle Green cloverworm Japanese beetle Leafhoppers	Rednecked peanutworm Three cornered alfalfa hopper Thrips Velvetbean caterpillar	1	For optimum control of thrips, use directed or banded sprays with hollow cone spray nozzles. Ensure adequate coverage for the underside of leaves.
	Armyworm Corn earworm Fall armyworm	Stink bugs Webworms	1 to 1 1/2	For cutworm control, this product is most effective against species which feed on the upper portions of the plant.
	Whitefringed beetle adults	Cutworms	2	

RESTRICTIONS AND PRECAUTIONS: PEANUTS

- Do not apply within 14 days of harvest.
- Do not apply more than a total of 8 quarts per acre per crop.
- Observe plant response precautions.

PRICKLY PEAR CACTUS*

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Prickly Pear Cactus	Cochineal scale (crawlers)	2	Apply using ground equipment in sufficient volume to insure good coverage. Apply as needed on 7 to 10 day intervals. For grasshopper control, refer to the general Grasshopper Section.

RESTRICTIONS AND PRECAUTIONS: PRICKLY PEAR CACTUS

- Do not apply within 3 days of harvest.
- Do not apply more than a total of 6 quarts per acre per season.

*** Use not permitted in CA unless otherwise directed by supplemental labeling.**

ROOT AND TUBER CROPS

ROOT AND TUBER CROPS EXCEPT SUGAR BEETS AND SWEET POTATOES

CROP	PEST		QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Root and Tuber Crops:	Flea beetles Leafhoppers		1/2 to 1	Repeat applications as necessary up to a total of 6 times but not more often than once every 7 days.
Garden Beets, Carrots, Horseradish, Parsnips, Radishes, Rutabagas, Salsify, Potatoes	Armyworm Aster leafhopper Colorado potato beetle Corn earworm Cutworms European corn borer Fall armyworm	Lace bugs Lygus bugs Spittlebugs Stink bugs Tarnished plant bug	1 to 2	For cutworm control, this product is most effective against species which feed on the upper portions of the plant.

RESTRICTIONS AND PRECAUTIONS: ROOT AND TUBER CROPS EXCEPT SUGAR BEETS AND SWEET POTATOES

- Do not apply within 7 days of harvest.
- Do not apply more than a total of 6 quarts per acre per crop.

SUGAR BEETS

CROP	PEST		QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Sugar beets	Armyworm Beet leaf beetle Fall armyworm	Flea beetles Leafhoppers Webworms	1 to 1 1/2	Repeat applications as necessary up to a total of 2 times but not more often than once every 14 days.
	Cutworms		1 1/2	For cutworm control, this product is most effective against species which feed on the upper portions of the plant.

RESTRICTIONS AND PRECAUTIONS: SUGAR BEETS

- Do not apply within 28 days of harvest for roots or forage.
- Do not apply more than a total of 3 quarts per acre per crop.

SWEET POTATOES

CROP	PEST		QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Sweet Potatoes	Corn earworm Cucumber beetles Flea beetles Sweet potato hornworm	Sweet potato weevil Tortoise beetles Whitefringed beetle	1 to 2	**Preplant dip for control of sweet potato weevil**: Just prior to planting, dip sweet potato cuttings in a suspension containing 2 gallons of this product in 100 gallons of water (2.6 fluid ounces of this product per gallon of water).
	Yellowstriped armyworm		2	For foliar sprays, repeat applications as necessary up to a total of 8 times but not more often than once every 7 days.

RESTRICTIONS AND PRECAUTIONS: SWEET POTATOES

- Do not apply within 7 days of harvest.
- Do not apply more than a total of 8 quarts per acre per crop with in-season sprays.
- Do not apply more than a total of 1.2 quarts per acre as a preplant dip treatment.

SMALL FRUITS AND BERRIES

CROP	PEST		QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Small Fruits and Berries: Caneberries, Blueberries, Cranberries, Grapes, Strawberries	European fruit lecanium European raspberry aphid Flea beetles Grape leaffolder Grape leafroller Japanese beetle Leafhoppers Leafrollers Meadow spittlebug Omnivorous leaftier	Rose chafer Snowy tree cricket Strawberry bud weevil Strawberry clipper Strawberry fruitworm Strawberry leafroller Strawberry weevil Western grapeleaf skeletonizer Western yellowstriped armyworm	1 to 2	OBSERVE BEE CAUTION. Repeat applications as necessary up to a total of 5 times but not more often than once every 7 days. For cutworm control, this product is most effective against species which feed on the upper portions of the plant. In grapes for grape leaffolder control, apply before first brood larvae emerge from rolls.
	Blueberry maggot Cherry fruitworm Cranberry fireworm Cranberry fruitworms Cranberry twig girdler	Elm spanworm Gypsy moth Spaganothus worm Tarnished plant bug	1 1/2 to 2	In grapes, do not concentrate spray on the bunch or visible residues may result.
	Eight-spotted forester Cutworms Grape berry moth June beetles Omnivorous leafroller	Orange tortrix Raspberry fruitworm Raspberry sawfly Redbanded leafroller Saltmarsh caterpillar	2	

RESTRICTIONS AND PRECAUTIONS: SMALL FRUITS AND BERRIES

- Do not apply within 7 days of harvest.
- Do not apply more than a total of 10 quarts per acre per crop.
- CAUTION: Use in cranberries may kill shrimp and crabs. Do not use in areas where these are important resources.
- Carbaryl may injure Early Dawn and Sunrise varieties of strawberries.

SUNFLOWERS

CROP	PEST		QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Sunflowers **DO NOT USE IN CALIFORNIA**	Stem weevil Sunflower beetle		1 to 1 1/2	Up to 2 applications may be made but not more often than once every 7 days.
	Armyworm Cutworms	Fall armyworm Sunflower moth	1 1/2	For cutworm control, this product is most effective against species which feed on the upper portions of the plant.

RESTRICTIONS AND PRECAUTIONS: SUNFLOWERS

- Do not apply within 30 days of grazing or harvest for forage or within 60 days of harvest for seed.
- Do not apply more than a total of 3 quarts per acre per crop.

TOBACCO

CROP	PEST		QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Tobacco	Budworms Fall armyworm Tobacco flea beetles Hornworms	Japanese beetle June beetle Suckfly	1 to 2	**Plant bed and Field Treatment** Repeat treatments as necessary up to a total of 4 times per crop but not more often than once every 7 days. Use lower rate on young plants (up to knee height). Use at least 10 gallons of prepared spray per acre. Begin treatments when worms are small.

RESTRICTIONS AND PRECAUTIONS: TOBACCO

- Tobacco may be harvested on the day of treatment.
- Do not apply more than a total of 8 quarts per acre per crop.
- Observe plant response precautions.

TREE FRUIT CROPS

On all tree fruit crops, apply in sufficient volume for adequate coverage. This will vary depending on the pest and its severity, the tree condition, size, and density, and other factors.

CITRUS FRUITS

CROP	PEST		QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Citrus Fruits	Avocado leafroller California orangedog Citrus cutworm Fruittree leafroller	Orange Tortrix Western tussock moth	2 to 3	OBSERVE BEE CAUTION. Repeat applications as necessary up to a total of 8 times but not more often than once every 14 days.
	Citrus rust mite Eriophyid mites	Plant bugs Scale insects [Black scale, brown soft scale, California red scale (except in California), citrus snow scale, yellow scale (except in California)]	3 to 5	For scale control, apply when crawlers are present. For best control of Eriophyid mites including citrus rust mite, apply when pest populations are low.
	Apopka weevil (adult) Citrus root weevils (adults)	Fuller Rose Beetle Little leaf notcher (adult)	5 to 7 1/2	
	California only: California red scale	Yellow scale	5 to 16	Do not make more than 1 application per season for California red scale. Apply when crawlers are present.

RESTRICTIONS AND PRECAUTIONS: CITRUS FRUITS

- Do not apply within 5 days of harvest.
- Do not apply more than a total of 20 quarts per acre per crop.

OLIVES

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Olives	Scale insects (olive scale, black scale)	5 to 7 1/2	Up to 2 applications per crop may be made but not more often than once every 14 days.

RESTRICTIONS AND PRECAUTIONS: OLIVES

- Do not apply within 14 days of harvest.
- Do not apply more than a total of 15 quarts per acre per crop.

POME FRUITS

CROP	PEST		QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Pome Fruits: apples, pears, loquats, crabapples, oriental pears	White apple leafhopper		1/2 to 1 1/2	OBSERVE BEE CAUTION On apples, avoid use during the period from full bloom until 30 days after full bloom unless fruit thinning is desired. Use for pest control during this period also may result in fruit removal. Repeat applications as necessary up to a total of 8 times per crop (including thinning sprays on apples) but not more often than once every 14 days. For psylla control, apply when eggs hatch or young nymphs are present. For scale control, apply when crawlers are present.
	Apple aphid	Codling moth	1 to 3	
	Apple aphid Apple maggot Apple mealybug Apple rust mite Bagworms California pearslug (pear sawfly) European apple sawfly Eyespotted bud moth Fruittree leafroller Gypsy moth Japanese beetle Lesser appleworm Lygus bugs Orange tortrix	Pearleaf blister mite Pear psylla Pear rust mite Periodical cicada Plum curculio Redbanded leafroller Rosy apply aphid Scale insects (Forbes scale, Lecanium scale, San Jose scale) Tarnished plant bug Tentiform leafminers Woolly apple aphid Yellowheaded fireworm	1 1/2 to 3	

POME FRUITS
(continued)

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Apples Only, for Fruit Thinning		1 to 3	OBSERVE BEE CAUTION Apply 1 to 3 quarts per acre of SEVIN® brand 4F Carbaryl Insecticide between 80% petal fall and 16 mm fruit size. Use the higher rates on hard to thin varieties at the early timing which is the 80% petal fall to 6 mm fruit size. Use the lower rates on easy to thin varieties and at the later thinning period which is the 10 to 16 mm fruit size. The rate to use per acre will depend on varieties, tree size, row spacing, weather conditions at the time of and following applications. **Consult with the local fruit thinning experts in your area for the proper rate to use under your conditions.** The optimum spray gallonage will depend on the tree size, planting density, row spacing and amount of foliage. Use sufficient spray volume to insure adequate coverage (100 to 400 gallons/acre). Avoid spray to the point of runoff. **Reduce spray coverage to the lower portion of the tree since overthinning may occur here.** Factors such as climatic temperature, high humidity, frost, tree age, variety, nutrition, previous crop, pruning and bloom may influence fruit thinning results with the product. Exercise caution to avoid possible overthinning. For the most effective results, apply under good drying conditions and when daytime temperatures (°F) will be 70 to low 80's for the following one to three days. Application with daytime temperatures in excess of 80° F may result in overthinning. SEVIN® brand 4F may be mixed with other fruit thinners, however, use caution to avoid overthinning and other adverse effects. Consult with local fruit thinning experts in your area for recommendations. Refer to the other product labels for specific use directions. **Consult with local fruit thinning experts in your area for advice on the proper use of this product on your varieties under your growing conditions.** **CAUTION:** The use of SEVIN® brand 4F may result in fruit deformity under certain environmental conditions. Before using on any variety of apples, the user must weigh the risk versus benefits when using this product, particularly when using between **80% petal fall and 6 mm fruit size**. Red Delicious are more sensitive to this phenomenon and in particular, the varieties Bisbee, Red Chief and Vallee Spur are very susceptible to conditions causing fruit deformity. Precipitation and temperatures below 65° F increases the possibility of fruit deformity. The use with summer spray oils and wetting agents may increase the risk of fruit deformity and injury.

RESTRICTIONS AND PRECAUTIONS: POME FRUITS

- Do not apply to quince.
- Do not use on pears between the tight flower cluster up to the 20 mm fruit size. Use during this period may result in undesirable fruit thinning and/or deformed fruit.
- Do not apply within 3 days of harvest.
- Do not apply more than a total of 15 quarts per acre per crop.
- Do not make more than a total of 8 applications per crop.

FOR PROTECTION OF HONEY BEES:

- Remove all bee hives from orchard to be treated prior to application.
- Do not apply this product if bees are actively foraging in orchard.
- If weed bloom is present, mow the cover crop on the orchard floor prior to applying this product.

STONE FRUITS

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Stone Fruits: Apricots, Cherries, Nectarines, Peaches, Plums, and Prunes	Apple pandemis Black cherry aphid Cherry fruitworm Cherry maggot (Cherry fruit fly) Codling moth Cucumber beetles Eastern tent caterpillar Eyespotted bud moth European earwig Fruittree leafroller Green fruitworm Gypsy moth Japanese beetle June beetle Lesser peachtree borer Mealy plum aphid Orange tortrix Oriental fruit moth Peach twig borer Periodical cicada Plum curculio Prune leafhopper Redbanded leafroller Rose chafer Scale insects (Brown soft scale, Forbes scale, Lecanium scale, Olive scale, Oystershell scale, San Jose scale) Tarnished plant bug Tussock moth Variegated leafroller	2 to 3	OBSERVE BEE CAUTION. Repeat applications as necessary up to a total of 3 times per crop but not more often than once every 7 days. An additional application at the dormant or delayed dormant timing may be made. For optimum scale control, apply when crawlers are present. For lesser peachtree borer, best results have been found by thoroughly spraying limbs and tree trunks at weekly intervals during moth flight.
	California Only: Black cherry aphid Cherry fruitworm Cherry maggot (Cherry fruit fly) Codling moth Cucumber beetles Eyespotted bud moth European earwig Fruittree leafroller Green fruitworm Mealy plum aphid Orange tortrix Oriental fruit moth Peach twig borer Scale insects (Brown soft scale, Forbes scale, Lecanium scale, Olive scale, Oystershell scale, San Jose scale) Tarnished plant bug Tussock moth	3 to 4	OBSERVE BEE CAUTION. Repeat applications as necessary up to a total of 3 times per crop but not more often than once every 14 days. An additional application at the dormant or delayed dormant timing may be made. For optimum scale control, apply when crawlers are present.
	Peach twig borer Scale insects (Brown soft scale, Forbes scale, Lecanium scale, Olive scale, Oystershell scale, San Jose scale)	4 to 5	**For dormant or delayed dormant timing,** apply in combination with a recommended dormant oil. Refer to the dormant oil product label for additional use directions and restrictions.

RESTRICTIONS AND PRECAUTIONS: STONE FRUIT

- Do not apply within 3 days of harvest, except in California. In California, do not apply within 1 day of harvest.
- Do not apply more than a total of 14 quarts per acre per crop.
- Do not apply more than a total of 5 quarts per acre at the dormant or delayed dormant timing.
- Do not apply more than a total of 9 quarts per acre during the production season.

TREE NUT CROPS

On all tree nut crops, apply in sufficient volume for adequate coverage. This will vary depending on the pest and its severity, the tree condition, size, and density, and other factors.

PISTACHIOS

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Pistachios	Brown soft scale Lecanium scale Navel orangeworm	3 to 5	Repeat applications as necessary up to a total of 4 times per crop (including any applications at the dormant or delayed dormant timing) but not more often than once every 7 days. For scale control, apply when crawlers are present.
	Scale insects	4 to 5	**For dormant or delayed dormant timing**, apply in combination with a recommended dormant oil. Refer to the dormant oil product label for additional use directions and restrictions.

RESTRICTIONS AND PRECAUTIONS: PISTACHIOS

- Do not apply within 14 days of harvest.
- Do not apply more than a total of 15 quarts per acre per crop, including any application at the dormant or delayed dormant timing.

TREE NUTS

CROP	PEST		QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Tree Nuts: Almonds, Chestnuts, Filberts, Pecans, Walnuts	Black margined aphid Calico scale Codling moth European fruit lecanium Fall webworm Filbert aphid Filbert leafroller Filbertworm Frosted scale Fruittree leafroller Hickory shuckworm Lesser webworm	Navel orangeworm Peach twig borer Pecan leaf phylloxera Pecan stem phylloxera Pecan nut casebearer Pecan spittlebug Pecan weevil San Jose scale Twig girdler Walnut caterpillar	2 to 5	OBSERVE BEE CAUTION Repeat applications as necessary up to a total of 4 times per crop (including any applications at the dormant or delayed dormant timing) but not more often than once every 7 days. Use lower rates for pests attacking leaves. Use higher rates for pests attacking fruit and for higher infestations. For scale control, apply when crawlers are present. For peach twig borer, best results with foliar applications have been found by making applications in "popcorn" or petal fall stages when the May brood begins to hatch. For navel orangeworm in almonds and walnuts, best results have been found by timing early and midseason applications to correspond with moth flight peaks. For filbert leafroller, best results have been found by making applications when eggs are hatching, repeating application on first appearance of moths and again 3 to 4 weeks later. For codling moth in walnuts, best results have been found by making applications when average cross-sectional diameters of developing nuts are 0.5 to 0.75 inches and again during middle or late June as needed.
	Chestnut weevil	European earwig	4 to 5	For chestnut weevil, best results have been found with 4 applications at weekly intervals beginning in late July. The last application should be made prior to shuck split. For European earwig, thorough coverage of trunks, branches, and nuts is needed for best results.
Almonds only	Peach twig borer	Scale insects	4 to 5	**For dormant or delayed dormant timing,** apply in combination with a recommended dormant oil. Refer to the dormant oil product label for additional use directions and restrictions.

RESTRICTIONS AND PRECAUTIONS: TREE NUTS

- Do not apply within 14 days of harvest.
- Do not apply more than a total of 15 quarts per acre per crop, including any application at the dormant or delayed dormant timing.

FORESTED AREAS AND RANGELAND TREES

Apply in sufficient volume for adequate coverage. This will vary depending on the tree size, density and stage of growth.

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Forested areas: Non-urban Forests, Tree Plantations, Planted Christmas Trees, Parks, Rural Shelter Belts Rangeland Trees	Ants Apple aphid Armyworm Ash whitefly Azalea leafminer Bagworms Balsam twig aphid Birch leafminer Blister beetle Boxelder bug Boxwood leafminer Brown tail moth Cankerworms Catalpa sphinx Chiggers Cooley spruce gall adelgid Cutworms Cypress tip moth Douglas-fir tussock moth Eastern spruce gall adelgid Elm leaf aphid Elm leaf beetle Elm spanworm Eriophyid mites European pine shoot moth Fall armyworm Flea beetle Fuchia gall mite Fuller rose beetle Gall midges Gall wasps Greenstriped mapleworm Grasshoppers Hackberry nipplegall maker Holly bud moth Holly leafminer Jackpine budworm Japanese beetle Jeffrey pine needleminer June beetles Lace bugs Leafhoppers Leafrollers Locust borer Maple leafcutter Mealy bugs Mimosa webworm Nantucket pine tip moth Oak leafminers Oak moth Oak skeletonizer Oakworm complex Oleander caterpillar Olive ash borer Orange-striped oakworm Periodical cicada Pine looper Pine sawfly Pine spittlebug Pitch pine tip moth Spruce budworm Plant bugs Poinsettia hornworm Psyllids Puss caterpillar Redhumped oakworm Rose aphid Rose chafer Rose slug Saddled prominent Sawflies (exposed) Scale insects (crawlers) Sowbugs Spiney elm caterpillar Springtails Spruce needleminer Subtropical pine tip moth Tent caterpillars Thorn bug Thrips (exposed) Ticks Walnut caterpillar Webworms Western hemlock looper Western spruce budworm Willow leaf beetles Wooly gall aphid Yellow poplar weevil	1	Observe plant response precautions. Obtain thorough coverage of upper and lower leaf surfaces. The addition of a sticker may improve residual control. To control scale insects, treat trunks, stems and twigs in addition to plant foliage. For optimum worm control, treat when pests are small. Do not use on syrup-producing sugar maples where sap is harvested. Applications for control of maple leafcutter on sugar maple should be made when larvae are in 2nd instar after mining and as cases are being formed. Repeat treatments as necessary up to a total of 2 times per year but not more often than once every 7 days. For gypsy moth control, use the higher rate for heavy infestations.
	Gypsy Moth	3/4 to 1	

FORESTED AREAS AND RANGELAND TREES, CONTINUED

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Forested areas: Non-urban Forests, Tree Plantations, Planted Christmas Trees, Parks, Rural Shelter Belts Rangeland Trees	Elm bark beetle Ips engraver beetles Mountain pine beetle Roundheaded pine beetle Spruce beetle Western pine beetle	2% solution (5 fluid ounces per gallon)	**Direct Trunk Treatment**: Effective as a preventative treatment only. Repeat annually as required to prevent beetle attacks. Apply 1 gallon of spray per 50 square feet of bark prior to beetle flight or host-tree attack. Treat tree trunk from ground level up, until trunk diameter is less than 5 inches. For elm bark beetle: apply approximately 20-30 gallons of spray mixture for each 50 feet of elm tree for thorough coverage of all bark surfaces on trunks, limbs and twigs. Do not make more than 2 applications per year or repeat applications more often than once every six months.

RESTRICTIONS AND PRECAUTIONS: FORESTED AREAS AND RANGELAND TREES

- Do not make more than 2 applications per year.
- To prepare small volumes of spray mixture, use 1/3 fl. oz. (approximately 2 teaspoons) of this product in an adequate amount of water and apply to 500 sq.ft. where rates of 1 quart per acre are indicated.
- DO NOT ALLOW PUBLIC USE OF TREATED AREAS DURING APPLICATIONS OR UNTIL SPRAYS HAVE DRIED.

CONTROL OF SPECIFIC PESTS ACROSS MULTIPLE SITES

GRASSHOPPERS

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
All crops on this label	Grasshoppers	1/2 to 1 1/2*	Apply 1/2 to 3/4 quarts per acre of this product for nymphs on small plants or sparse vegetation. Apply 1 to 1 1/2 quarts per acre for mature grasshoppers or applications to dense foliage or if extended residual control is desired. Be certain spray volumes are appropriate to assure adequate coverage.

RESTRICTIONS AND PRECAUTIONS: GRASSHOPPER CONTROL

- ***NOTE**: Refer to individual site listings elsewhere on this label for use limitations and restrictions. Do not use rates higher than listed for the site or exceed other use restrictions.

CONTROL OF TICKS WHICH VECTOR LYME DISEASE

For control of juvenile and adult ticks which vector Lyme Disease, apply the recommended amount is sufficient volume for thorough coverage.

CROP/SITE	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
All crops on this label Pastures Forested Areas Wasteland, Rights-of-Way, Hedgerows, Ditchbanks, Roadsides, Set-Aside and Conservation Reserve Program Acreage	*Ixodes* spp. (Deer tick, Bear tick, Black legged tick) *Amblyomma* spp. (Lone star tick)	1 to 2*	Use the high rate for heavy tick infestations.* Use higher spray volumes for dense ground cover or heavy leaf litter. Target applications for nymphal control in late spring or early summer. Control of adult tick can be obtained with late summer and fall applications. Do not use spot treatments. Treat entire area and perimeter areas where exposure to ticks may occur. Ticks may be reintroduced from surrounding areas on host animals. Retreat as necessary to maintain adequate control levels*.

RESTRICTIONS AND PRECAUTIONS: CONTROL OF TICKS WHICH VECTOR LYME DISEASE

- ***NOTE**: Refer to individual site listings elsewhere on this label for use limitations and restrictions. Do not use rates higher than listed for the site or exceed other use restrictions.
- DO NOT ALLOW PUBLIC USE OF TREATED AREAS DURING APPLICATION OR UNTIL SPRAYS HAVE DRIED.

IMPORTED FIRE ANTS

CROP/SITE	PEST	QUARTS OF SEVIN® 4F PER VOLUME OF WATER	SPECIFIC DIRECTIONS
Pastures Rangeland Forested Areas Wasteland	Imported fire ants	3/4 fluid ounce per gallon	**DRENCH APPLICATION**: Apply a total of 2 gallons of the diluted solution over the surface of each mound or at least 1 quart per 6 inches of mound diameter using a bucket, can or other appropriate equipment. Thoroughly wet mound and surrounding areas to a 4 ft diameter (12 sq.ft.). Do not disturb mound prior to treatment. Pour solution from a height of about three feet to give sufficient force to break mound apex and flow into ant tunnels. For best results apply in cool weather (65-80°F) or in early morning or late evening hours. Repeat application if mound activity resumes after 7 days. Treat new mounds as they appear. Pressurized sprays may disturb the ants and cause migration, reducing product effectiveness.
Nursery Stock, Vegetable Transplants*, Foliage Plants, Bedding Plants **(Outdoor Use Only)**	Imported fire ants	1 1/2 quarts per 100 gallons	Avoid contact with foliage and treat only the growing media when using on bedding plants. Do not make more than one application, either as a root dip or drench treatments (applied to the point of saturation).

RESTRICTIONS AND PRECAUTIONS: IMPORTED FIRE ANT CONTROL

- DO NOT ALLOW PUBLIC USE OF TREATED AREAS DURING APPLICATIONS OR UNTIL DRENCH HAS DRIED.
- DO NOT USE IN GREENHOUSES.
- ***NOTE**: DO NOT USE ON ANY FOOD CROP NOT LISTED ON THIS LABEL. Refer to the specific crop section for additional restrictions and precautions.
- To prepare small amounts, use 3/4 fluid ounce (approximately 1 1/2 tablespoons) of SEVIN® BRAND 4F per each gallon of mix where 1 1/2 quarts per 100 gallons are indicated.

ADULT MOSQUITO CONTROL

Apply in sufficient gallonage for thorough coverage.

CROP	PEST	QUARTS OF SEVIN® 4F PER ACRE	SPECIFIC DIRECTIONS
Pastures Rangeland Forested Lands Wastelands	Mosquitoes (adults)	1/4 to 1*	OBSERVE BEE CAUTION. Treat shrubbery and areas where adult mosquitoes congregate. Treat when adult mosquitoes are active in early mornings or late evenings. Repeat applications as necessary*. Use 1/4 to 1/2 quart per 100 gallons in mistblowers, 1/2 to 1 quart per acre in aerial sprays, and 1 quart per acre in low pressure ground sprayers.

RESTRICTIONS AND PRECAUTIONS: ADULT MOSQUITO CONTROL.

- DO NOT ALLOW PUBLIC USE OF TREATED AREAS DURING APPLICATION OR UNTIL SPRAYS HAVE DRIED.
- CAUTION: May kill shrimp and crabs. Do not use in areas where these are important resources.
- ***NOTE**: Refer to individual site listings elsewhere on this label for use limitations and restrictions. Do not use rates higher than listed for the site or exceed other use restrictions.
- To prepare small volumes of spray mixture, use 1/3 fl. oz. (approximately 2 teaspoons) of this product in an adequate amount of water and apply to 500 sq.ft. where rates of 1 quart per acre are indicated.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and should be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

NET CONTENTS: 2.5 GALLONS

SEVIN is the registered trademark of Bayer.

Bayer CropScience

Bayer CropScience LP
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Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)

09/27/04

SEVIN® BRAND 4F CARBARYL INSECTICIDE

SECTION 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Product Name: SEVIN® BRAND 4F CARBARYL INSECTICIDE
Chemical Name
Synonym: Carbaryl
MSDS Number: 194
Chemical Family
Chemical Formulation: C12H11NO2
EPA Registration No.: 264-349
Canadian Registrat. No.
Bayer CropScience
2 T.W. Alexander Drive
Research Triangle PK, NC 27709
USA
For Product Use Information: (866)-992-2937 Monday through Friday (CRLF) 8:00AM-4:30PM (CRLF)
For Medical Emergency contact DART: 1-800-334-7577 24 Hours/Day (CRLF)
For Transportation Emergency CHEMTREC: 1-800-424-9300 24 Hours/Day
MSDS Number: 000000000194
MSDS Version 2.1

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

Component Name	CAS No.	Concentration % by Weight	
		Minimum	Maximum
CARBARYL (1-NAPHTHYL N-METHYLCARBAMATE)	63-25-2	41.2000	
1,2-Propylene glycol	57-55-6		
ETHANOL	64-17-5		
Other ingredients (Trade secret)			

SECTION 3. HAZARDS IDENTIFICATION

NOTE: Please refer to Section 11 for detailed toxicological information.
Emergency Overview: Caution. May be harmful if swallowed or inhaled.
Physical State: liquid
Odor: mild
Appearance: off-white to pale yellow
Immediate Effects
Eye: Causes redness, irritation, tearing.
Skin: Harmful if absorbed through skin. May produce symptoms similar to those from ingestion.
Ingestion: Harmful if ingested. This product causes reversible cholinesterase inhibition. Repeated overexposure may cause more severe cholinesterase inhibition with more pronounced signs and symptoms. May lead to rapid onset of nausea, vomiting, diarrhea, abdominal pain, involuntary shaking, excess salivation, pinpoint pupils, blurred vision, profuse sweating, temporary paralysis, respiratory depression, and convulsions.
Inhalation: Harmful if inhaled. May produce symptoms similar to those from ingestion.
Chronic or Delayed Long-Term: This product does not contain any ingredients designated by IARC, NTP, ACGIH or OSHA as probable or suspected human carcinogens.
Medical Conditions Aggravated by Exposure: Inhalation of product may aggravate existing chronic respiratory problems such as asthma, emphysema or bronchitis. Skin contact may aggravate existing skin disease.

SECTION 4. FIRST AID MEASURES

Eye: Hold eyelids open and flush with a steady, gentle stream of water for at least 15 minutes. Seek medical attention.
Skin: In case of contact, immediately wash with plenty of soap and water for at least 5 minutes. Seek medical attention if irritation develops or persists. Remove contaminated clothing and shoes while washing. Clean contaminated clothing and shoes before re-use.
Ingestion: If victim is conscious and alert, give 2-3 glasses of water to drink and induce vomiting by touching back of throat with a finger. Do not induce vomiting or give anything by mouth to an unconscious person. Seek immediate medical attention. Do not leave victim unattended. Vomiting may occur spontaneously. To prevent aspiration of swallowed product, lay victim on side with head lower than waist. If vomiting occurs and the victim is conscious, give water to further dilute the chemical.
Inhalation: Remove victim from immediate source of exposure and assure that the victim is breathing. If breathing is difficult, administer oxygen, if available. If victim is not breathing, administer CPR (cardio-pulmonary resuscitation). Seek medical attention.
Note to Physician
All treatment should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred. This product contains a methyl carbamate insecticide, which is a chloinesterase inhibitor. Overexposure to this substance may cause toxic signs and symptoms due to stimulation of the cholinergic nervous system. These effects of overexposure are spontaneously and rapidly reversible.
Specific treatment consists of parenteral atropine sulfate. Improve tissue oxygenation as much as possible before administering atropine to minimize the risk of ventricular fibrillation. Mild cases may be given 1 to 2 mg intramuscularly every 10 minutes until full atropinization has been achieved and repeated thereafter whenever symptoms reappear. Severe cases should be given 2 to 4 mg intravenously every 10 minutes until fully atropinized, then intramuscularly every 30 to 60 minutes as needed to maintain the effect for at least 12 hours. Dosages for children should be appropriately reduced. Complete recovery from overexposure is to be expected within 24 hours.
To aid in confirmation of a diagnosis, urine samples should be obtained within 24 hours of exposure and immediately frozen. Call 1-800-334-7577 before sending samples. Analysis will be arranged by Bayer.
Persons regularly exposed in manufacturing and handling this product should have a preexposure and periodic red blood cell cholinesterase level checks. Narcotics and other sedatives should not be used. Further, drugs like 2-PAM (pyridine-2-aldoxime methiodide) are NOT recommended.

SECTION 5. FIRE FIGHTING MEASURES

Flash Point: *> 93°C / > 199°F*
Lower Flammable Limit: Data
Upper Flammable Limit: No Data
Fire and Explosion Hazards: Product will burn under fire conditions.
Suitable Extinguishing Media
Small Fires: carbon dioxide (CO_2), dry chemical
Large Fires: alcohol foam, polymer foam, water spray
Fire Fighting Instructions: Firefighters should wear NIOSH/MSHA approved self-contained breathing apparatus and full protective clothing. Keep unnecessary people away, isolate hazard area and deny entry. Evacuate residents who are downwind of fire. Dike area to prevent runoff and contamination of water sources. Dispose of fire control water later. Persons who may have been exposed to contaminated smoke should be immediately examined by a physician and checked for symptoms of poisoning. The symptoms should not be mistaken for heat exhaustion or smoke inhalation.

SECTION 6. ACCIDENTAL RELEASE MEASURES

General and Disposal
Evacuation Procedures and Safety: Wear appropriate gear for the situation. See Personal Protection information in Section 8.
Cleanup and Disposal of Spill: Recover material, if possible. Absorb with vermiculite or other inert absorbent. Shovel up into an appropriate closed container (see Section 7: Handling and Storage). Clean up residual material by washing area with water. Decontaminate tools and equipment following cleanup.
Land Spill or Leaks
Containment of Spill: Dike spill using absorbent or impervious materials such as earth, sand or clay. Follow procedure under Cleanup and Disposal of Spill. Collect and contain contaminated absorbent and dike material for disposal.
Environmental and Regulatory Reporting: Runoff from fire control or dilution water may cause pollution. Prevent material from entering public sewer system or any waterway. Spills may be reportable to the National Response Center (800-424-8802) and to state and/or local agencies. If spilled on the ground, the affected area should be removed to a depth of one or two inches and placed in an appropriate container for disposal.

SECTION 7. HANDLING AND STORAGE

Handling Procedures: Avoid direct or prolonged contact with skin and eyes. Do not ingest.
Storing Procedures: Store in original container. Keep in a dry, cool place. Store in an area that is away from foodstuffs or animal feed, out of reach of children and animals.
Work/Hygienic Procedures
Personal hygiene is an important work practice exposure control measure and the following general measures should be taken when working with or handling this material:
Do not store, use, and/or consume foods, beverages, tobacco products, or cosmetics in areas where this material is stored.
Wash hands and face carefully before eating, drinking, using tobacco, applying cosmetics, or using the toilet.
Wash exposed skin promptly to remove accidental splashes of contact with this material.
In addition, based upon the specific hazard of this product: Do not take clothing/objects contaminated by this material off the work site. Shower and change into street clothes before leaving the work site.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Where engineering controls are indicated by use conditions of a potential for excessive exposure exists, the following traditional exposure control techniques may be used to effectively minimize employee exposures: general area dilution/exhaust ventilation
Eye/Face Protection
Eye and face protection requirements will vary dependent upon work environment conditions and material handling practices. Appropriate ANSI Z87 approved equipment should be selected for the particular use intended for this material.
Eye contact should be prevented through use of chemical safety glasses with side shields or splash proof goggles. An emergency eye wash must be readily accessible to the work area.
Body Protection: Skin contact should be minimized through use of gloves and suitable long-sleeved clothing (i.e., shirts and pants). Consideration must be given both to durability as well as permeation resistance.
Respiratory Protection
When respirators are required, select NIOSH/MSHA approved equipment based on actual or potential airborne concentrations and in accordance with the appropriate regulatory standards and/or industrial recommendations.
Under normal conditions, in the absence of other airborne contaminants, the following should provide protection from this material up to the conditions specified by the appropriate OSHA, WHMIS or ANSI standard(s): Air-purifying (half-mask/full-face) respirator with cartridge/canister approved for use against pesticides.
Under conditions immediately dangerous to life or health, or emergency conditions with unknown concentrations, use a full-face positive pressure air-supplied respirator equipped with an emergency escape air supply unit or use a self-contained breathing apparatus unit.
Exposure Limits
CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE) 63-25-2

ACGIH	TWA		5 mg/m3
NIOSH	REL		5 mg/m3
OSHA Z1	PEL		5 mg/m3
OSHA Z1A	TWA		5 mg/m3
US CA OEL	TWA PEL		5 mg/m3

1,2-Propylene glycol 57-55-6

WEEL	TWA		50 ppm
Form of Exposure		Total vapor and aerosol.	
WEEL	TWA		10 mg/m3
Form of Exposure		Aerosol.	
ACGIH	TWA		3 mg/m3
Form of Exposure		Respirable.	
US CA OEL	TWA PEL		5 mg/m3
Form of Exposure		Respirable fraction.	
US CA OEL	TWA PEL		10 mg/m3
Form of Exposure		Total dust.	
US CA OEL	TWA PEL		5 mg/m3
Form of Exposure		Respirable fraction.	
US CA OEL	TWA PEL		5 mg/m3
Form of Exposure		Respirable fraction.	
US CA OEL	TWA PEL		10 mg/m3
Form of Exposure		Total dust.	
US CA OEL	TWA PEL		10 mg/m3
Form of Exposure		Total dust.	
ACGIH	TWA		10 mg/m3
Form of Exposure		Inhalable particulate.	

ETHANOL 64-17-5

ACGIH	TWA		1,000 ppm
NIOSH	REL	1,000 ppm	1,900 mg/m3
OSHA Z1	PEL	1,000 ppm	1,900 mg/m3
OSHA Z1A	TWA	1,000 ppm	1,900 mg/m3
US CA OEL	TWA PEL	1,000 ppm	1,900 mg/m3

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: off-white to pale yellow
Physical State: liquid
Odor: mild
pH: 4 - 5 at 5 wt/wt%.
Vapor Pressure: 17.8 mmHg at 20°C
Vapor Density (air = 1): *0.62*
Specific Gravity: 1.1 at 20°C
Boiling Point: 98°C at 760 mmHg
Melting/Freezing Point: -3°C
Solubility (in water): miscible
Molecular Weight: 201.2 g/mol
Decomposition Temperature: 140°C
Other Information: Physical and Chemical properties here represent typical properties of this product. Contact the business area using the Product information phone number in Section 1 for its exact specifications.

SECTION 10. STABILITY AND REACTIVITY

Chemical Stability: This material is stable under normal handling and storage conditions described in Section 7.
Conditions to Avoid
extreme heat
open flame
Incompatibility
strong acids
bases
Hazardous Products of Decomposition
Decomposition Type: thermal
oxides of nitrogen
carbon oxides
methyl isocyanate (trace; no adverse effects expected)
Hazardous Polymerization (Conditions to avoid):
not applicable

SECTION 11. TOXICOLOGICAL INFORMATION

Acute Oral Toxicity: Rat: LD50: 590 mg/kg
Acute Dermal Toxicity: Rabbit: LD50: > 2,000 mg/kg
Acute Inhalation Toxicity
Rat: LC50: > 1.8 mg/l: 4 h
Acute Respiratory Irritation: No test data found for product.
Skin Irritation: Rabbit: Minimally Irritating
Eye Irritation: Rabbit: Slightly irritating.
Chronic Toxicity: Carbaryl has been shown to cause tumors in laboratory animals in lifetime feeding studies. Carbaryl, when administered by various routes, at doses toxic to the maternal animals, has been shown to produce developmental toxicity in a number of species. Carbaryl produces no teratogenic effect in the absence of maternal toxicity.
Assessment Carcinogenicity
ACGIH
CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE) 63-25-2: Group A4
ETHANOL 64-17-5: Group A4
NTP
None
IARC
CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE) 63-25-2: 3
OSHA
None

SECTION 12. ECOLOGICAL INFORMATION

Ecological Information: For ecotoxicological data call the product information phone number listed in Section 1.
Environmental Fate: For chemical fate data call the product information phone number listed in Section 1.

SECTION 13. DISPOSAL CONSIDERATIONS

General Disposal Guidance
Chemical additions, processing or otherwise altering this material may make the waste management information presented in this MSDS incomplete, inaccurate or otherwise inappropriate. Please be advised that state and local requirements for waste disposal may be more restrictive or otherwise different from federal laws and regulations. Consult state and local regulations regarding the proper disposal of this material.
EPA Hazardous Waste - No
RCRA Classification
63-25-2 CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE)
US. EPA Resource Conservation and Recovery Act (RCRA) U List of Hazardous Wastes (40 CFR 261.33(f) and 40 CFR 302 [CERCLA]): U279

SECTION 14. TRANSPORT INFORMATION

For Transportation Regulatory Information call the Product Information phone number in Section 1.

SECTION 15. REGULATORY INFORMATION

US Federal
EPA Registration No.: 264-349
TSCA list
CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE) 63-25-2
1,2-Propylene glycol 57-55-6
ETHANOL 64-17-5
TSCA 12b export notification
None
SARA Title III - section 302 - notification and information
None
SARA Title III - section 313 - toxic chemical release reporting
CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE) 63-25-2: 1.0%
US States Regulatory
CA Prop65
This product does not contain any substances known to the State of California to cause cancer.
This product does not contain any substances known to the State of California to cause reproductive harm.
US State right-to-know ingredients
CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE) 63-25-2: CA, CT, IL, MA, MN, NJ, PA, RI
1,2-Propylene glycol 57-55-6: PA, RI
ETHANOL 64-17-5: CA, CT, IL, MA, MN, NJ, PA, RI
Canadian Regulations
Canadian Registrat. No.
Canadian Domestic Substance List
1,2-Propylene glycol 57-55-6
ETHANOL 64-17-5
Environmental
CERCLA
CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE) 63-25-2: 100 lbs
ETHANOL 64-17-5: 100 lbs
Clean Water Section 307 Priority Pollutants
None
Safe Drinking Water Act Maximum Contaminant Levels
None
International Regulations
EU Classification
None
European Inventory of Existing Commercial Substances (EINECS)
CARBARYL, (1-NAPHTHYL N-METHYLCARBAMATE) 63-25-2
1,2-Propylene glycol 57-55-6
ETHANOL 64-17-5

SECTION 16. OTHER INFORMATION

	Health	Flammability	Reactivity	Others
HMIS	2	1	1	
NFPA	2	1	1	

Reason for Revisions: Company name change.
Print Date: 12/18/2002
Supersedes MSDS, which is older than: 12/16/2002
This information is provided in good faith but without express or implied warranty. Buyer assumes all responsibility for safety and use not in accordance with label instructions. The product names are registered trademarks of Bayer AG. Bayer CropScience VID 5.8.03

AHETF Study No. AHE55

Product-Specific Risk Statement
(Must be attached to the Informed Consent Form)

The product you will handle is identified as follows:

Name: Sevin® Brand XLR Plus Carbaryl Insecticide (EPA Registration No. 264-333)

Active Ingredient (AI): Carbaryl (insecticide, CAS No. 63-25-2)

Formulation and Packaging: 4 lb AI/gallon Flowable liquid in 2.5 gallon plastic jugs

You may handle up to: 25 gallons of product

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This carbaryl product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye irritation and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 9/21/04
MSDS date: 1/17/08 (Bayer MSDS 102000001927, Version 2.1)

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

Bayer CropScience

SEVIN® brand XLR PLUS Carbaryl Insecticide

For Agricultural or Commercial Use Only

ACTIVE INGREDIENT:

Carbaryl (1-naphthyl N-methylcarbamate) ..... **44.1% by wt.**

INERT INGREDIENTS ..... **55.9% by wt.**

(Contains 4 Pounds Carbaryl Per Gallon)

E.P.A. Reg. No 264-333 **E.P.A. Est. No. 264-MO-02**

KEEP OUT OF REACH OF CHILDREN

CAUTION

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577

For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

Carbaryl is an N-Methyl Carbamate Insecticide.

IF SWALLOWED:	• Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything by mouth to an unconscious person.
IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577. **Have the product container or label with you when calling a poison control center or doctor or going for treatment.**	

GENERAL

Contact a physician immediately in all cases of suspected poisoning. Transport to a physician or hospital immediately and SHOW A COPY OF THIS LABEL TO THE PHYSICIAN. If poisoning is suspected in animals, contact a veterinarian.

ANTIDOTE STATEMENT

ATROPINE SULFATE IS HIGHLY EFFECTIVE AS AN ANTIDOTE. Narcotics and other sedatives should not be used. Further, drugs like 2-PAM (pyridine-2-aldoxime methiodide) are NOT recommended. See NOTE TO PHYSICIAN.

NOTE TO PHYSICIAN

Treat symptomatically. Overexposure to materials other than this product may have occurred.

Carbaryl is an N-methyl carbamate insecticide, which is a cholinesterase inhibitor. Overexposure to this substance may cause toxic signs and symptoms due to stimulation of the cholinergic nervous system. These effects of overexposure are spontaneously and rapidly reversible. Gastric lavage may be used if this product has been swallowed. Carbaryl poisoning may occur rapidly after ingestion and prompt removal of stomach contents is indicated.

Specific treatment consists of parenteral atropine sulfate. Caution should be maintained to prevent over atropinization. Improve tissue oxygenation as much as possible before administering atropine to minimize the risk of ventricular fibrillation. Mild cases may be given 1

to 2 mg intramuscularly every 10 minutes until full atropinization has been achieved and repeated thereafter whenever symptoms reappear. Severe cases should be given 2 to 4 mg intravenously every 10 minutes until fully atropinized, then intramuscularly every 30 to 60 minutes as needed to maintain the effect for at least 12 hours. Dosages for children should be appropriately reduced. Complete recovery from overexposure is to be expected within 24 hours.

Narcotics and other sedatives should not be used. Further, drugs like 2-PAM (pyridine-2-aldoxime methiodide) are NOT recommended.

To aid in confirmation of a diagnosis, urine samples should be obtained within 24 hours of exposure and immediately frozen. Analysis will be arranged by Bayer CropScience.

Consultation on therapy can be obtained at all hours by calling the Bayer CropScience emergency number 1-800-334-7577.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS (& DOMESTIC ANIMALS)

CAUTION

HARMFUL IF SWALLOWED, ABSORBED THROUGH THE SKIN, INHALED, OR IF IN EYES.
Avoid breathing vapors or spray mist. Avoid contact with eyes, skin or clothing. Keep out of reach of children and domestic animals.

OVEREXPOSURE MAY CAUSE: Salivation, watery eyes, pinpoint eye pupils, blurred vision, muscle tremors, difficult breathing, excessive sweating, abdominal cramps, nausea, vomiting, diarrhea, weakness, headache. IN SEVERE CASES CONVULSION, UNCONSCIOUSNESS AND RESPIRATORY FAILURE MAY OCCUR. SIGNS AND SYMPTOMS OCCUR RAPIDLY FOLLOWING OVEREXPOSURE TO THIS PRODUCT.

PERSONAL PROTECTIVE EQUIPMENT:

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category E on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear long-sleeved shirt and long pants, chemical resistant gloves such as barrier laminate, nitrile rubber, neoprene rubber, or viton, shoes plus socks, and chemical-resistant headgear for overhead exposure.

Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning and maintaining Personal Protective Equipment (PPE). If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

User Safety Recommendations

Users should wash hands before eating, drinking chewing gum, using tobacco, or using the toilet.

Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to aquatic and estuarine invertebrates. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Discharge from rice fields may kill aquatic and estuarine invertebrates. Do not apply when weather conditions favor drift from area treated. Do not contaminate water by cleaning equipment or disposal of wastes. Do not contaminate water when disposing of equipment washwaters.

BEE CAUTION

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. However, field studies have shown that SEVIN® brand XLR PLUS Carbaryl Insecticide is less hazardous to honey bees than other carbaryl products when direct application to bees is avoided and the spray residues have dried. For maximum honey bee hazard reduction, apply from late evening to early morning or when bees are not foraging. Do not apply this product or allow it to drift to blooming crops or weeds if bees are foraging in the treatment area. However, applications may be made during foraging periods if the beekeeper takes one of the following precautionary measures prior to bee flight activity on the day of treatment: (1) Confine the honey bees to the hive by covering the colony or screening the entrance or; (2) locate hives beyond bee flight range from the treated area. Precautionary measures may be discontinued after spray residues have dried. Contact your cooperative Agricultural Extension Service or your local Bayer CropScience representative for further information.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Read the entire label before using this product.

Strictly observe label directions and cautions. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is coveralls, chemical-resistant gloves such as barrier laminate, nitrile rubber, neoprene rubber, or viton, shoes plus socks, and chemical-resistant headgear for overhead exposure.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

The area being treated must be vacated by unprotected persons.

Keep unprotected persons out of treated areas until sprays have dried.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE

Store unused SEVIN® brand XLR PLUS Carbaryl Insecticide in original container only, in cool, dry area out of reach of children and animals. Do not store in areas where temperatures frequently exceed 100°F.

If container is damaged, before cleaning up, put on Personal Protective Equipment.

PESTICIDE DISPOSAL

Open dumping is prohibited. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility

CONTAINER DISPOSAL

Triple rinse (or equivalent). Then offer container for recycling or reconditioning or puncture and dispose of container in a sanitary landfill, by incineration, or, if allowed by state and local authorities, by burning. If container is burned, stay out of smoke.

GENERAL CAUTIONS AND RESTRICTIONS

SEVIN® brand XLR PLUS Carbaryl Insecticide is a suspension of microfine SEVIN® brand carbaryl insecticide in an aqueous medium. It readily disperses in water to form a spray which may be applied by air or ground.

PLANT RESPONSE PRECAUTIONS

Application to wet foliage or during periods of high humidity may cause injury to tender foliage.

Do not use on Boston Ivy, Virginia creeper and maidenhair fern as injury may result. Carbaryl may also injure Virginia and sand pines.

The use of adjuvants may increase the potential for crop injury to sensitive crops.

PREHARVEST AND GRAZING RESTRICTIONS AND LIMITATIONS

Tolerances established under the Federal Food, Drug and Cosmetic Act permit the sale of labeled crops bearing probable carbaryl residues when this product is used in accordance with the label directions. If used as directed, treated forage may be grazed or used as feed for dairy and meat animals without causing illegal residues in meat or milk. Do not apply at greater rates or at more frequent intervals than stated on the label. To do so may result in illegal residues in crops, meat, and milk.

Do not use reclaimed irrigation water from crops treated with carbaryl on crops for which carbaryl tolerances are not established.

Do not plant rotational food and feed crops not listed on this or other carbaryl labels in carbaryl treated soil.

APPLICATION STATEMENTS

Calibrate and adjust application equipment to insure proper rate and accurate placement. To clean spray system after use, drain and flush with a water and detergent mixture. Rinse thoroughly with clean water. Refer to the Storage and Disposal section for disposal instructions.

NOTE: Staining may occur on certain surfaces such as stucco, brick, cinder block, and wood. Spray deposits on painted or stained surfaces or finishes (i.e., cars, houses, trailers, boats, etc.) should be immediately removed by washing to prevent discoloration. Avoid applications to surfaces where visible spray residues are objectionable.

RESISTANT SPECIES NOTICE

All references to armyworm on the crops listed below refer to the species, *Pseudaletia unipuncta*, often called the "true armyworm". Except where indicated otherwise, this product is not registered for the control of other armyworm species. Regional differences have been noted in the susceptibility of certain strains of fall armyworm, diamondback moth, Colorado potato beetle and Southern green stink bug to carbaryl. If local experience indicates inadequate control, use an alternative pesticide.

MIXING, LOADING AND HANDLING INSTRUCTIONS

TO ASSURE A UNIFORM SUSPENSION, AGITATE, STIR OR RECIRCULATE ALL CONTAINERS OF THIS PRODUCT PRIOR TO USE. Remove oil, rust, scale, pesticide residues and other foreign matter from mix tanks and entire spray system. Flush with clean water. Fill spray or mix tank with 1/2 to 3/4 the desired amount of water. Start mechanical or hydraulic agitation. Slowly add the required amount of SEVIN® brand XLR PLUS Carbaryl Insecticide, and then the remaining volume of water. Include rinse water from container. Prepare only as much spray mixture as can be applied on the day of mixing. MAINTAIN CONTINUOUS AGITATION DURING MIXING AND APPLICATION TO ASSURE A UNIFORM SUSPENSION. DO NOT STORE SPRAY MIXTURE FOR PROLONGED PERIODS OR DEGRADATION OF CARBARYL MAY OCCUR. Local water conditions may also accelerate the degradation of spray mixtures containing carbaryl. See COMPATIBILITY STATEMENT below.

COMPATIBILITY INFORMATION

SEVIN® brand XLR PLUS Carbaryl Insecticide, when diluted with at least an equal volume of water, is compatible with a wide range of pesticides. It is not compatible with diesel fuel, kerosene, fuel oil or aromatic solvents. If compatibility with another product and the resulting crop response is unknown, the mixture should be tested on a small scale. Curdling, precipitation, greasing, layer formation or increased viscosity are symptoms of incompatibility. Incompatibility will reduce insect control and may cause application and handling difficulties or plant injury. Observe all cautions and limitations on labeling of all products used in mixtures. WHEN PREPARING COMBINATION SPRAYS, FIRST ADD SEVIN® BRAND XLR PLUS CARBARYL INSECTICIDE TO AT LEAST AN EQUAL VOLUME OF WATER, MIX THOROUGHLY, AND THEN ADD COMBINATION PRODUCTS TO THE MIXTURE. DO NOT APPLY TANK MIX COMBINATIONS UNLESS YOUR PREVIOUS EXPERIENCE INDICATES THE MIXTURE IS EFFECTIVE AND WILL NOT RESULT IN APPLICATION PROBLEMS OR PLANT INJURY.

Carbaryl is unstable under highly alkaline conditions and mixtures with strong bases, such as Bordeaux, lime-sulfur and casein-lime spreaders, will result in chemical degradation of the insecticide. Do not use this product in water with pH values above 8.0 unless a buffer is added. If necessary, water should be buffered to neutral (pH = 7.0) before adding this product to the spray tank. Overhead irrigation with alkaline or muddy water after application will also accelerate chemical degradation and may result in reduced insect control.

APPLICATION PROCEDURES AND PRECAUTIONS

On all crops use sufficient gallonage to obtain thorough and uniform coverage. Observe crop label instructions for specific directions regarding spray volume where they occur. Calibrate spray equipment to deliver the required volume. The flow rate of this product diluted 1:1 with water is similar to water. Use of 50 mesh slotted strainers in spray system and 25 mesh slotted strainers behind nozzles is recommended.

WASHOFF RESISTANCE AND COVERAGE

Dilution of 1 volume of SEVIN® brand XLR PLUS Carbaryl Insecticide with 1 volume of water provided maximum resistance to washoff by rainfall or overhead irrigation. Dilutions higher than 1 part SEVIN® brand XLR PLUS Carbaryl Insecticide to 39 parts water (1:39) are not recommended when washoff resistance is desired.

To achieve washoff resistance, SEVIN® brand XLR PLUS Carbaryl Insecticide must be diluted as stated above, and droplets must dry on the foliage. When atmospheric humidity is low, a drying time of at least two hours is generally adequate. Under high humidity a longer drying time is required. Washoff resistance cannot be expected if this product is applied to wet foliage and has not thoroughly dried prior to rainfall or overhead irrigation.

On all crops, use sufficient spray volume to obtain thorough coverage. Optimum pest control under certain crop, pest or climatic conditions may require spray gallonages higher than the 1:39 dilution. For example, in hot, arid weather (low humidity), higher spray gallonage per acre may be required to compensate for loss from evaporation and insure thorough coverage. The total spray volume required for effective pest control can best be determined by previous experience, pest and crop conditions and local recommendations.

GROUND APPLICATION

Apply in sufficient volume for adequate coverage on all crops and sites. To prepare small volumes of spray mixture, use 1/3 fl. oz. (approximately 2 teaspoons) of this product in an adequate amount of water and apply to 500 sq.ft. where rates of 1 quart per acre are indicated.

AERIAL APPLICATION

For adequate distribution, use at least 10 gallons of spray mixture per acre for application for orchard crops or at least 2 gallons of spray mixture per acre for application to other crops. **EXCEPTION:** For the use of SEVIN® brand XLR Plus Carbaryl Insecticide on rangeland for control of grasshoppers under the Reduced Area and Agent Treatments (RAATs) program **only**, use at least 16 ounces of finished spray mixture per acre for aerial application.

SPRINKLER IRRIGATION SYSTEMS

Apply this product only through sprinkler irrigation systems including center pivot and solid set. Do not apply this product through any other type of irrigation system.

SPRAY PREPARATION: First prepare a suspension of SEVIN® brand XLR PLUS Carbaryl Insecticide in a mix tank. Fill tank with 1/2 to 3/4 the desired amount of water. Start mechanical or hydraulic agitation. Add the required amount of SEVIN® brand XLR PLUS, and then the remaining volume of water. (Suspension concentrations using the appropriate dosage per acre recommended on this label of SEVIN® brand XLR PLUS, per 1 to 4 gallons of water are recommended). Then set sprinkler to deliver 0.1 to 0.3 inch of water per acre. Start sprinkler and uniformly inject the suspension of SEVIN® brand XLR PLUS into the irrigation water line so as to deliver the desired rate per acre. The suspension of SEVIN® brand XLR PLUS should be injected with a positive displacement pump into the main line

ahead of a right angle turn to insure adequate mixing. If you should have any other questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts.

NOTE: When treatment with SEVIN® brand XLR PLUS has been completed, further field irrigation over the treated area should be avoided for 24 to 48 hours to prevent washing the chemical off the crop.

GENERAL PRECAUTIONS FOR APPLICATIONS THROUGH SPRINKLER IRRIGATION SYSTEMS

Maintain continuous agitation in mix tank during mixing and application to assure a uniform suspension.

Greater accuracy in calibration and distribution will be achieved by injecting a larger volume of a more dilute solution per unit time.

The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump. The pesticide injection pipeline must also contain a functional, normally closed solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shutdown. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock. Do not apply when wind speed favors drift beyond the area intended for treatment.

Do not apply when wind speed favors drift, when system connection or fittings leak, when nozzles do not provide uniform distribution or when lines containing the product must be dismantled and drained.

Crop injury, lack of effectiveness, or illegal pesticide residues in the crop may result from nonuniform distribution of treated water.

Allow sufficient time for pesticide to be flushed through all lines and all nozzles before turning off irrigation water. A person knowledgeable of the chemigation system and responsible for its operation shall shut the system down and make necessary adjustments should the need arise.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the label-prescribed safety devices for public water supplies are in place.

SPECIFIC USE DIRECTIONS

CROP/SITE GROUPINGS:

Asparagus
Brassica Leafy Vegetable Crops
Cereal Grain Crops (Field and Pop Corn; Grain Sorghum; Rice; Sweet Corn; Wheat and Proso Millet)
Cucurbit Vegetables
Flax
Forage Crops (Alfalfa, Clovers, Birdsfoot Trefoil; Pasture and Grasses Grown for Seed; Rangeland)
Fruiting Vegetables
Leafy Vegetables
Legume Vegetables
Noncropland (Conservation Reserve Program; Wasteland; Rights-of-Way; Hedgerows; Ditchbanks; Roadsides)
Okra
Peanuts
Prickly Pear Cactus
Root and Tuber Crops (Root and Tuber Crops except Sugar Beets and Sweet Potatoes; Sugar Beets; Sweet Potatoes)
Small Fruits and Berries
Sunflower
Tobacco
Tree Fruit Crops (Citrus Fruits; Olives; Pome Fruits; Stone Fruits)
Tree Nut Crops (Pistachios; Tree Nuts)
Forested Areas and Rangeland Trees
Control of Specific Pests Across Multiple Sites
- Grasshoppers
- Ticks which Vector Lyme Disease
- Imported Fire Ants
- Adult Mosquito Control

Directions for Use as a Cereal Grain Bait

INSECT CONTROL

Begin application when insect populations reach recognized economic threshold levels. Consult the Cooperative Extension Service, Consultants, or other qualified authorities to determine appropriate threshold levels for treatment and specific use information in your area. Where a dosage range is indicated, use the lower rate on light to moderate infestations, young plants and early instars and use the higher rate on heavy infestations, mature plants, advanced instars and adults. Thorough and uniform spray coverage is essential for effective control.

ASPARAGUS

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Asparagus	Apache cicada Asparagus beetle Cutworms	1 to 2	Repeat applications as necessary up to a total of 3 times prior to harvest or a total of 5 times per crop but not more often than once every 3 days. For cutworm control, this product is most effective against species which feed on the upper portions of the plant.
		2 to 4	**Application to ferns or brush growth following harvest of spears**: Repeat applications as necessary but not more often than every 7 days. Do not make more than a total of 5 applications per year to spears and ferns combined.

RESTRICTIONS AND PRECAUTIONS: ASPARAGUS

- Do not apply within 1 day of harvest.
- Do not apply more than a total of 6 quarts per acre before harvest of spears.
- Do not apply more than a total of 10 quarts per acre per year.

BRASSICA LEAFY VEGETABLES CROPS

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Broccoli Brussel Sprouts Cauliflower Cabbage Chinese Cabbage Collards Kale Kohlrabi Mustard Greens	Flea beetles Harlequin bug Leafhoppers	1/2 to 1	Repeat applications as needed up to a total of 4 times but not more often than once every 7 days.
	Armyworm Aster leafhopper Corn earworm Diamondback moth Fall armyworm Imported cabbageworm Lygus bugs Spittle bugs Stink bugs Tarnished plant bug	1 to 2	

RESTRICTIONS AND PRECAUTIONS: BRASSICA LEAFY VEGETABLES

- For Broccoli, Brussel Sprouts, Cabbage Cauliflower, and Kohlrabi, do not apply within 3 days of harvest.
- For Chinese Cabbage, Collards, Kale, and Mustard Greens, do not apply within 14 days of harvest.
- Do not apply more than a total of 6 quarts per acre per crop.

CEREAL GRAIN CROPS

FIELD CORN AND POPCORN

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Field corn and Popcorn	Armyworm, Chinch bugs, Corn earworm, Corn rootworm adults, Fall armyworm, Flea beetles, Japanese beetle, Sap beetles, Southwestern corn borer, Leafhoppers	1 to 2	OBSERVE BEE CAUTION. Repeat applications as needed up to a total of 4 times but not more often than once every 14 days. Optimum timing and good coverage are essential for effective control.
	European corn borer	1 1/2 to 2	For optimum chinch bug control, use ground equipment to apply at least 20 gallons of water per acre and direct spray toward stalk to provide thorough coverage. For optimum European corn borer control, do not apply in less than 3 gallons of water per acre by air and 15 gallons of water by ground. For western bean cutworm, treat when infestation averages 15% and at 90 to 100% tassel emergence. Treatment after 100% silk emergence will reduce effectiveness. For optimum cutworm control, apply in a 12-inch band, over the row, using sufficient volume of water to obtain thorough coverage. For broadcast application, use at least 20 gallons by ground or 5 gallons by air per acre. For cutworm control, this product is most effective against species which feed on the upper portions of the plant.
	Western bean cutworm, Cutworms	2	

RESTRICTIONS AND PRECAUTIONS: FIELD AND POP CORN

- Do not apply within 48 days of harvest of grain and fodder or within 14 days of harvest or grazing of forage or silage.
- Do not apply more than a total of 8 quarts per acre per crop.

GRAIN SORGHUM

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Grain Sorghum	Armyworm, Chinch bugs, Corn earworm, Fall armyworm, Stink bugs, Webworms	1 to 2	Repeat applications as necessary up to a total of 4 times but not more often than once every 7 days.
	Southwestern corn borer	1 1/2	Direct spray into forming heads for optimum control of insects attacking heads.
	Cutworms	2	For optimum chinch bug control, use high gallonage ground application at the base of plants. For cutworm control, this product is most effective against species which feed on the upper portions of the plant.

RESTRICTIONS AND PRECAUTIONS: GRAIN SORGHUM

- Do not apply within 21 days of harvest for grain or fodder or within 14 days of harvest or grazing of forage or silage.
- Do not apply more than a total of 6 quarts per acre per crop.

RICE

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Rice	Armyworm, Chinch bugs, Fall armyworm, Leafhoppers, Stink bugs	1 to 1 1/2	Up to 2 applications per crop may be made but not more often than once every 7 days.
	Tadpole shrimp	1 1/2	**California only** For optimum tadpole shrimp control, apply to water when pest first appears.

RESTRICTIONS AND PRECAUTIONS: RICE

- Do not apply within 14 days of harvest for grain or straw.
- Do not apply more than a total of 4 quarts per acre per crop.
- **CAUTION**: May kill shrimp, crabs, and crayfish.
- Do not apply propanil herbicides within 15 days before or after application of this product or plant injury will result.

SWEET CORN

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Sweet Corn	Armyworm Chinch bugs Corn earworm Corn rootworm adults Fall armyworm Flea beetles Japanese beetle Sap beetles Southwestern corn borer Leafhoppers	1 to 2	OBSERVE BEE CAUTION Repeat applications as necessary up to a total of 8 times but not more often than once every 3 days. Optimum timing and good coverage are essential for effective control
	European corn borer	1 1/2 to 2	For insects attacking silks and ears, insecticide sprays should be applied starting when first silks appear and continuing until silks begin to dry. During silking, the minimum retreatment interval (3 days) may not provide adequate levels of protection under conditions of rapid growth or severe pest pressure. The use of an alternative product should be considered in conjunction with this product. For optimum chinch bug control, use ground equipment to apply at least 20 gallons of water per acre and direct spray toward stalk to provide thorough coverage. For optimum European corn borer control, do not apply in less than 3 gallons of water per acre by air and 15 gallons of water by ground. For western bean cutworm, treat when infestation average 15% and at 90 to 100% tassel emergence. Treatment after 100% silk emergence will reduce effectiveness. For optimum cutworm control, apply in a 12-inch band, over the row, using sufficient volume of water to obtain thorough coverage. For broadcast application, use at least 20 gallons by ground or 5 gallons by air per acre. For cutworm control, this product is most effective against species which feed on the upper portions of the plant.
	Western bean cutworm Cutworms	2	

RESTRICTIONS AND PRECAUTIONS: SWEET CORN

- Do not apply within 2 days of harvest of ears, within 14 days of harvest or grazing of forage, or within 48 days of harvest of fodder.
- Do not apply more than a total of 16 quarts per acre per crop.

WHEAT AND PROSO MILLET

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Wheat Proso Millet **DO NOT USE IN CALIFORNIA**	Flea beetles	1/2 to 1	Up to 2 applications per crop may be made but not more often than once every 14 days.
	Cereal leaf beetle	1	Application is effective against eggs, larvae, and adults of the cereal leaf beetle.
	Armyworm Fall armyworm	1 to 1 1/2	Application for armyworm control should be made when armyworms are actively feeding on the upper foliage and night temperatures and not expected to drop below 55°F. If applying by air to lush growth, use a minimum spray volume of 5 gallons per acre to optimize coverage.

RESTRICTIONS AND PRECAUTIONS: WHEAT AND PROSO MILLET

- Do not apply within 21 days of harvest for grain or straw or within 7 days of harvest or grazing of forage.
- Do not apply more than a total of 3 quarts per acre per crop.

CUCURBIT VEGETABLES

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Cucurbit Vegetables: Cucumbers Melons Pumpkins Squash	Pickleworm Melonworm	1/2 to 1	Repeat applications as necessary up to a total of 6 times but not more often than once every 7 days.
	Cucumber beetles Flea beetles Leafhoppers Squash bugs	1	For optimum control of squash bugs, apply sufficient spray volume for thorough coverage and time sprays for early morning or late afternoon.

RESTRICTIONS AND PRECAUTIONS: CUCURBIT VEGETABLES

- Do not apply within 3 days of harvest.
- Do not apply more than a total of 6 quarts per acre per crop.
- Observe plant response precautions.

FLAX

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Flax **DO NOT USE IN CALIFORNIA**	Armyworm	1 to 1 1/2	Up to 2 applications per crop may be made but not more often than once every 14 days.

RESTRICTIONS AND PRECAUTIONS: FLAX

- Do not apply within 42 days of harvest for seed or straw.
- Do not apply more than a total of 3 quarts per acre per crop.

FORAGE CROPS

ALFALFA, CLOVERS, AND BIRDSFOOT TREFOIL

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Alfalfa, Clovers, and Birdsfoot Trefoil	Blister beetles Mexican bean beetle	1/2 to 1	OBSERVE BEE CAUTION. Observe plant response precautions.
	Alfalfa caterpillar Bean leaf beetle Cucumber beetles Green cloverworm Japanese beetle Leafhoppers Potato leafhopper Three cornered alfalfa hopper Thrips Velvetbean caterpillar	1	On dense growth, use 25 to 40 gallons of water per acre with ground equipment to ensure adequate coverage.
	Alfalfa blotch leafminer Armyworm Cloverhead weevil Corn earworm Cutworms Egyptian alfalfa weevil larvae Essex skipper European alfalfa beetle Fall armyworm Lygus bugs Stink bugs Webworms Yellow striped armyworm	1 to 1 1/2	For alfalfa weevil larvae, if pretreatment damage is extensive, cut alfalfa and treat the stubble. This product is not effective against **adult** alfalfa weevils. For cutworm control, this product is most effective against species which feed on the upper portions of the plant.
	Alfalfa weevil larvae (west of the Rocky Mountains)	1 to 1 1/2	
	Alfalfa weevil larvae (east of the Rocky Mountains)	1 1/2	

RESTRICTIONS AND PRECAUTIONS: FORAGE CROPS

- Do not apply more than once per cutting.
- Do not apply within 7 days of harvest or grazing.
- Do not exceed 1.5 quarts per acre per cutting.
- Carbaryl may cause a temporary bleaching of tender alfalfa foliage.

PASTURE AND GRASSES GROWN FOR SEED

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Pasture and Grasses Grown for Seed	Armyworm Chinch bugs Essex skipper Fall armyworm Striped grass looper Thrips Range caterpillar Range crane fly Ticks	1 to 1 1/2	Up to 2 applications per year may be made but not more often than once every 14 days. To control thrips in grasses grown for seed, use high spray pressure to improve penetration into boot. Carefully mark swaths to avoid over-application.

RESTRICTIONS AND PRECAUTIONS: PASTURE AND GRASSES GROWN FOR SEED

- Do not apply within 14 days of harvest or grazing.
- Do not exceed a total of 3 quarts per acre per year.

RANGELAND

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Rangeland	Black grass bug Grasshoppers* Mormon cricket Range caterpillar Range crane fly	1/2 to 1*	Do not make more than 1 application per year. Carefully mark swaths to avoid over-application.
	Ticks	1	

RESTRICTIONS AND PRECAUTIONS: RANGELAND

- May be harvested or grazed the same day as treatment.
- Do not apply more than 1 quart per acre per year.

* † REDUCED AREA AND AGENT TREATMENTS (RAATS)

The RAATs approach takes advantage of grasshopper movement to allow SEVIN® brand XLR Plus Carbaryl Insecticide to be applied at reduced rates on a reduced treated area while maintaining acceptable grasshopper control. Under this program, SEVIN® brand XLR Plus may be applied to as little as 50% of the infested area (treating a 100 ft swath, skipping a 100 ft swath), up to 100% of infested area. The amount of area treated will depend on grasshopper age, density and plant canopy. By leaving untreated swaths, the RAATs program provides reserves for natural biological control agents. This strategy fully utilizes an Integrated Pest Management approach for grasshopper control.

Apply 8 ounces to 1 quart per acre of SEVIN® brand XLR Plus by air or ground on 50 – 100% of infested area for control of grasshopper nymphs between the 2nd and 5th instar. The rate to use per acre will depend on grasshopper age, population density and plant canopy. Use the higher rates on more mature grasshoppers, severe infestations and dense vegetation. Use the lower rates on younger grasshoppers, light to moderate infestations and sparse vegetation. **Consult with the local grasshopper control experts in your area for the proper rate and swath width to use under your conditions.** Computer software packages such as HOPPER (USDA) and CARMA (University of Wyoming) are available to assist in grasshopper management decisions.

The optimum spray gallonage will depend on the plant canopy (foliage density), air temperature and wind speed. Under optimum application conditions (sparse vegetation, low air temperatures and 0 – 5 mph wind speed), use 16 ounces to 2 gallons of finished spray per acre. This product cannot be applied in a concentration greater than 1 part SEVIN® brand XLR Plus to 1 part water. **Under adverse conditions (dense vegetation, high temperatures and low humidity) higher spray gallonage per acre may be required to compensate for loss from evaporation and ensure thorough coverage.**

CAUTION: The use of SEVIN® brand XLR Plus Carbaryl Insecticide under the RAATs program is meant to provide ranchers with an economic and environmentally sound means to reduce grasshopper competition on their rangeland. RAATs program results indicate that this reduction in grasshopper competition for range forage provides economic control of most species under most conditions. However, if a higher level of grasshopper control is required, refer to the SEVIN® brand XLR Plus label for specific recommendations.

† Not Registered for Use in California.

FRUITING VEGETABLES

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Fruiting Vegetables: Tomatoes, Peppers, Eggplant	Colorado potato beetle European corn borer Fall armyworm Lace bugs Stink bugs (suppression) Tarnished plant bug Thrips (suppression) Tomato fruitworm Tomato hornworm Tomato pinworm	1 to 2	Repeat applications as necessary up to a total of 7 times but not more often than once every 7 days. Thorough coverage is essential to effectively suppress stink bugs. When disease transmission is suspected, monitor fields following application and retreat if reinfestation occurs but not more often than once every 7 days.
	Flea beetles Leafhoppers	1/2 to 1	
	Cutworms	2	For cutworm control, this product is most effective against species which feed on the upper portions of the plant.

RESTRICTIONS AND PRECAUTIONS: FRUITING VEGETABLES

- Do not apply within 3 days of harvest.
- Do not apply more than a total of 8 quarts per crop.

LEAFY VEGETABLES

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Leafy vegetables: Celery, Dandelion, Endive, Lettuce (head and leaf), Parsley, Spinach, Swiss Chard	Flea beetles Harlequin bug Leafhoppers	1/2 to 1	Repeat applications as necessary up to a total of 5 times but not more often than once every 7 days.
	Armyworm Aster leafhopper Corn earworm Fall armyworm Imported cabbageworm Lygus bugs Spittlebugs Stink bugs Tarnished plant bug	1 to 2	

RESTRICTIONS AND PRECAUTIONS: LEAFY VEGETABLES

- Do not apply within 14 days of harvest.
- Do not apply more than a total of 6 quarts per acre per crop.

LEGUME VEGETABLES

CROP	PEST		QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Legume Vegetables: Soybeans, Fresh and Dried Beans (*Phaseolus* species including snap, navy and kidney), Fresh and Dried Peas (*Pisum* species), Lentils, Cowpeas, Southern Peas **DO NOT USE ON LENTILS IN CALIFORNIA**	Bean leaf beetle Blister beetle Cucumber beetles Grape colapsis	Green cloverworm Japanese beetle Mexican bean beetle Velvetbean caterpillar	1/2 to 1	Repeat applications as necessary up to a total of 4 times but not more often than once every 7 days.
	Corn earworm		1/2 to 1 1/2	For cutworm control, this product is most effective against species which feed on the upper portions of the plant.
	Alfalfa caterpillar Colorado potato beetle Flea beetles Leafhoppers	Three cornered alfalfa hopper Thrips Western bean cutworm	1	Use lower rates for light to moderate populations and smaller instars and to provide maximum survival of beneficial insects and spiders. Use the higher rates for heavy populations and larger instars.
	Armyworm Cutworms European corn borer Fall armyworm	Stink bugs Tarnished plant bug Webworms	1 to 1 1/2	
	Alfalfa looper (suppression) Cowpea curculio (suppression) Painted lady (Thistle caterpillar) Pea leaf weevil	Pea weevil Saltmarsh caterpillar Woollybean caterpillar Yellowstriped armyworm	1 1/2	
	California only: Corn earworm (suppression) Limabean podborer (suppression)	Lygus bugs (suppression) Stink bugs (suppression)	1 1/2	

RESTRICTIONS AND PRECAUTIONS: LEGUME VEGETABLES

- Do not apply within 14 days of grazing or harvest for forage or within 3 days of harvest of fresh beans or peas or within 21 days of harvest of dried beans or peas, seed, or hay.
- Do not apply more than a total of 6 quarts per acre per crop.
- Do not apply a combination of this product and 2,4-DB herbicides to soybeans as crop injury may result.
- Observe plant response precautions.

NONCROPLAND

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Conservation Reserve Program Acreage Set-Aside Program Acreage Wasteland Rights-of-Way Hedgerows Ditchbanks Roadsides	Black grass bug	1/4 to 1/2	Up to 2 applications per year may be made but not more often than once every 14 days.
	Mormon cricket Range caterpillar Range crane fly	1/2 to 1	Carefully mark swaths to avoid over-application.
	Ticks	1 to 1 1/2	

RESTRICTIONS AND PRECAUTIONS: NONCROPLAND

- Do not apply within 14 days of grazing or harvest for forage or hay.
- Do not apply more than a total of 3 quarts per acre per year.

OKRA*

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Okra	Corn earworm Stink bugs	1 to 1 1/2	Apply using ground equipment in sufficient volume to insure good coverage. Apply as needed on 6 to 8 day intervals. For grasshopper control, refer to the general Grasshopper Section.

RESTRICTIONS AND PRECAUTIONS: OKRA

- Do not apply within 3 days of harvest.
- Do not apply more than a total of 6 quarts per acre per season.

*** Use not permitted in CA unless otherwise directed by supplemental labeling.**

PEANUTS

CROP	PEST		QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Peanuts	Blister beetles Mexican bean beetle		1/2 to 1	Repeat applications as necessary up to a total of 5 times but not more often than once every 7 days.
	Alfalfa caterpillar Bean leaf beetle Cucumber beetle Green cloverworm Japanese beetle Leafhoppers	Rednecked peanutworm Three cornered alfalfa hopper Thrips Velvetbean caterpillar	1	For optimum control of thrips, use directed or banded sprays with hollow cone spray nozzles. Ensure adequate coverage for the underside of leaves.
	Armyworm Corn earworm Fall armyworm	Stink bugs Webworms	1 to 1 1/2	For cutworm control, this product is most effective against species which feed on the upper portions of the plant.
	Whitefringed beetle adults	Cutworms	2	

RESTRICTIONS AND PRECAUTIONS: PEANUTS

- Do not apply within 14 days of harvest.
- Do not apply more than a total of 8 quarts per acre per crop.
- Observe plant response precautions.

PRICKLY PEAR CACTUS*

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Prickly Pear Cactus	Cochineal scale (crawlers)	2	Apply using ground equipment in sufficient volume to insure good coverage. Apply as needed on 7 to 10 day intervals. For grasshopper control, refer to the general Grasshopper Section.

RESTRICTIONS AND PRECAUTIONS: PRICKLY PEAR CACTUS

- Do not apply within 3 days of harvest.
- Do not apply more than a total of 6 quarts per acre per season.

*** Use not permitted in CA unless otherwise directed by supplemental labeling.**

ROOT AND TUBER CROPS

ROOT AND TUBER CROPS EXCEPT SUGAR BEETS AND SWEET POTATOES

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Root and Tuber Crops:	Flea beetles Leafhoppers	1/2 to 1	Repeat applications as necessary up to a total of 6 times but not more often than once every 7 days.
Garden Beets, Carrots, Horseradish, Parsnips, Radishes, Rutabagas, Salsify, Potatoes	Armyworm Aster leafhopper Colorado potato beetle Corn earworm Cutworms European corn borer Fall armyworm Lace bugs Lygus bugs Spittlebugs Stink bugs Tarnished plant bug	1 to 2	For cutworm control, this product is most effective against species which feed on the upper portions of the plant.

RESTRICTIONS AND PRECAUTIONS: ROOT AND TUBER CROPS EXCEPT SUGAR BEETS AND SWEET POTATOES

- Do not apply within 7 days of harvest.
- Do not apply more than a total of 6 quarts per acre per crop.

SUGAR BEETS

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Sugar beets	Armyworm Beet leaf beetle Fall armyworm Flea beetles Leafhoppers Webworms	1 to 1 1/2	Repeat applications as necessary up to a total of 2 times but not more often than once every 14 days.
	Cutworms	1 1/2	For cutworm control, this product is most effective against species which feed on the upper portions of the plant.

RESTRICTIONS AND PRECAUTIONS: SUGAR BEETS

- Do not apply within 28 days of harvest for roots or forage.
- Do not apply more than a total of 3 quarts per acre per crop.

SWEET POTATOES

CROP	PEST		QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Sweet Potatoes	Corn earworm Cucumber beetles Flea beetles Sweet potato hornworm	Sweet potato weevil Tortoise beetles Whitefringed beetle	1 to 2	**Preplant dip for control of sweet potato weevil**: Just prior to planting, dip sweet potato cuttings in a suspension containing 2 gallons of this product in 100 gallons of water (2.6 fluid ounces per gallon of water)
	Yellowstriped armyworm		2	For foliar sprays, repeat applications as necessary up to a total of 8 times but not more often than once every 7 days.

RESTRICTIONS AND PRECAUTIONS: SWEET POTATOES

- Do not apply within 7 days of harvest.
- Do not apply more than a total of 8 quarts per acre per crop with in-season sprays.
- Do not apply more than a total of 1.2 quarts per acre as a preplant dip treatment.

SMALL FRUITS AND BERRIES

CROP	PEST		QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Small Fruits and Berries: Caneberries, Blueberries, Cranberries, Grapes, Strawberries	European fruit lecanium European raspberry aphid Flea beetles Grape leaffolder Grape leafroller Japanese beetle Leafhoppers Leafrollers Meadow spittlebug Omnivorous leaftier	Rose chafer Snowy tree cricket Strawberry bud weevil Strawberry clipper Strawberry fruitworm Strawberry leafroller Strawberry weevil Western grapeleaf skeletonizer Western yellowstriped armyworm	1 to 2	OBSERVE BEE CAUTION. Repeat applications as necessary up to a total of 5 times but not more often than once every 7 days. For cutworm control, this product is most effective against species which feed on the upper portions of the plant. In grapes for grape leaffolder control, apply before first brood larvae emerge from rolls.
	Blueberry maggot Cherry fruitworm Cranberry fireworm Cranberry fruitworms Cranberry twig girdler	Elm spanworm Gypsy moth Spaganothus worm Tarnished plant bug	1 1/2 to 2	In grapes, do not concentrate spray on the bunch or visible residues may result.
	Eight-spotted forester Cutworms Grape berry moth June beetles Omnivorous leafroller	Orange tortrix Raspberry fruitworm Raspberry sawfly Redbanded leafroller Saltmarsh caterpillar	2	

RESTRICTIONS AND PRECAUTIONS: SMALL FRUITS AND BERRIES

- Do not apply within 7 days of harvest.
- Do not apply more than a total of 10 quarts per acre per crop.
- **CAUTION**: Use in cranberries may kill shrimp and crabs. Do not use in areas where these are important resources.
- Carbaryl may injure Early Dawn and Sunrise varieties of strawberries.

SUNFLOWERS

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Sunflowers DO NOT USE IN CALIFORNIA	Stem weevil Sunflower beetle	1 to 1 1/2	Up to 2 applications may be made but not more often than once every 7 days. For cutworm control, this product is most effective against species which feed on the upper portions of the plant.
	Armyworm Cutworms Fall armyworm Sunflower moth	1 1/2	

RESTRICTIONS AND PRECAUTIONS: SUNFLOWERS

- Do not apply within 30 days of grazing or harvest for forage or within 60 days of harvest for seed.
- Do not apply more than a total of 3 quarts per acre per crop.

TOBACCO

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Tobacco	Budworms Fall armyworm Tobacco flea beetles Hornworms Japanese beetle June beetle Suckfly	1 to 2	**Plant bed and Field Treatment** Repeat treatments as necessary up to a total of 4 times per crop but not more often than once every 7 days. Use lower rate on young plants (up to knee height). Use at least 10 gallons of prepared spray per acre. Begin treatments when worms are small.

RESTRICTIONS AND PRECAUTIONS: TOBACCO

- Tobacco may be harvested on the day of treatment.
- Do not apply more than a total of 8 quarts per acre per crop.
- Observe plant response precautions.

TREE FRUIT CROPS

On all tree fruit crops, apply in sufficient volume for adequate coverage. This will vary depending on the pest and its severity, the tree condition, size, and density, and other factors.

CITRUS FRUITS

CROP	PEST		QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Citrus Fruits	Avocado leafroller California orangedog Citrus cutworm Fruittree leafroller	Orange Tortrix Western tussock moth	2 to 3	OBSERVE BEE CAUTION. Repeat applications as necessary up to a total of 8 times but not more often than once every 14 days.
	Citrus rust mite Eriophyid mites	Plant bugs Scale insects [Black scale, brown soft scale, California red scale (except in California), citrus snow scale, yellow scale (except in California)]	3 to 5	For scale control, apply when crawlers are present. For best control of Eriophyid mites including citrus rust mite, apply when pest populations are low.
	Apopka weevil (adult) Citrus root weevils (adults)	Fuller Rose Beetle Little leaf notcher (adult)	5 to 7 1/2	
	California only: California red scale	Yellow scale	5 to 16	Do not make more than 1 application per season for California red scale. Apply when crawlers are present.

RESTRICTIONS AND PRECAUTIONS: CITRUS FRUITS

- Do not apply within 5 days of harvest.
- Do not apply more than a total of 20 quarts per acre per crop.

OLIVES

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Olives	Scale insects (olive scale, black scale)	5 to 7 1/2	Up to 2 applications per crop may be made but not more often than once every 14 days.

RESTRICTIONS AND PRECAUTIONS: OLIVES

- Do not apply within 14 days of harvest.
- Do not apply more than a total of 15 quarts per acre per crop.

POME FRUITS

CROP	PEST		QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Pome Fruits: apples, pears, loquats, crabapples and oriental pears	White apple leafhopper		1/2 to 1 1/2	OBSERVE BEE CAUTION. On apples, avoid use during the period from full bloom until 30 days after full bloom unless fruit thinning is desired. Use for pest control during this period also may result in fruit removal. Repeat applications as necessary up to a total of 8 times per crop (including thinning sprays on apples) but not more often than once every 14 days. For psylla control, apply when eggs hatch or young nymphs are present. For scale control, apply when crawlers are present.
	Apple aphid	Codling moth	1 to 3	
	Apple aphid Apple maggot Apple mealybug Apple rust mite Bagworms California pearslug (pear sawfly) European apple sawfly Eyespotted bud moth Fruittree leafroller Gypsy moth Japanese beetle Lesser appleworm Lygus bugs Orange tortrix	Pearleaf blister mite Pear psylla Pear rust mite Periodical cicada Plum curculio Redbanded leafroller Rosy apply aphid Scale insects (Forbes scale, Lecanium scale, San Jose scale) Tarnished plant bug Tentiform leafminers Woolly apple aphid Yellowheaded fireworm	1 1/2 to 3	

POME FRUITS
(continued)

CROP	PINTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Apples Only, for Fruit Thinning	2 to 6	OBSERVE BEE CAUTION Apply 2 to 6 pints per acre of SEVIN® XLR Plus between 80% petal fall and 16 mm fruit size. Use the higher rates on hard to thin varieties at the early timing which is the 80% petal fall to 6 mm fruit size. Use the lower rates on easy to thin varieties and at the later thinning period which is the 10 to 16 mm fruit size. The rate to use per acre will depend on varieties, tree size, row spacing, weather conditions at the time of and following applications. **Consult with the local fruit thinning experts in your area for the proper rate to use under your conditions.** The optimum spray gallonage will depend on the tree size, planting density, row spacing and amount of foliage. Use sufficient spray volume to insure adequate coverage (100 to 400 gallons/acre). Avoid spray to the point of runoff. **Reduce spray coverage to the lower portion of the tree since overthinning may occur here.** Factors such as climatic temperature, high humidity, frost, tree age, variety, nutrition, previous crop, pruning and bloom may influence fruit thinning results with the product. Exercise caution to avoid possible overthinning. For the most effective results, apply under good drying conditions and when daytime temperatures (°F) will be 70 to low 80's for the following one to three days. Application with daytime temperatures in excess of 80° F may result in overthinning. SEVIN® XLR Plus may be mixed with other fruit thinners, however, use caution to avoid overthinning and other adverse effects. Consult with local fruit thinning experts in your area for recommendations. Refer to the other product labels for specific use directions. **Consult with local fruit thinning experts in your area for advice on the proper use of this product on your varieties under your growing conditions.** **CAUTION:** The use of SEVIN® XLR Plus may result in fruit deformity under certain environmental conditions. Before using on any variety of apples, the user must weigh the risk versus benefits when using this product, particularly when using between **80% petal fall and 6 mm fruit size**. Red Delicious are more sensitive to this phenomenon and in particular, the varieties Bisbee, Red Chief and Vallee Spur are very susceptible to conditions causing fruit deformity. Precipitation and temperatures below 65° F increases the possibility of fruit deformity. The use with summer spray oils and wetting agents may increase the risk of fruit deformity and injury.

RESTRICTIONS AND PRECAUTIONS: POME FRUITS

- Do not apply to quince.
- Do not use on pears between the tight flower cluster up to the 20 mm fruit size. Use during this period may result in undesirable fruit thinning and/or deformed fruit.
- Do not apply within 3 days of harvest.
- Do not apply more than a total of 15 quarts per acre per crop.
- Do not make more than a total of 8 applications per crop.

FOR PROTECTION OF HONEY BEES:

- Remove all bee hives from orchard to be treated prior to application.
- Do not apply this product if bees are actively foraging in orchard.
- If weed bloom is present, mow the cover crop on the orchard floor prior to applying this product.

STONE FRUITS

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Stone Fruits: Apricots, Cherries, Nectarines, Peaches, Plums, and Prunes	Apple pandemis Black cherry aphid Cherry fruitworm Cherry maggot (Cherry fruit fly) Codling moth Cucumber beetles Eastern tent caterpillar Eyespotted bud moth European earwig Fruittree leafroller Green fruitworm Gypsy moth Japanese beetle June beetle Lesser peachtree borer Mealy plum aphid Orange tortrix Oriental fruit moth Peach twig borer Periodical cicada Plum curculio Prune leafhopper Redbanded leafroller Rose chafer Scale insects (Brown soft scale, Forbes scale, Lecanium scale, Olive scale, Oystershell scale, San Jose scale) Tarnished plant bug Tussock moth Variegated leafroller	2 to 3	OBSERVE BEE CAUTION. Repeat applications as necessary up to a total of 3 times per crop but not more often than once every 7 days. An additional application at the dormant or delayed dormant timing may be made. For optimum scale control, apply when crawlers are present. For lesser peachtree borer, best results have been found by thoroughly spraying limbs and tree trunks at weekly intervals during moth flight.
	California Only: Black cherry aphid Cherry fruitworm Cherry maggot (Cherry fruit fly) Codling moth Cucumber beetles Eyespotted bud moth European earwig Fruittree leafroller Green fruitworm Mealy plum aphid Orange tortrix Oriental fruit moth Peach twig borer Scale insects (Brown soft scale, Forbes scale, Lecanium scale, Olive scale, Oystershell scale, San Jose scale) Tarnished plant bug Tussock moth	3 to 4	OBSERVE BEE CAUTION. Repeat applications as necessary up to a total of 3 times per crop but not more often than once every 14 days. An additional application at the dormant or delayed dormant timing may be made. For optimum scale control, apply when crawlers are present.
	Peach twig borer Scale insects (Brown soft scale, Forbes scale, Lecanium scale, Olive scale, Oystershell scale, San Jose scale)	4 to 5	**For dormant or delayed dormant timing,** apply in combination with a recommended dormant oil. Refer to the dormant oil product label for additional use directions and restrictions.

RESTRICTIONS AND PRECAUTIONS: STONE FRUIT

- Do not apply within 3 days of harvest, except in California. In California, do not apply within 1 day of harvest.
- Do not apply more than a total of 14 quarts per acre per crop.
- Do not apply more than a total of 5 quarts per acre at the dormant or delayed dormant timing.
- Do not apply more than a total of 9 quarts per acre during the production season.

TREE NUT CROPS

On all tree nut crops, apply in sufficient volume for adequate coverage. This will vary depending on the pest and its severity, the tree condition, size, and density, and other factors.

PISTACHIOS

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Pistachios	Brown soft scale Lecanium scale Navel orangeworm	3 to 5	Repeat applications as necessary up to a total of 4 times per crop (including any applications at the dormant or delayed dormant timing) but not more often than once every 7 days. For scale control, apply when crawlers are present.
	Scale insects	4 to 5	**For dormant or delayed dormant timing**, apply in combination with a recommended dormant oil. Refer to the dormant oil product label for additional use directions and restrictions.

RESTRICTIONS AND PRECAUTIONS: PISTACHIOS

- Do not apply within 14 days of harvest.
- Do not apply more than a total of 15 quarts per acre per crop, including any application at the dormant or delayed dormant timing.

TREE NUTS

CROP	PEST		QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Tree Nuts: Almonds, Chestnuts, Filberts, Pecans, Walnuts	Black margined aphid Calico scale Codling moth European fruit lecanium Fall webworm Filbert aphid Filbert leafroller Filbertworm Frosted scale Fruittree leafroller Hickory shuckworm Lesser webworm	Navel orangeworm Peach twig borer Pecan leaf phylloxera Pecan stem phylloxera Pecan nut casebearer Pecan spittlebug Pecan weevil San Jose scale Twig girdler Walnut caterpillar	2 to 5	OBSERVE BEE CAUTION Repeat applications as necessary up to a total of 4 times per crop (including any applications at the dormant or delayed dormant timing) but not more often than once every 7 days. Use lower rates for pests attacking leaves. Use higher rates for pests attacking fruit and for higher infestations. For scale control, apply when crawlers are present. For peach twig borer, best results with foliar applications have been found by making applications in "popcorn" or petal fall stages when the May brood begins to hatch. For navel orangeworm in almonds and walnuts, best results have been found by timing early and midseason applications to correspond with moth flight peaks. For filbert leafroller, best results have been found by making applications when eggs are hatching, repeating application on first appearance of moths and again 3 to 4 weeks later. For codling moth in walnuts, best results have been found by making applications when average cross-sectional diameters of developing nuts are 0.5 to 0.75 inches and again during middle or late June as needed.
	Chestnut weevil	European earwig	4 to 5	For chestnut weevil, best results have been found with 4 applications at weekly intervals beginning in late July. The last application should be made prior to shuck split. For European earwig, thorough coverage of trunks, branches, and nuts is needed for best results.
Almonds only	Peach twig borer	Scale insects	4 to 5	**For dormant or delayed dormant timing**, apply in combination with a recommended dormant oil. Refer to the dormant oil product label for additional use directions and restrictions.

RESTRICTIONS AND PRECAUTIONS: TREE NUTS

- Do not apply within 14 days of harvest.
- Do not apply more than a total of 15 quarts per acre per crop, including any application at the dormant or delayed dormant timing.

FORESTED AREAS AND RANGELAND TREES

Apply in sufficient volume for adequate coverage. This will vary depending on the tree size, density and stage of growth.

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Forested areas: Non-urban Forests, Tree Plantations, Planted Christmas Trees, Parks, Rural Shelter Belts Rangeland Trees	Ants Apple aphid Armyworm Ash whitefly Azalea leafminer Bagworms Balsam twig aphid Birch leafminer Blister beetle Boxelder bug Boxwood leafminer Brown tail moth Cankerworms Catalpa sphinx Chiggers Cooley spruce gall adelgid Cutworms Cypress tip moth Douglas-fir tussock moth Eastern spruce gall adelgid Elm leaf aphid Elm leaf beetle Elm spanworm Eriophyid mites European pine shoot moth Fall armyworm Flea beetle Fuschia gall mite Fuller rose beetle Gall midges Gall wasps Greenstriped mapleworm Grasshoppers Hackberry nipplegall maker Holly bud moth Holly leafminer Jackpine budworm Japanese beetle Jeffrey pine needleminer June beetles Lace bugs Leafhoppers Leafrollers Locust borer Maple leafcutter Mealy bugs Mimosa webworm Nantucket pine tip moth Oak leafminers Oak moth Oak skeletonizer Oakworm complex Oleander caterpillar Olive ash borer Orange-striped oakworm Periodical cicada Pine looper Pine sawfly Pine spittlebug Pitch pine tip moth Spruce budworm Plant bugs Poinsettia hornworm Psyllids Puss caterpillar Redhumped oakworm Rose aphid Rose chafer Rose slug Saddled prominent Sawflies (exposed) Scale insects (crawlers) Sowbugs Spiney elm caterpillar Springtails Spruce needleminer Subtropical pine tip moth Tent caterpillars Thorn bug Thrips (exposed) Ticks Walnut caterpillar Webworms Western hemlock looper Western spruce budworm Willow leaf beetles Wooly gall aphid Yellow poplar weevil	1	Observe plant response precautions. Obtain thorough coverage of upper and lower leaf surfaces. The addition of a sticker may improve residual control. To control scale insects, treat trunks, stems and twigs in addition to plant foliage. For optimum worm control, treat when pests are small. Do not use on syrup-producing sugar maples where sap is harvested. Applications for control of maple leafcutter on sugar maple should be made when larvae are in 2nd instar after mining and as cases are being formed. Repeat treatments as necessary up to a total of 2 times per year but not more often than once every 7 days. For gypsy moth control, use the higher rate for heavy infestations.
	Gypsy Moth	3/4 to 1	

FORESTED AREAS AND RANGELAND TREES, CONTINUED

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Forested areas: Non-urban Forests, Tree Plantations, Planted Christmas Trees, Parks, Rural Shelter Belts Rangeland Trees	Elm bark beetle Ips engraver beetles Mountain pine beetle Roundheaded pine beetle Spruce beetle Western pine beetle	2% solution (5 fluid ounces per gallon)	**Direct Trunk Treatment**: Effective as a preventative treatment only. Repeat annually as required to prevent beetle attacks. Apply 1 gallon of spray per 50 square feet of bark prior to beetle flight or host-tree attack. Treat tree trunk from ground level up, until trunk diameter is less than 5 inches. For elm bark beetle: apply approximately 20-30 gallons of spray mixture for each 50 feet of elm tree for thorough coverage of all bark surfaces on trunks, limbs and twigs. Do not make more than 2 applications per year or repeat applications more often than once every six months.

RESTRICTIONS AND PRECAUTIONS: FORESTED AREAS AND RANGELAND TREES

- Do not make more than 2 applications per year.
- To prepare small volumes of spray mixture, use 1/3 fl. oz. (approximately 2 teaspoons) of this product in an adequate amount of water and apply to 500 sq.ft. where rates of 1 quart per acre are indicated.
- DO NOT ALLOW PUBLIC USE OF TREATED AREAS DURING APPLICATIONS OR UNTIL SPRAYS HAVE DRIED.

CONTROL OF SPECIFIC PESTS ACROSS MULTIPLE SITES

GRASSHOPPERS

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
All crops on this label	Grasshoppers	1/2 to 1 1/2*	Apply 1/2 to 3/4 quarts per acre of this product for nymphs on small plants or sparse vegetation. Apply 1 to 1 1/2 quarts per acre for mature grasshoppers or applications to dense foliage or if extended residual control is desired. Be certain spray volumes are appropriate to assure adequate coverage.

RESTRICTIONS AND PRECAUTIONS: GRASSHOPPER CONTROL

***NOTE**: Refer to individual site listings elsewhere on this label for use limitations and restrictions. Do not use rates higher than listed for the site or exceed other use restrictions. Refer to the Rangeland Use Directions for the Reduced Area and Agent Treatments (RAATs) program.

CONTROL OF TICKS WHICH VECTOR LYME DISEASE

For control of juvenile and adult ticks which vector Lyme Disease, apply the recommended amount is sufficient volume for thorough coverage.

CROP/SITE	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
All crops on this label Pastures Forested Areas Wasteland, Rights-of-Way, Hedgerows, Ditchbanks, Roadsides, Set-Aside and Conservation Reserve Program Acreage	*Ixodes* spp. (Deer tick, Bear tick, Black legged tick) *Amblyomma* spp. (Lone star tick)	1 to 2*	Use the high rate for heavy tick infestations.* Use higher spray volumes for dense ground cover or heavy leaf litter. Target applications for nymphal control in late spring or early summer. Control of adult tick can be obtained with late summer and fall applications. Do not use spot treatments. Treat entire area and perimeter areas where exposure to ticks may occur. Ticks may be reintroduced from surrounding areas on host animals. Retreat as necessary to maintain adequate control levels*.

RESTRICTIONS AND PRECAUTIONS: CONTROL OF TICKS WHICH VECTOR LYME DISEASE

- ***NOTE**: Refer to individual site listings elsewhere on this label for use limitations and restrictions. Do not use rates higher than listed for the site or exceed other use restrictions.
- DO NOT ALLOW PUBLIC USE OF TREATED AREAS DURING APPLICATION OR UNTIL SPRAYS HAVE DRIED.

IMPORTED FIRE ANTS

CROP/SITE	PEST	QUARTS OF SEVIN® XLR PLUS PER VOLUME OF WATER	SPECIFIC DIRECTIONS
Pastures Rangeland Forested Areas Trees and Ornamentals Turfgrass Wasteland	Imported fire ants	3/4 fluid ounce per gallon	**DRENCH APPLICATION**: Apply a total of 2 gallons of the diluted solution over the surface of each mound or at least 1 quart per 6 inches of mound diameter using a bucket, can or other appropriate equipment. Thoroughly wet mound and surrounding areas to a 4 ft diameter (12 sq.ft.). Do not disturb mound prior to treatment. Pour solution from a height of about three feet to give sufficient force to break mound apex and flow into ant tunnels. For best results apply in cool weather (65-80°F) or in early morning or late evening hours. Repeat application if mound activity resumes after 7 days. Treat new mounds as they appear. Pressurized sprays may disturb the ants and cause migration, reducing product effectiveness.
Nursery Stock, Vegetable Transplants*, Foliage Plants, Bedding Plants **(Outdoor Use Only)**	Imported fire ants	1 1/2 quarts per 100 gallons	Avoid contact with foliage and treat only the growing media when using on bedding plants. Do not make more than one application, either as a root dip or drench treatments (applied to the point of saturation).

RESTRICTIONS AND PRECAUTIONS: IMPORTED FIRE ANT CONTROL

- DO NOT ALLOW PUBLIC USE OF TREATED AREAS DURING APPLICATIONS OR UNTIL DRENCH HAS DRIED.
- DO NOT USE IN GREENHOUSES.
- ***NOTE**: DO NOT USE ON ANY FOOD CROP NOT LISTED ON THIS LABEL. Refer to the specific crop section for additional restrictions and precautions.
- To prepare small amounts, use 3/4 fluid ounce (approximately 1 1/2 tablespoons) of SEVIN® brand XLR PLUS per each gallon of mix where 1 1/2 quarts per 100 gallons are indicated.

ADULT MOSQUITO CONTROL

Apply in sufficient gallonage for thorough coverage.

CROP	PEST	QUARTS OF SEVIN® XLR PLUS PER ACRE	SPECIFIC DIRECTIONS
Pastures Rangeland Forested Lands Trees and Ornamentals Turfgrass Wastelands	Mosquitoes (adults)	1/4 to 1*	OBSERVE BEE CAUTION. Treat shrubbery and areas where adult mosquitoes congregate. Treat when adult mosquitoes are active in early mornings or late evenings. Repeat applications as necessary*. Use 1/4 to 1/2 quart per 100 gallons in mistblowers, 1/2 to 1 quart per acre in aerial sprays, and 1 quart per acre in low pressure ground sprayers.

RESTRICTIONS AND PRECAUTIONS: ADULT MOSQUITO CONTROL.

- DO NOT ALLOW PUBLIC USE OF TREATED AREAS DURING APPLICATION OR UNTIL SPRAYS HAVE DRIED.
- **CAUTION**: May kill shrimp and crabs. Do not use in areas where these are important resources.
- ***NOTE**: Refer to individual site listings elsewhere on this label for use limitations and restrictions. Do not use rates higher than listed for the site or exceed other use restrictions.
- To prepare small volumes of spray mixture, use 1/3 fl. oz. (approximately 2 teaspoons) of this product in an adequate amount of water and apply to 500 sq.ft. where rates of 1 quart per acre are indicated.

CEREAL GRAIN BAIT

DIRECTIONS FOR USE AS A CEREAL GRAIN BAIT

FOR END USE ONLY. NOT FOR REPACKAGING.

FOR USE ONLY BY GOVERNMENT PERSONNEL OR PERSONS UNDER THEIR DIRECT SUPERVISION (e.g., USDA, STATE AND LOCAL EXTENSION PERSONNEL, ETC.).

Mixing Instructions

Mix the appropriate amount of SEVIN® brand XLR Plus Carbaryl Insecticide with a cereal grain substrate (cereal grains or their by-products, such as flaky wheat bran, rolled wheat, rolled oats and/or barley or oat millings) to make a carbaryl bait containing 2% to 10% active carbaryl. For example, for a bait containing 5% carbaryl, mix 1 quart SEVIN® brand XLR Plus Carbaryl Insecticide (contains 1 lb. active carbaryl) with each 19 pounds of cereal grain substrate. Mix only the amount of bait necessary for each insect control program.

Storage Instructions

Store carbaryl bait in cool, dry area out of reach of children and animals. Do not contaminate water, food, or feed by storage or disposal.

NOTE: Carbaryl bait should only be stored temporarily while awaiting application.

Application Instructions

Applications may be made with ground equipment (hand cyclone spreader) or with aerial application equipment with a metered bait spreader attachment.

PASTURES, RANGELAND, WASTELAND, ROADSIDES

Use 0.50 lbs. active ingredient/acre for the control of grasshoppers and Mormon crickets. Use of low bait assay is suggested for control of high grasshopper populations. Do not make more than 1 application per acre per year. May be harvested or grazed the same day as treatment.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and should be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

NET CONTENTS: 2.5 GALLONS

SEVIN is the registered trademark of Bayer.

Bayer CropScience

Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)

09/21/04.

Bayer CropScience

Material Safety Data Sheet

SEVIN® BRAND XLR PLUS CARBARYL INSECTICIDE

MSDS Number: 102000001927
MSDS Version 2.1
Revision Date: 01/17/2008

SECTION 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Product Name	SEVIN® BRAND XLR PLUS CARBARYL INSECTICIDE
MSDS Number	102000001927
EPA Registration No.	264-333

Bayer CropScience
2 T.W. Alexander Drive
Research Triangle PK, NC 27709
USA

For MEDICAL, TRANSPORTATION or other EMERGENCY call: 1-800-334-7577 (24 hours/day)
For Product Information call: 1-866-99BAYER (1-866-992-2937)

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Component Name	CAS-No.	Average % by Weight
Carbaryl	63-25-2	44.10
1,2-Propanediol	57-55-6	

SECTION 3. HAZARDS IDENTIFICATION

NOTE: Please refer to Section 11 for detailed toxicological information.

Emergency Overview Caution! Harmful if swallowed, inhaled or absorbed through the skin. Harmful if gets in eyes. Do not breathe vapours or spray mist. Avoid contact with skin, eyes and clothing.

Physical State liquid suspension

Odor weak characteristic

Appearance white to beige

Routes of Exposure Ingestion, Inhalation, Eye contact, Skin Absorption

Immediate Effects

Eye Do not get in eyes. May cause redness, irritation, tearing.

Skin *Harmful if absorbed through skin. May produce symptoms similar to those from ingestion.*

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Ingestion	Harmful if swallowed. This product causes reversible cholinesterase inhibition. Repeated overexposure may cause more severe cholinesterase inhibition with more pronounced symptoms. May lead to rapid onset of nausea, vomiting, diarrhea, abdominal pain, involuntary shaking, excess salivation, pinpoint pupils, blurred vision, profuse sweating, temporary paralysis, respiratory depression, and convulsions.
Inhalation	Harmful if inhaled. Do not breathe vapours or spray mist. May produce symptoms similar to those from ingestion.
Chronic or Delayed Long-Term	This product is not listed by NTP, IARC or regulated as a carcinogen by OSHA. This product or its components may have target organ effects.
Medical Conditions Aggravated by Exposure	Inhalation of product may aggravate existing chronic respiratory problems such as asthma, emphysema or bronchitis. Skin contact may aggravate existing skin disease.
Potential Environmental Effect	Highly toxic to bees. Extremely toxic to aquatic and estuarine invertebrates.

SECTION 4. FIRST AID MEASURES

General	When possible, have the product container or label with you when calling a poison control center or doctor or going for treatment.
Eye	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a physician or poison control center immediately.
Skin	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Call a physician or poison control center immediately.
Ingestion	Call a physician or poison control center immediately. Rinse out mouth and give water in small sips to drink. DO NOT induce vomiting unless directed to do so by a physician or poison control center. Never give anything by mouth to an unconscious person. Do not leave victim unattended.
Inhalation	Move to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a physician or poison control center immediately.
Notes to Physician	
Signs and Symptoms	Temporary blurred vision due to contraction of the pupils (miosis) following contact with the eyes. *bradycardia* low blood pressure Salivation bronchial hypersecretion

Vomiting
Diarrhoea
sweating
muscular fasciculation
spasm
breathing difficulties
respiratory paralysis
somnolence
Coma
respiratory failure
hypothermia
Convulsions
Nausea

Hazards

This product contains a cholinesterase inhibitor carbamate.

Treatment

The product inhibits cholinesterase resulting in stimulation of the central nervous system, the parasympathetic nervous system, and the somatic motor nerves. If symptoms of carbamate poisoning are present, the administration of atropine sulfate is indicated.

ANTIDOTE: Administer atropine sulfate in large therapeutic doses. Repeat as necessary to the point of tolerance. In mild cases, start treatment by giving 1-2 mg of atropine intravenously every 15 minutes until signs of atropinization appear (dry mouth, flushing and dilated pupils if pupils were originally pinpoint). In severe cases 2 to 4 mg should be injected intravenously every 10 minutes until fully atropinized, then intramuscularly every 30 to 60 minutes as needed to maintain the effect for at least 12 hours. Dosages for children should be appropriately reduced.

Do not use oximes such as 2-PAM unless organophosphate intoxication is suspected. Do not give morphine. Watch for pulmonary edema, which may develop in serious cases of poisoning even after 24-48 hours. At first sign of pulmonary edema, the patient should be placed in an oxygen tent and treated symptomatically.

SECTION 5. FIRE FIGHTING MEASURES

Flash point

> 100 °C / 212 °F
No flash point - Determination conducted up to the boiling point.

Fire and Explosion Hazards

In the event of fire the following can be released:
Carbon monoxide (CO)
Nitrogen oxides (NOx)

Suitable Extinguishing Media

Water spray, Foam, Carbon dioxide (CO2), Dry powder

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Fire Fighting Instructions	Do not allow run-off from fire fighting to enter drains or water courses. Firefighters should wear NIOSH approved self-contained breathing apparatus and full protective clothing.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Keep unauthorized people away. Isolate hazard area. Avoid contact with spilled product or contaminated surfaces.
Methods for Cleaning Up	Recover the product by pumping, suction or absorption using a dry and inert absorbent clay. Collect and transfer the product into a properly labelled and tightly closed container. When picked up, treat product as prescribed in Ch. 13. "Disposal considerations".
Additional Advice	Use personal protective equipment. Information regarding safe handling, see section 7. Information regarding personal protective equipment, see section 8.

SECTION 7. HANDLING AND STORAGE

Handling Procedures	Use only in area provided with appropriate exhaust ventilation. Handle and open container in a manner as to prevent spillage. Maintain exposure levels below the exposure limit through the use of general and local exhaust ventilation.
Storing Procedures	Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area. Keep away from food, drink and animal feedingstuffs.
Work/Hygienic Procedures	Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, using the toilet or applying cosmetics. Remove soiled clothing immediately and clean thoroughly before using again. Wash thoroughly and put on clean clothing.
Min/Max Storage Temperatures	Recommended maximum transport/storage temperature: 38 °C / 100 °F

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

General Protection	Cholinesterase activity of the worker should be supervised. Follow all label instructions. Train employees in safe use of the product. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such

	instructions for washables, use detergent and warm/tepid water. Keep and wash PPE separately from other laundry.
Eye/Face Protection	Tightly fitting safety goggles
Hand Protection	Chemical-resistant gloves (barrier laminate, butyl rubber, nitrile rubber or Viton)
Body Protection	Wear long-sleeved shirt and long pants and shoes plus socks. Chemical resistant headgear for overhead exposure
Respiratory Protection	When respirators are required, select NIOSH approved equipment based on actual or potential airborne concentrations and in accordance with the appropriate regulatory standards and/or industry recommendations.

Exposure Limits

Carbaryl	63-25-2	ACGIH	TWA	5 mg/m3
		ACGIH NIC	TWA	0.5 mg/m3
		Form of exposure		Inhalable fraction and vapor
		NIOSH	REL	5 mg/m3
		OSHA Z1	PEL	5 mg/m3
		OSHA Z1A	TWA	5 mg/m3
		US CA OEL	TWA PEL	5 mg/m3
		TX ESL	ST ESL	50 ug/m3
		TX ESL	AN ESL	5 ug/m3
1,2-Propanediol	57-55-6	WEEL	TWA	10 mg/m3
		Form of exposure		Aerosol.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	white to beige
Physical State	liquid suspension
Odor	weak characteristic
pH	4.0 - 5.0 (10 %) at 20 °C
Density	approx. 1.07 - 1.10 g/cm³ at 20 °C
Melting / Freezing Point	-4 °C / 25 °F
Water solubility	miscible
Decomposition Temperature	175 - 190 °C Exothermic decomposition.
Viscosity	500 - 700 mPa.s at 25 °C

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SECTION 10. STABILITY AND REACTIVITY

Incompatibility	Acids Bases
Hazardous Reactions	No hazardous reactions when stored and handled according to prescribed instructions.

SECTION 11. TOXICOLOGICAL INFORMATION

The non-acute information pertains to the technical-grade active ingredient, carbaryl.

Acute Oral Toxicity	rat: LD50: 699 mg/kg
Acute Dermal Toxicity	rat: LD50: > 4,000 mg/kg
Acute Inhalation Toxicity	rat: LC50: > 3.8 mg/l Exposure time: 4 h (actual) rat: LC50: 15.2 mg/l Exposure time: 1 h Extrapolated from the 4 hr LC50. (actual)
Skin Irritation	rabbit: No skin irritation.
Eye Irritation	rabbit: Slight irritation.
Sensitization	guinea pig: Non-sensitizing.
Chronic Toxicity	Carbaryl causes reversible cholinesterase inhibition. Changes in urinary bladder, thyroid, kidney and liver were observed in chronic studies in rats.

Assessment Carcinogenicity

Carbaryl has been shown to cause tumors in laboratory animals in lifetime feeding studies.

ACGIH
None.
NTP
None.
IARC
None.
OSHA
None.

Reproductive & Developmental Toxicity	REPRODUCTION: Carbaryl was not a reproductive toxicant in a two-generation study in rats.

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DEVELOPMENTAL: Carbaryl was not a primary developmental toxicant in rats and rabbits. Developmental effects were observed in both species but were considered secondary to maternal toxicity.

Neurotoxicity Carbaryl caused transient neurobehavioral effects (e.g., tremors) related to cholinergic toxicity without correlating neuropathological changes in acute and subchronic neurotoxicity studies in rats. Carbaryl did not cause developmental neurotoxic effects in offspring in a one-generation developmental neurotoxicity study in rats.

Mutagenicity Carbaryl poses only a slight mutagenic risk based on the overall weight of evidence in a battery of in vitro and in vivo tests.

SECTION 12. ECOLOGICAL INFORMATION

Environmental Precautions Do not apply when weather conditions favor runoff or drift. Do not contaminate surface or ground water by cleaning equipment or disposal of wastes, including equipment wash water. Apply this product as specified on the label. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not allow to get into surface water, drains and ground water.

Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

SECTION 13. DISPOSAL CONSIDERATIONS

General Disposal Guidance Do not contaminate water, food, or feed by disposal. Dispose in accordance with all local, state/provincial and federal regulations. It is best to use all of the product in accordance with label directions. If it is necessary to dispose of unused product, please follow container label instructions and applicable local guidelines.

Container Disposal Do not re-use empty containers. Triple rinse containers. Puncture container to avoid re-use. Consult state and local regulations regarding the proper disposal of container.

RCRA Classification The RCRA Classifications may be on the individual component(s) and not necessarily on the product as a whole.

63-25-2 Carbaryl
US. EPA Resource Conservation and Recovery Act (RCRA) Composite List of Hazardous Wastes and Appendix VIII Hazardous Constituents (40 CFR 261): U279

63-25-2 Carbaryl
US. EPA Resource Conservation and Recovery Act (RCRA) U List of Hazardous Wastes (40 CFR 261.33(f) and 40 CFR 302 [CERCLA]): U279

Bayer CropScience

Material Safety Data Sheet

SEVIN® BRAND XLR PLUS CARBARYL INSECTICIDE

MSDS Number: 102000001927
MSDS Version 2.1

SECTION 14. TRANSPORT INFORMATION

TDG CLASSIFICATION:
Not regulated for Road and Rail

DOT CLASSIFICATION:
NON BULK:
Not Regulated for Domestic Surface Transportation
BULK:
Environmentally Hazardous Substances, Liquid, N.O.S. (Carbaryl) // 9 // UN3082 // PG III // RQ(Carbaryl)
Carbaryl RQ is 100 lbs. It takes 227 lbs or 25 gallons of product per package to meet RQ
Carbaryl is a Marine Pollutant

FREIGHT CLASSIFICATION:
Insecticides or Fungicides, N.O.I., other than poison

SECTION 15. REGULATORY INFORMATION

EPA Registration No. 264-333

US Federal Regulations

TSCA list

Carbaryl	63-25-2
1,2-Propanediol	57-55-6

US. Toxic Substances Control Act (TSCA) Section 12(b) Export Notification (40 CFR 707, Subpt D)
None.

SARA Title III - Section 302 - Notification and Information
None.

SARA Title III - Section 313 - Toxic Chemical Release Reporting

Carbaryl	63-25-2	1.0%

US States Regulatory Reporting

CA Prop65
This product does not contain any substances known to the State of California to cause cancer.

This product does not contain any substances known to the State of California to cause reproductive harm.

US State Right-To-Know Ingredients

Carbaryl	63-25-2	CA, CT, IL, MA, MN, NJ, PA, RI
1,2-Propanediol	57-55-6	MN, RI

Canadian Regulations

Canadian Domestic Substance List

1,2-Propanediol	57-55-6

Environmental

Bayer CropScience

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MSDS Number: 102000001927
MSDS Version 2.1

CERCLA

Carbaryl	63-25-2	100 lbs

Clean Water Section 307 Priority Pollutants
None.

Safe Drinking Water Act Maximum Contaminant Levels
None.

International Regulations

European Inventory of Existing Commercial Substances (EINECS)

1,2-Propanediol	57-55-6

SECTION 16. OTHER INFORMATION

NFPA 704 (National Fire Protection Association):
Health - 1 Flammability - 2 Reactivity - 1 Others - none
0 = minimal hazard, 1 = slight hazard, 2 = moderate hazard, 3 = severe hazard, 4 = extreme hazard

Reason to Revise: Updated Section 3: HAZARDS IDENTIFICATION; Updated Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION; Updated Section 11: TOXICOLOGICAL INFORMATION.

Revision Date: 01/17/2008

AHETF Study No. AHE55

Risk of Toxicity from Pesticide Product Handled (Must be attached to the Informed Consent Form)

The product you will handle is identified as follows:

Name: Gowan Malathion 8 (EPA Registration No. 10163-21)

Active Ingredient: Malathion (insecticide, CAS No. 121-75-5)

Formulation and Packaging: 8 lbs AI/gallon Emulsifiable Concentrate in [redacted]

You may handle up to: 12.5 gallons of product

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This malathion product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye and/or skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label ID: 04-R0699
MSDS date: 2/1/07 (Gowan Malathion 8 Flowable)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Version date: 1-25-08 DRAFT

GOWAN MALATHION 8

AGRICULTURAL INSECTICIDE

ACTIVE INGREDIENT:	% By Wt.
Malathion: (O,O-dimethyl phosphorodithioate of diethyl mercaptosuccinate)	79.5%
OTHER INGREDIENTS	20.5%
	TOTAL 100.0%

Contains 8 lbs. malathion per gallon

KEEP OUT OF REACH OF CHILDREN

CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID

Organophosphate Insecticide

IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by placing finger at the back of the throat. Do not induce vomiting or give anything by mouth to an unconscious person.
IF INHALED: Remove victim to fresh air and apply artificial respiration if indicated.
IF ON SKIN: Wash thoroughly with soap and water. Get medical attention.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

FOR EMERGENCY MEDICAL RESPONSE AND HAZARD COMMUNICATIONS *ONLY*, CALL 1-888-478-0798.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed. Avoid breathing of spray mist. Avoid contact with skin. Avoid contamination of feed and food.
NOTE TO PHYSICIAN: Malathion upon use may cause cholinesterase inhibition. Atropine is antidotal.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category ***F*** on an EPA chemical resistance category selection chart.
Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves, such as barrier laminate, butyl rubber ≥14mils, nitrile ≥14mils, or Viton ≥14mils
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

User should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish, aquatic invertebrates and aquatic life stages of amphibians. For terrestrial uses, do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. For aquatic use, do not apply to water except as specified on this label. Do not contaminate water when disposing of equipment washwaters.
This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are actively visiting the treatment area.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.
Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.
Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI). Exception: If the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.
PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves, such as barrier laminate, butyl rubber ≥14mils, nitrile ≥14mils, or Viton ≥14mils
- Shoes plus socks

NET CONTENTS _____ GALLONS

EPA Reg. No. 10163-21
EPA Est. No. 67545-AZ-1

Gowan

Gowan Company
P. O. Box 5569
Yuma, AZ 85366-5569

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

When using GOWAN MALATHION 8 in the greenhouse or stored grain facilities (as recommended on the label), use only with adequate ventilation. After application, ventilate thoroughly before occupying enclosed spaces.

GENERAL USE INFORMATION

In order that pesticide residues on food and forage crops will not exceed tolerances established by the Federal Food and Drug Administration, use only the recommended rates and intervals, and do not apply closer to harvest than specified.

Unless otherwise specified, apply at the first sign of infestation and repeat at 7-10 day intervals as needed to maintain control, but observe use limitations for specific crop. Consult your State Agriculture Experiment Station or the State Agricultural Extension Service for additional information as the timing of applications needed will vary with local conditions.

Applications may be made by aircraft or by ground equipment according to the DIRECTIONS FOR DILUTION below. The amount of water needed to treat an acre varies, therefore the following directions are given to cover a broad range of applications.

DIRECTIONS FOR DILUTION

DILUTE APPLICATION

Field and Row Crops: Use specified rate in 20 to 60 gallons of water per acre.

Trees and Vines: Use specified rate in 100 to 800 gallons of water per acre.

CONCENTRATE APPLICATION

Field and Row Crops: Use specified rate in not less than 5 gallons of water per acre.

Trees and Vines: Use specified rate in 20 to 100 gallons of water per acre.

AIR APPLICATION

Field and Row Crops: Use specified rate in 5 to 20 gallons of water per acre.

Trees and Vines: Use specified rate in at least 10 gallons of water per acre.

MIXING DIRECTIONS

Pour specified amount of product into nearly filled spray tank. Add balance of water to fill tank. Keep agitator running during filling and spraying operations. If mixture does not mix readily but tends to separate as an oily layer, do not use as injury to plants may result.

Do not combine with wettable powders unless previous use of the mixture has proven physically compatible and safe to plants. Always thoroughly emulsify this product with at least half of total water before adding wettable powders.

PHYTOTOXICITY ADVISORY STATEMENT

As is common with most emulsifiable concentrate formulations, adverse effects such as spotting or discoloration of the fruit or foliage can occur. Some conditions known to contribute to phytotoxicity include but are not limited to : high temperatures, poor spray drying conditions, excessive spray runoff, certain spray mixtures, stage of crop development, or tank mixes with other pesticides.

RECOMMENDATIONS

Rates are given in terms of pints of GOWAN MALATHION 8 per acre.

PREHARVEST INTERVAL

Minimum days between last application and harvest are given in **( )** after each crop name.

TREES AND VINES

CROP	REI (HRS)	RATE (PTS./ACRE)	PESTS	COMMENTS
APRICOTS (7)	12	4 - 10	Aphid, Codling Moth, European Lecanium Scale, Orange Tortrix, Soft Brown Scale, Terrapin Scale	
AVOCADOS (7)	12	4 - 9	Green House Thrips, Latania Scale, Omnivorous Looper, Soft Brown Scale, Orange Tortrix	
BLACKBERRIES (1), **BOYSENBERRIES** (1), **DEWBERRIES** (1), **LOGANBERRIES** (1), **RASPBERRIES** (1)	12	1 - 4	Japanese Beetle, Leafhoppers, Mites, Thrips	
		2 - 4	Aphid, Rose Scale	
CITRUS (GRAPEFRUIT, KUMQUATS, LEMONS, LIMES, ORANGES, TANGELOS, TANGERINES-Mandarin or Mandarin Oranges, Tangors, and other hybrids of tangerines with other citrus) (7)	24	7 - 25	Aphids, Black Scale (single and off-brooded), California Red Scale, Citricola Scale, Orangeworm, Purple Scale, Soft Scale, Thrips, Yellow Scale	
		1 - 8	Mediterranean Fruit Fly	
	• Do not apply when trees are in bloom.			
CURRANTS (1), **GOOSEBERRIES** (3)	12	1 - 2	Japanese Beetle, Mites	
		2	Currant Aphid, Imported Currantworm	
FIGS (3)	12	2 ½	Dried Fruit Beetles, Vinegar Flies	Apply with 1 - 2 gals. sulfured molasses per acre.
GRAPES (3)	24	2 - 2 ½	*Drosophila*, European Fruit Lecanium, Grape Leafhopper, Japanese Beetle, Leafhoppers, Mealybugs, Spider Mites, Terrapin Scale	Injury may occur to grape berries when applications are made after bloom.
GUAVA (2), **MANGO** (2), **PASSION FRUIT** (2) (Except California)	12	¾	Fruit Flies	Apply with 1 lb. partially hydrolyzed yeast protein or enzymatic yeast hydrolyzate.
MACADAMIA NUTS (0)	12	3 - 15	Green Stink Bug	
NECTARINES (7)	12	2 ½ - 9	Black Cherry Aphid, Black Peach Aphid, Green Peach Aphid, Japanese Beetle, Rusty Plum Aphid	May be mixed with spray oil for dormant and delayed dormant applications. Follow spray oil manufacturer's directions.

TREES AND VINES (continued)

CROP	REI (HRS)	RATE (PTS./ACRE)	PESTS	COMMENTS
PEACHES (7)	24	5 - 9	Cottony Peach Scale, Lesser Peach Tree Borer, Plum Curculio, Oriental Fruit Moth, San Jose Scale, Terrapin Scale	
PECANS (0)	12	2 ½ - 12 ½	Aphids, Mites, Pecan Bud Moth, Pecan Leaf Casebearer, Pecan Nut Casebearer, Pecan Phylloxera	
WALNUTS (0)	12	4 - 12 ½	Aphids, Mites, Walnut Husk Fly	

FIELD AND ROW CROPS

CROP	REI (HRS)	RATE (PTS./ACRE)	PESTS	COMMENTS
ALFALFA, CLOVER, BIRDSFOOT TREFOIL, CLOVER, LESPEDEZA, LUPINE, VETCH ((0) if 1½ pints and less; (7) 2 pint rate)	12	1 - 2	Alfalfa Weevil Larvae, Aphids, Armyworms, Clover Leaf Weevil, Grasshoppers, Lygus Bugs, Pea Aphid, Potato Leafhoppers, Spider Mites, Spittlebugs, Vetch Bruchid	Use higher rate for armyworm control. For hard to control insects, use up to 2 pts. per acre.
	• Apply to alfalfa in bloom only in the evening or early morning when bees are not working in the fields or are not hanging on the outside of hives.			
ALFALFA, BIRDSFOOT TREFOIL, CLOVER, LESPEDEZA, LUPINE, VETCH (SEED CROPS) (0)	12	1 - 1 ¼	Aphids, Leafhoppers, Lygus Bugs	
	• Apply to plants in bloom only in the evening or early morning when bees are not working in the fields or are not hanging outside the hives.			
BEANS-DRY AND SUCCULENT (Field and Greenhouse) (1)	12	1 ½	Aphids, Cucumber Beetle, Japanese Beetles, Potato Leafhopper, Mexican Bean Beetle, Nitidulid Beetle, Spider Mites, Pea Leaf Weevil	
	• Do not graze or feed forage to livestock.			
BEANS-DRY (West of the Rocky Mountains Only) (1)	12	1 - 1 ½	Lygus Bugs	
	• Do not graze or feed forage to livestock.			
BEETS, GARDEN (Seed Crop) (7)	12	1 ¼	Lygus Bugs	Apply in 5 to 10 gals. of water per acre at seedball stage to hard seed stage. Repeat as needed to maintain control.
BEETS, TABLE (7)	12	2 ½	Aphids, Beet Armyworm, Blister Beetles, Flea Beetles	
CELERY (7)	12	1 - 1½	Aphids, Spider Mites	
COLE CROPS (BRASSICA (COLE) LEAFY VEGETABLE CROP GROUP: BROCCOLI (3), **BROCCOLI RAAB (rapini)** (7), **BRUSSELS SPROUTS** (7), **CABBAGE** (7), **CAULIFLOWER** (7), **CAVALO BROCCOLO** (7), **CHINESE BROCCOLI** (7), **CHINESE CABBAGE (bok choy, napa)** (7), **CHINESE MUSTARD CABBAGE** (7), **COLLARDS** (7), **KALE** (7), **KOHLRABI** (7), **MIZUNA** (7), **MUSTARD GREENS** (7), **MUSTARD SPINACH** (7), **RAPE GREENS** (7)	12	1 ½ - 2 ½	Aphids, Cabbage Looper, Flea Beetle, Imported Cabbageworm	
CORN-GRAIN OR FORAGE (5)	12	1	Aphids, Corn rootworm adults, Sap beetles, Thrips, Young grasshoppers	
	CAUTION: Injury may occur in whorl and silk stages.			
COTTON (0)	12	1 - 4	Aphids, Brown Cotton Leafworm, Cotton Leaf Perforator, Leafhoppers, Spider Mites, Whiteflies	
		1 ¼ - 4	Boll Weevils, Cotton Fleahoppers, Fall Armyworm, Grasshoppers, Garden Webworm, Lygus Bugs	
	• Do not graze or feed forage to livestock.			
CUCUMBERS (field and greenhouse) (1), **SQUASH** (1)	12	1 ¾	Aphids, Cucumber Beetle, Cutworms, Darkling Ground Beetle, Leafhoppers, Pickleworm, Spider Mites, Squash Vine Borer, Thrips	For vine borer, apply weekly to stems and vines at base of plant.
	• Do not apply unless plants are dry.			
EGGPLANT (Field and Greenhouse) (3)	12	¾ - 3 ½	Aphids, Spider Mites	
		2 - 3 ½	Lace Bug	

FIELD AND ROW CROPS (continued)

CROP	REI (HRS)	RATE (PTS./ACRE)	PESTS	COMMENTS
FLAX (45)	12	½	Grasshoppers	
GARLIC (3), **LEEKS** (3), **SHALLOTS** (7)	12	1 - 2	Aphids, Thrips	
GRASSES and RANGELAND (such as BARN GRASS, BERMUDA, CANARY GRASS, FESCUE, ORCHARD GRASS, RED TOP, TIMOTHY and YELLOW FOXTAIL) (1)	12	1 - 1 ¼	Aphids, Grasshoppers, Leafhoppers	Apply in sufficient water for good coverage or use 1¼ pts. plus 1 gal. of diesel fuel oil per acre by means of an airplane or turbine-blower type sprayer.
HOPS (7) (Except California)	12	½ - 1 ¼	Aphids	
HORSERADISH (7), **PARSNIPS** (7), **RADISHES** (7), **SALSIFY** (7)	12	2	Aphids, Diamondback Moth, Flea Beetles, Leafhoppers	
LEAFY VEGETABLES (EXCEPT BRASSICA VEGETABLES) CROP GROUPING: AMARANTH leafy amaranth, Chinese spinach, tampala) (7), **ARRUGULA (roquette)** (7), **CELTUCE** (7), **CHERVIL** (7), **CHRYSANTHEMUM-Edible-leafed, Garland** (7), **CORN SALAD** (7), **DANDELIONS** (7), **DOCK (sorrel)** (7), **FLORENCE FENNEL** (7), **ORACH** (7), **PARSLEY** (21), **PURSLANE-Garden and Winter** (7), **SWISS CHARD** (7) (Except California)	12	1 - 2	Aphids	
LENTILS (3)	12	1	Aphids	
	• Do not graze or feed forage to livestock.			
LETTUCE (Field or Greenhouse) (7 days for head lettuce; 14 days for leaf lettuce), **ENDIVE** (Field or Greenhouse) (7)	12	2	Aphids, Alfalfa loopers, Leafhoppers, Mites	
MUSHROOMS (Greenhouse) (1) (Except California)	12	1 ½	Phorid Flies, Sciarid Flies	Apply in 130 gals. of water per acre, or 1 tablespoon per 3 gals. of water per 1000 sq. ft. bed. Make thorough application as soon as possible after picking. Repeat application as necessary, usually twice per week.
OKRA (1) (Except California)	12	1 ½	Aphids, Japanese Beetles	
ONIONS- BULB AND GREEN (Field or Greenhouse) (3)	12	1 - 2	Thrips	
		2	Onion Maggot	
PEAS (3)	12	1 - 2 ½	Aphids, Pea Weevils	
	• Do not graze or feed forage to livestock.			
PEPPERMINT (7), **SPEARMINT** (7)	12	1	Adult Flea Beetles, Leafhoppers	
PEPPERS (Field or Greenhouse) (3)	12	1 ½	Aphids, Pepper Maggot	
POTATOES (0)	12	1	False Chinch Bug, Leafhoppers, Mealybugs	
		3	Aphids, Blister Beetles	
RICE-DOMESTIC, GRAIN OR WILD (7)	12	1 ½	Rice Leaf Miners, Rice Stink Bug	Broadcast use only over intermittently flooded areas.
	• Do not apply propanil within 15 days of malathion treatment. • Application may not be made around bodies of water where fish or shellfish are grown and/or harvested commercially.			
RUTABAGAS (3)	12	1 - 2	Aphids	
SMALL GRAINS (BARLEY, OATS, RYE, WHEAT) (7)	12	1 - 1 ¼	Armyworms, English Grain Aphid, Grasshoppers, Greenbugs	

FIELD AND ROW CROPS (continued)

CROP	REI (HRS)	RATE (PTS./ACRE)	PESTS	COMMENTS
SORGHUM-GRAIN OR FORAGE (7)	12	1 ½	Greenbugs	
	• Do not graze or feed forage to livestock.			
SPINACH (7)	12	1½	Aphids	
STRAWBERRIES (3)	12	1 ½ - 2	Aphids, Field Crickets, Lygus Bugs, Potato Leafhopper, Spider Mites, Spittlebugs, Strawberry Leafroller, Strawberry Root Weevils, Thrips, Whiteflies	
SWEET CORN (Field or Greenhouse) (5)	12	1	Japanese Beetle	**CAUTION:** Injury may occur in whorl and silk stages.
SWEET POTATOES (3)	12	1 - 1 ¾	Leafhoppers	
		1 ¾	Morning Glory Leafminer	
TOMATOES (Field and Greenhouse) (1)	12	1 ½	Aphids, Spider Mites	Apply a full coverage application to fruit and foliage.
		2	*Drosophila* flies	
WATERCRESS (7)	12	1-2	Aphids	

ORNAMENTALS

Note: Before treating a large number of ornamental plants with GOWAN MALATHION 8 alone or as a tank mixture with any other material, make a test application on a few plants and observe for 7-10 days prior to treating large areas to reduce the possibility of plant injury.

CROP	REI (HRS)	RATE	PESTS	COMMENTS
FLOWERS, SHADE TREES, and SHRUBS	12	1 pt. in 100 gals. of water as a dilute spray	Aphids, Euonymus Scale, European Pine Shoot Moth, Four-lined Leaf Bug, Japanese Beetle Adults, Lace Scale, Mealybugs, Millipedes, Oyster Shell Scale, Potato Leafhopper, Rose Leafhopper, Scurfy Scale, Spider Mites, Springtails, Sowbugs, Tarnished Plant Bug, Thrips, Whiteflies	**CAUTION:** Avoid use on certain ferns including Boston, Maidenhair and Pteris, as well as some species of Crassula and Canaetri Juniper. For Oyster shell, Fletch, Juniper, Oak kermes and Pine needle scales apply when scale crawlers have settled on foliage.
		1 ¼ pts. in 100 gals. of water as a dilute spray	Azalea Scale, Bagworm, Birch Leafminer, Boxwood Leafminer, Fletch Scale, Florida-Red Scale, Juniper Scale, Magnolia Scale, Oak Kermes, Pine Leaf Scale, Tent Caterpillar	
		1 $^{3}/_{5}$ pts. in 100 gals. of water	Black Scale Crawler, Monterey Pine Scale	
		2 ½ pts. in 100 gals. of water	Pine Needle Scale, Wax Scale	

SLASH PINE, PINE SEED ORCHARDS, AND CHRISTMAS TREE PLANTATIONS

CROP	REI (HRS)	RATE	PESTS	COMMENTS
SLASH PINE, PINE SEED ORCHARDS, and CHRISTMAS TREE PLANTATIONS	12	For ground application, mix $^{3}/_{4}$ to $^{4}/_{5}$ gals. of GOWAN MALATHION 8 in 100 gals. of water.	Slash Pine Flower Thrips, European Pine Sawfly	Apply ¾ gals. of the mixture per tree on the smallest flowering trees. Mist blowers or airblast sprays may be used.
		For air application, mix $^{2}/_{5}$ gals. of GOWAN MALATHION 8 in a least 5 gals. of water		Apply a minimum of 5 gals. of mixture per acre. Make two applications, the first when female flowers are in twig bud stage, the second one week prior to maximum flower receptivity to pollen.

MOSQUITO CONTROL

MOSQUITOES, FLIES, AND SMALL FLYING INSECTS: For use by trained personnel as a 2% to 5% Malathion fog, aerosol or space spray. To make a **2%** solution dilute 1 part GOWAN MALATHION 8 in 45 parts water, fuel oil or diesel oil. When using a kerosene-type solvent as a carrier, dilute 1 part GOWAN MALATHION 8 in 45 parts solvent consisting of 4 parts kerosene-type solvent and 1 part aromatic hydrocarbon-type solvent. Apply 0.58 - 2.86 gallons finished spray per acre. For a **5%** solution, dilute 1 part GOWAN MALATHION 8 in 18 parts solvent. Apply 0.24 - 1.18 gallons finished spray per acre.

MOSQUITO LARVAE IN STANDING WATER

(Only for use in intermittently flooded areas, stagnant water, temporary rail ponds, and log ponds- KEEP OUT OF ANY FISH BEARING WATERS): Apply GOWAN MALATHION 8 at the rate of 8 fluid ounces per acre. Mix in sufficient water or oil to obtain even coverage when applied by air or ground equipment. Repeat applications as necessary. Avoid applying oil-based formulations to valuable ornamental plants as injury may occur. Broadcast use only over intermittently flooded areas. Application may not be made around bodies of water where fish or shell fish are grown and/or harvested commercially.

AROUND THE OUTSIDE OF BUILDINGS

(Around buildings which house domestic animals, around homes, yards, commercial and industrial buildings, agricultural buildings, out-door garbage cans, compost/compost piles, garbage dumps, and cull fruit and vegetable dumps): Apply 1 gallon of GOWAN MALATHION 8 undiluted per 1000 sq. ft. on painted surfaces. Apply 2 gallons of GOWAN MALATHION 8 undiluted per 1000 square feet on unpainted surfaces where flies alight or congregate. In most cases, adding molasses or sugar to the spray prolongs the insecticidal activity of Malathion and serves as a fly attractant.

CAUTION: Avoid contamination of milk, milk equipment and water. Avoid contamination of feed and food products, also drinking fountains and feed troughs.

SMALL GRAIN STORAGE FACILITIES

For a residual wall, floor, and machinery spray in grain elevators, in treating truck beds, box cars, and ships' holds before loading grain, apply 5 pts. per 25 gallons of water making thorough application. Before applying spray, clean elevators, box cars, etc. thoroughly. Remove and burn all sweepings and debris. Only **corn, wheat, rye, oats, and barley grain storage facilities may be treated.**

DROSOPHILA FLY AND DRIED FRUIT BEETLE CONTROL ON OR AROUND CULL FRUIT AND VEGETABLE DUMPS

Mix 7½ pints in 100 gallons of water. Apply as a drench, using 8 to 10 gallons of spray per 100 square feet. For best results, dumps should not be over 18 inches deep. Do not feed treated fruit and vegetables.

FLY CONTROL

STRAIGHT MALATHION SPRAYS		MALATHION BAIT SPRAYS			
AMOUNT OF SPRAY	AMOUNT MALATHION 8	AMOUNT OF BAIT SPRAY	AMOUNT MALATHION 8	SUGAR (or)	UNSULFURIZED MOLASSES/ CORN SYRUP
2 ½ gals.	¾ cup	2 ½ gals.	¾ cup	1 cup	1 cup
12 gals.	1 ¼ pts.	12 gals.	1 ¼ pts.	2 1/2 lbs.	1 qt.
100 gals.	1 ¼ gals.	100 gals.	1 ¼ gals.	20 lbs.	2 gals.

APPLICATION THROUGH IRRIGATION SYSTEMS - CHEMIGATION

Apply this product only through sprinkler, including center pivot, lateral move, end tow side (wheel) roll, traveler, big gun, solid set, or hand move, or drip (including surface and subsurface) irrigation systems. Do not apply this product through any other type of irrigation system.

Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from nonuniform distribution of treated water.

If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Mix in clean supply tank the recommended amount of this product for acreage to be covered, and needed quantity of water.

This product should not be tank-mixed with other pesticides, surfactants or fertilizers unless prior use has shown the combination noninjurious under your conditions of use. Follow precautionary statements and directions for all tank-mix products.

On all crops, use sufficient gallonage of water to obtain thorough and uniform coverage, but not cause runoff or excessive leaching. This will vary depending on equipment, pest problem and stage of crop growth. Application of more or less than optimal quantity of water may result in decreased chemical performance, crop injury or illegal pesticide residues.

Meter this product into the irrigation water uniformly during the period of operation. Do not overlap application. Follow recommended label rates, application timing, and other directions and precautions for crop being treated. Continuous mild agitation of pesticide mixture may be needed to assure a uniform application, particularly if the supply tank requires a number of hours to empty.

Do not apply when wind speed favors drift beyond the area intended for treatment.

CHEMIGATION SYSTEMS CONNECTED TO PUBLIC WATER SYSTEMS

Note: *Gowan Company does not encourage connecting chemigation systems to public water supplies. The following information is provided for users who have diligently considered all other application and water supply options before electing to make such a connection.*

Public water systems means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of a least 25 individuals daily at least 60 days out of the year. Chemigation systems connected to public water systems must contain a functional reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from a point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of a least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.

The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shutdown.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of material that are compatible with pesticides and capable of being fitted with a system interlock.

SPRINKLER CHEMIGATION (FOLIAR SPRAY USES)

The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.

The pesticide injection pipeline must also contain functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

DRIP (INCLUDING SURFACE AND SUBSURFACE) CHEMIGATION

The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.

The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pipe and connected to the system interlock to prevent fluid from being withdrawn form the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

STORAGE AND DISPOSAL

DO NOT contaminate water, food or feed by storage or disposal.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

FOR 24-HOUR EMERGENCY ASSISTANCE (SPILL, LEAK OR FIRE), CALL CHEMTREC® (800) 424-9300.

For other product information, contact Gowan Company or see Material Safety Data Sheet.

NOTICE ON CONDITIONS OF SALE

Our recommendation for use of this product are based upon tests believed to be reliable. The use of this product being beyond the control of the manufacturer, no guarantee, expressed or implied, is made as to the effects of such or the results to be obtained if not used in accordance with directions or established safe practice. The buyer must assume all responsibilities, including injury or damage, resulting from its misuse as such, or in combination with other materials.

04-R0699

Gowan®

MATERIAL SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

Formulator: Gowan Company
P.O. Box 5569
Yuma, Arizona 85366-5569
(928) 783-8844

Emergency Phone: (928) 783-3803
For 24-Hour Emergency Assistance (Spill, Leak, Fire, or Exposure), Call CHEMTREC®:
Inside the U.S.: (800) 424-9300
Outside the U.S.: (703) 527-3887
For *MEDICAL* Emergency: (888) 478-0798

Product: **Malathion 8 Flowable**
EPA Signal Word: Caution
EPA Registration No.: 10163-21
Active Ingredient: Malathion (79.5%)
CAS No.: 121-75-5
Chemical Name: O,O-Dimethyl dithiophosphate of diethyl mercaptosuccinate
Chemical Class Organophosphate

2. HAZARDS IDENTIFICATION

Physical Properties
Appearance: Clear, light amber colored liquid
Odor: Mild mercaptan odor

Symptoms of Overexposure
Malathion causes inhibition of cholinesterase activity. Symptoms of intoxication include depressed ChE activity, headache, lacrimation, excessive salivation, anorexia, vomiting, uneasiness, restlessness, anxiety, ataxia, tremors, sweating, coma with absence of reflexes, dyspnea, cough, fluid in the lungs, non-reactive pin-point pupils, blurred vision, diarrhea, nausea, abdominal cramps, involuntary urination, muscular twitching, fasciculation, muscle cramping, weakness, and cyanosis. Severe overexposure may lead to muscular fibrillation, pulmonary edema, convulsions, possible cardiac arrest and death. Exposure to butanol in this formulation may produce drowsiness and irritation of the throat.

Medical Conditions Likely to be Aggravated by Exposure
Pre-existing skin, eye, liver, kidney and nervous disorders. Persons with depressed cholinesterase levels or hemolytic anemia, or who are under treatment with morphine, theophylline, aminophylline or phenothiazine drugs may show pronounced effects from exposure to this product.

Primary Routes of Exposure
Harmful if inhaled, ingested or if eye and skin contact occurs.

Hazardous Decomposition Products
Carbon monoxide, carbon dioxide, sulfur dioxide, phosphorus trioxide, methyl mercaptan, hydrogen sulfide, and dimethyl sulfide.

Unusual Fire, Explosion, and Reactivity Hazards
Containers in fire may burst or explode from excessive heat. Stay well back from fire area. Vapors may travel along floor to ignition source and flash back.

3. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT NAME	OSHA – PEL	ACGIH – TLV	OTHER	NTP/IARC/OSHA CARCINOGEN
Malathion (79.5%)	15.0 mg/m^3	10.0 mg/m^3	Not established	No
1-Butanol (3.1%) CAS# 71-36-3	300 mg/m^3	152 mg/m^3	Not established	No

Only the identities of the active ingredient(s) and any *hazardous* inert ingredients are listed. Specific information on all of this product's ingredients can be obtained by the treating medical professional or spill emergency responder for the management of exposures, spills, or safety assessments.

4. FIRST AID MEASURES

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

IF ON SKIN CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes and then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

FOR MEDICAL EMERGENCIES INVOLVING THIS PRODUCT , CALL TOLL FREE: 1-888-478-0798

5. FIRE FIGHTING MEASURES

Flashpoint (test method): > 200°F (TCC)

Appropriate Extinguishing Media

Dry chemical, foam, CO_2, water spray or fog. Avoid use of heavy water stream.

Fire Fighting Guidance

Smoke and fumes from fire may contain hazardous components. Use self-contained breathing apparatus and full-protective clothing. Fight fire from upwind side. Avoid run-off. Keep non-essential personnel away from immediate fire area, and out of any fall-out or run-off areas. If water is used to fight fire or cool containers, contain run-off by diking to prevent contamination of water supplies.

Unusual Fire, Explosion, and Reactivity Hazards

Containers in fire may burst or explode from excessive heat. Stay well back from fire area. Vapors may travel along floor to ignition source and flash back.

6. ACCIDENTAL RELEASE MEASURES

In Case of Spills or Leaks

Isolate and post spill area. Wear prescribed protective clothing and equipment. Keep out animals and unprotected persons. Keep material out of streams and sewers. Dike to confine spill, and absorb with an absorbent such as clay, sand or cat litter. Vacuum, shovel or pump wastes into an approved drum. To decontaminate spill area, tools and equipment, wash with a suitable solution (i.e., organic solvent, detergent, bleach or caustic), and add the solution to the drums of wastes already collected. Label drums for contents. Dispose of drummed wastes, including decontamination solution, according to the method outlined in Section 13 – Disposal Considerations.

7. HANDLING AND STORAGE

Precautions in Storing

DO NOT contaminate water, food or feed by storage or disposal. Store in a cool, dry, well-ventilated place. Avoid excess heat. Store in original containers only. Keep out of reach of children and animals. Do not contaminate other pesticides or fertilizers by storage or disposal.

Storage

Store in a cool, dry, well-ventilated place. Avoid excess heat. Store in original containers only. Keep out of reach of children and animals.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls

Thoroughly ventilate all transport vehicles prior to unloading. Use local exhaust at all process locations to control employee exposure.

Eye/Face	Not required; use normal safety precautions.
Skin Protection	Applicators and other handlers must wear long-sleeved shirt and long pants, chemical-resistant gloves such as barrier laminate, butyl rubber ≥ 14mils, nitrile ≥ 14mils, or Viton ≥ 14mils, and shoes plus socks.
Respiratory Protection	Not required; use normal safety precautions.
Additional Protection Information	Inspect gloves regularly for leaks. Emergency eyewash fountain should be located nearby. Follow manufacturer's instructions for cleaning/maintaining personal protective equipment (PPE). If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.
Applicators/Handlers	Applicators and other handlers must wear long-sleeved shirt and long pants, chemical-resistant gloves such as barrier laminate, butyl rubber ≥ 14mils, nitrile ≥ 14mils, or Viton ≥ 14mils, and shoes plus socks.
User Safety Recommendations	Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, light amber colored liquid
Odor:	Mild mercaptan odor
Melting Point:	Not applicable
Boiling Point:	> 300°F
Specific Gravity/ Density:	1.21 / 10.06 lbs./gal
Solubility in H_20 Malathion	Emulsifies
Vapor Pressure Malathion	31 (Reid-ASTM D323)

10. STABILITY AND REACTIVITY

Stability:	Stable
Hazardous Polymerization:	Will not occur
Decomposition Products:	Carbon monoxide, carbon dioxide, sulfur dioxide, phosphorus trioxide, methyl mercaptan, hydrogen sulfide, and dimethyl sulfide.
Hazardous Mixtures:	None known
Conditions To Avoid:	Excessive heat and fire, alkalis and oxidizers. Thermal decomposition and burning may produce highly toxic by-products.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity/Irritation Studies

Ingestion:	Acute oral LD_{50} =5400(M) / 5700(F) mg/kg (rat)
Dermal:	Acute dermal LD_{50} >2000 mg/kg (rat)
Inhalation:	Acute inhalation LC_{50} >5.2 mg/L (rat)
Eye Irritation:	Slight conjunctival irritation: clear by 7 days (rabbit)
Skin Irritation:	Slight dermal irritant (rabbit)
Skin Sensitizer:	Not a sensitizer (guinea pig)

Mutagenic Potential
None

Reproductive Hazard Potential
Acceptable

Chronic/Subchronic Toxicity Studies
Acceptable

Carcinogenic Potential
Acceptable

12. ECOLOGICAL INFORMATION

Summary of Effects

Malathion

This pesticide is toxic to fish, aquatic invertebrates and aquatic life stages of amphibians. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash waters. This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are actively visiting the treatment area.

13. DISPOSAL CONSIDERATION

Pesticide Disposal

Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to the label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

14. TRANSPORT INFORMATION

DOT Classification

Not regulated.*
*For 30 gallon and 55 gallon containers DOT classification will be:
UN 3082, RQ, Environmentally Hazardous Substance, Liquid, N.O.S., (Malathion), 9, PG III

International Maritime Organization

UN 3082, Environmentally Hazardous Substance, Liquid, N.O.S., (Malathion), 9, PG III, Marine Pollutant, NAERG# 171

International Civil Aviation Organization

UN 3082, Environmentally Hazardous Substance, Liquid, N.O.S., (Malathion), 9, PG III, Marine Pollutant, NAERG# 171

15. REGULATORY INFORMATION

SARA Title III Classification

Section 302/304:	Not applicable
Section 311/312:	Immediate (acute) health hazard Fire hazard
Section 313 chemical(s):	Malathion, 1-Butanol

Proposition 65

Not applicable

CERCLA Reportable Quantity (RQ)

12.5 gals. of product (100 lbs. of Malathion)

RCRA Classification

Under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste.

TSCA Status

Exempt from TSCA

16. OTHER INFORMATION

NFPA Hazard Ratings

Health:	2
Flammability:	2
Reactivity:	0

0	Least
1	Slight
2	Moderate
3	High
4	Severe

Notice: The information and recommendations contained herein are provided in good faith and are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information herein.

Prepared By:

Gowan Company
(928) 783-8844

AHETF Study No. AHE55

Risk of Toxicity from Pesticide Product Handled (Must be attached to the Informed Consent Form)

The product you will handle is identified as follows:

Name: Malathion 8-E Insecticide (EPA Registration No. 34704-452)

Active Ingredient (AI): Malathion (insecticide, CAS No. 121-75-5)

Formulation and Packaging: 8 lbs AI/gallon Emulsifiable Concentrate in 1 gallon [redacted]

You may handle up to: 12.5 gallons of product

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This malathion product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include moderate eye irritation, slight skin irritation, possible allergic skin reaction, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: None found
MSDS date: 6/8/06 (Loveland MSDS #000452-06-LPI)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Version date: 1-24-08 DRAFT

MALATHION 8-E INSECTICIDE

Organophosphate Insecticide

AGRICULTURAL INSECTICIDE
EMULSIFIABLE LIQUID

ACTIVE INGREDIENT:	% BY WEIGHT
Malathion (O,O-dimethyl phosphorodithioate of diethyl mercaptosuccinate)	79.5%
INERT INGREDIENTS:	20.5%
TOTAL	100.0%

Contains 8 lbs. Malathion per gallon
AGRICULTURAL INSECTICIDE EMULSIFIABLE LIQUID

KEEP OUT OF REACH OF CHILDREN
CAUTION

See Below For Additional Precautionary Statements.

EPA REG. NO. 34704-452

EPA EST. NO. 34704-MS-1

NET CONTENTS 1 GAL. (3.78 L)

IHT 06Y06

FIRST AID

If swallowed:	• Call a poison control center or doctor immediately for treatment advice. • Have a person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If inhaled:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
If on skin or clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If in eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
FOR A MEDICAL EMERGENCY INVOLVING THIS PRODUCT CALL:
1-800-301-7976

PRECAUTIONARY STATEMENTS
HAZARDOUS TO HUMANS & DOMESTIC ANIMALS
CAUTION

Harmful if swallowed or absorbed through skin. Causes eye irritation. Avoid contact with eyes, skin, or clothing. May cause sensitization following repeated contact with skin. If sensitization reactions result, contact a physician.

Personal Protective Equipment:
Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category (F) on the EPA chemical resistance category selection chart.
Applicators and other handlers must wear: long-sleeved shirt and long pants, chemical-resistant gloves, such as: barrier laminate, butyl rubber, nitrile rubber, or viton; and shoes plus socks.
Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.
Engineering controls statements:
When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets with requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should:
Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish, aquatic invertebrates, and aquatic life stages of amphibians. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.
This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.
Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.
Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.
PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: coveralls, chemical-resistant gloves, such as: butyl rubber, nitrile rubber or viton; and shoes plus socks.

MALATHION 8-E
EPA REG. NO. 34704-452

NON-AGRICULTURAL USE REQUIREMENTS
The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.
Do not allow contact with treated surface until spray has dried.

STORAGE AND DISPOSAL
PROHIBITIONS: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container. Do not store under conditions which might adversely affect the container or its ability to function properly.
STORAGE: Store in safe manner. Store in original container only. Store in cool, dry place. Keep container tightly closed when not in use. Reduce stacking height where local conditions can affect package strength. Personnel should use clothing and equipment consistent with good pesticide handling.
PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.
CONTAINER DISPOSAL: Metal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. **Plastic:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

USE DIRECTIONS
Pour specified amount of this product into nearly filled spray tank. Add balance of water to fill tank. Keep agitator running during filling and spraying operations. If mixture does not mix readily, but tends to separate as an oily layer, do not use as injury to plants may result. Do not combine with wettable powders unless previous use of the mixture has proved physically compatible and safe to plants. Always thoroughly emulsify this product with at least half of total water before adding wettable powder.
Maximum permissible rate per acre, expressed as MALATHION 8-E is given in parenthesis, ( ), after each crop claim.
Rinse spray equipment.
In order that pesticidal residues on food and forage crops will not exceed tolerances established by the Federal Food and Drug Administration, use only at recommended rates and intervals, and do not apply closer to harvest than specified. **The grower is responsible** for residues on his crops as well as for damages caused by drifting from his property to that of others.
Consult State Agricultural Experiment Stations or the State Agricultural Extension Services for additional information as to the timing, number and rate of applications needed will vary with local conditions.

CHEMIGATION:
Refer to supplemental labeling entitled "APPLICATION THROUGH IRRIGATION SYSTEMS CHEMIGATION" for use directions for chemigation. Do not apply this product through any irrigation systems unless the supplemental labeling on chemigation is followed.

TREE FRUIT CROPS
Unless otherwise specified, rates are given in terms of pints MALATHION 8-E per 100 gallons of water for thorough coverage sprays. Unless otherwise specified, apply at the first sign of infestation and repeat at 7-10 day intervals as needed to maintain control, but observe use limitations given for specific crops.

GRAPEFRUIT, ORANGES, TANGERINES, TANGELOS—California red scale, yellow scale, purple scale, black scale (single and off-brooded) soft scale, thrips, citricola scale, orangeworm, aphids: ¾-1 pt. Do not apply within 7 days of harvest. Make no application when trees are in full bloom. California Do not apply unless parasite activity in the scale is at a low level or absent. (25 pts.)

VEGETABLE AND FIELD CROPS
(Also see Use Directions)
Unless otherwise indicated, dosages are given in pints of MALATHION 8-E per acre in sufficient water to provide thorough coverage. Begin applications when insects first appear and repeat at 7-10 day intervals as needed to maintain control, but observe use limitation given for specific crops.

ALFALFA, CLOVER—Alfalfa weevil larvae, aphids, armyworms, clover leaf weevil, grasshoppers, lygus bugs, pea aphid, leafhoppers (including potato leafhoppers), spider mites, spittlebugs, vetch bruchid: 1-1½ pt. Use higher rate for armyworm control. May be applied on day of harvest. Apply to alfalfa in bloom only in the evening or early morning when bees are not working in the field or are not hanging on the outside of the hives. For rate above 1½ pt., DO NOT apply within 7 days of harvest. (2 pts.)

BEANS (Dry & Succulent)—Aphids, asparagus beetle, cucumber beetle, Japanese beetle, leafhoppers (including potato leafhopper), Mexican bean beetle, nitidulid beetle, spider mites, pea leaf weevil: 1-1½ pt. Lygus bugs on dry beans in California: 1-1½ pt. Thrips, do not apply within 1 day of harvest (1¾ pt.). Do not graze or feed treated crop foliage.

COTTON—Aphids, brown cotton leafworm, cotton leaf perforator, leafhoppers, spider mites, whitefly: 1/3-1½ pt. Cotton aphis, thrips: 1 pt. Cotton fleahoppers: ¾-1 pt. Fall armyworms, boll weevils, grasshoppers, garden webworms and lygus bugs: 1-2 pts. (4 pts.). Do not graze or feed treated crop foliage.

CUCUMBERS, SQUASH—Aphids, cucumber beetle, cutworms, darkling ground beetles, leafhoppers, pickleworm, spider mites, squash vine borer, thrips: 1 ¾ pts. Do not apply on cucumber and squash unless plants are dry or within 1 day of harvest. (1¾ pts.)

GRAPES—European fruit lecanium, grape leafhopper, mealybug, spider mites: 1-2½ pts. Do not apply within 3 days of harvest. Injury may occur to Ribier, Cardinal and Almeria grapes varieties when applications are made after the clusters appear. (2¾ pts.)
Application on vegetables, row and field crops can be made by aircraft or ground power equipment. The amount of water needed to treat an acre varies, therefore the following rates are given to cover a broad range of conditions.
AIRCRAFT: 5-10 gals. water/acre GROUND: 20-100 gals. water/acre.

GRASS Grass hay pasture and Rangeland (barn grass, canary grass, fescue, orchard grass, red top, timothy and yellow foxtail) Aphids, leafhoppers: 1-1¼ pts. Repeat application as necessary. Apply up to and including one day of harvest on grasses. (Grasses 1¼ pts.)

LETTUCE, ENDIVE—Aphids, alfalfa looper, cabbage looper, leafhoppers, mites: 1-2 pts. Do not apply within 14 days of harvest on leaf lettuce; 7 days on endive and head lettuce. (2 pts.)

PEPPERS— Aphids, pepper maggot: 1½ pts. Do not apply within 3 days of harvest. (1½ pts.)

POTATOES—Aphids, blister beetles, false chinch bugs, leafhoppers, mealybugs: 1 to 3 pts. for control of chinch bug, leafhoppers and mealybugs; 2½ pts. for control of aphids and blister beetle (3 pts.)

SMALL GRAINS (Barley, oats, rye, wheat)—Armyworms, English grain aphids, grasshoppers, greenbugs: 1-1¼ pts. Do not apply within 7 day of harvest. (1¼ pts.)

STRAWBERRIES—Aphids, field crickets, lygus bugs, potato leafhoppers, spider mites, spittlebugs, strawberry leafroller, thrips, whitefly: 1½-2 pts. Do not apply within 3 days of harvest. (2 pts.)

TOMATOES—Aphids, spider mites, 1½ pts. Drosophila flies: 2 pts. in full coverage application to fruit and foliage. Do not apply within 1 day of harvest. (2 pts.)

PASTURE AND RANGELAND—Aphids, grasshoppers, leafhoppers: 1¼ pts. per acre in sufficient water for good coverage. Or use 1¼ pts. in 1 gallon of diesel fuel oil per acre by means of an airplane or a turbine-blower type sprayer. May be applied on day of harvest or grazing. (1¼ pts.)

ORNAMENTALS
Dosages given are for use in 100 gallons of dilute spray. Aphids, European pine shoot moth, four-line leaf bug, Japanese beetle adult, lace bug, mealybug, millipedes, potato leafhopper, rose leafhopper, sawflies, scurfy scale, spider mites, springtails, sowbugs, tarnished plant bug, thrips, whitefly, euonymus scale, oyster shell scale: 1 pt. Azalea scale, bagworms, birch leafminer, boxwood leafminer, Fletcher scale, Florida-red scale, juniper scale, magnolia scale, oak kermes, pine leaf scale, tent caterpillar ..... 1¼ pts.
Black scale crawlers, Monterey pine scale ..... 1 3/5 pts.
Pine needle scale, wax scale ..... 2½ pts.
For oyster shell, Fletcher, juniper, oak kermes and pine needle scales, apply when scale crawlers have settled on forage.
CAUTION: Avoid use on certain ferns including Boston, Maidenhair and Pteris, as well as some species of Crassula and Canaetri Juniper.

MOSQUITO CONTROL
Adult Mosquito and Fly Control: Apply 7.2 to 9.6 fluid ounces per acre by air or ground equipment for control of adult flies and mosquitoes. Mix in sufficient water for good coverage with equipment used. Repeat as necessary. Can be applied to alfalfa, clover, pasture and range grass, grass hay, grain crops (including barley, oats, rye, and wheat), beans, rice, tomatoes and non-agricultural lands. Do not apply within 7 days of harvest on grain crops and rice; 5 days of harvest on corn; 1 day of harvest on beans and tomatoes. No time limitation on alfalfa, clover, pasture and range grass, grass and grass hay. Do not apply to alfalfa and clover in bloom. Do not use on seed alfalfa. Treat shrubbery and vegetation where mosquitoes may result. Shrubbery and vegetation around stagnant pools, marshy areas, ponds and shorelines may be treated, but do not use the broadcast application method.

MALATHION 8-E may be applied as a 2% to 5% spray or fog by trained personnel of Public Health Organizations, Mosquito Abatement Districts, Public Mosquito control Programs and Professional Pest Control Operators. Apply spray or fog, using suitable equipment, to non-agricultural areas such as lawns, areas outside of homes, commercial and industrial buildings. Apply in early mornings or late evenings for better effectiveness. Application time for control of adult mosquitoes should coincide with time of most activity of the mosquito. Avoid application when winds exceed 5 miles per hour as effectiveness will be reduced. Do not apply oil-based spray mixtures to valuable plants as injury may occur. Avoid spray contact with automobiles. Spray droplets of malathion may permanently damage automobile paint. In case of accidental exposure, wash car immediately. To make a 2% solution, dilute 1 part MALATHION 8-E to 45 parts water, fuel oil or diesel oil. When using kerosene-type solvent as carrier, dilute 1 part MALATHION 8-E in 45 parts of mixture consisting of 4 parts kerosene-type solvent and 1 part aromatic

MALATHION 8-E
EPA REG. NO. 34704-452

hydrocarbon-type solvent. Apply 0.58 - 2.86 gallons finished spray per acre. For a 5% solution, dilute 1 part MALATHION 8-E in 18 parts of mixture using similar solvents. Apply 0.24 - 1.18 gallons finished spray per acre.

Mosquito Larva in Standing Water—Apply MALATHION 8-E at the rate of 8 fluid ounces (approximately ½ lb. actual malathion) per acre. Mix in sufficient water or oil to obtain even coverage when applied by air or ground equipment. Repeat applications as necessary. Avoid applying oil-based spray mixtures to valuable plants as injury may occur. Broadcast use only over intermittently flooded areas. Application may not be made around bodies of water where fish or shellfish are grown and/or harvested commercially.

FLY CONTROL—For use around outside of buildings which house domestic animals around outside of homes, around yards and outside of meat processing plants. Apply spray at rate of 1 gal. per 1,000 sq. ft. on painted surfaces and 2 gals. per 1,000 sq. ft. on unpainted surfaces where flies alight or congregate. In most cases, adding molasses or sugar to the spray prolongs the insecticidal activity of malathion and serves as a fly attractant.

STRAIGHT MALATHION SPRAYS			MALATHION BAIT SPRAYS		
Amount of Spray	Amount MALATHION 8EC	Amount of Bait Spray	Amount MALATHION 8EC	Sugar (or)	Unsulfurized Molasses or Corn Syrup
2½ gals.	¾ cup	2½ gals.	¾ cup	1 cup	1 cup
12 gals.	1¼ pts.	2 gals.	1¼ pts.	2½ lbs.	1 qt.
100 gals.	1¼ gals.	100 gals.	1¼ gals.	20 lbs.	2 gals.

DROSOPHILA FLIES AND DRIED FRUIT BEETLES—On or around cull fruit and vegetable dumps, mix 7½ pts. in 100 gals. of water and apply as a drench, using 8-10 gals. of spray per 100 sq. ft. (for best results, dumps should not be over 18" deep). Do not feed treated fruit and vegetables.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

BEFORE BUYING OR USING THIS PRODUCT, read the entire Directions for Use and the following Conditions of Sale and Limitation of Warranty and Liability. By buying or using this product, the buyer or user accepts the following Conditions of Sale and Limitation of Warranty and Liability, which no employee or agent of LOVELAND PRODUCTS, INC. or the seller is authorized to vary in any way.

Follow the Directions for Use of this product carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop or other plant injury, ineffectiveness, or other unintended consequences may result from such risks as weather or crop conditions, mixture with other chemicals not specifically identified in this product's label, or use of this product contrary to the label instructions, all of which are beyond the control of LOVELAND PRODUCTS, INC. and the seller. The buyer or user of this product assumes all such inherent risks.

Subject to the foregoing inherent risks, LOVELAND PRODUCTS, INC. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use when the product is used in strict accordance with such Directions for Use under normal conditions of use. EXCEPT AS WARRANTED IN THIS LABEL, THIS PRODUCT IS SOLD AS IS TO THE EXTENT ALLOWED BY APPLICABLE LAW. LOVELAND PRODUCTS, INC. MAKES NO OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ELIGIBILITY OF THIS PRODUCT FOR ANY PARTICULAR TRADE USAGE.

IN THE UNLIKELY EVENT THAT BUYER OR USER BELIEVES THAT LOVELAND PRODUCTS, INC. HAS BREACHED A WARRANTY CONTAINED IN THIS LABEL, BUYER OR USER MUST SEND, TO THE EXTENT REQUIRED BY APPLICABLE LAW, WRITTEN NOTICE OF SUCH CLAIM TO THE FOLLOWING ADDRESS: LOVELAND PRODUCTS, INC., ATTENTION: LAW DEPARTMENT, 7251 WEST 4TH STREET, GREELEY, CO 80634.

TO THE EXTENT ALLOWED BY APPLICABLE LAW, THE BUYER'S OR USER'S EXCLUSIVE REMEDY FOR ANY INJURY, LOSS, OR DAMAGE RESULTING FROM THE HANDLING OR USE OF THIS PRODUCT, INCLUDING BUT NOT LIMITED TO CLAIMS OF BREACH OF WARRANTY OR CONTRACT, NEGLIGENCE, STRICT LIABILITY, OR OTHER TORTS, SHALL BE LIMITED TO ONE OF THE FOLLOWING, AT THE ELECTION OF LOVELAND PRODUCTS, INC. OR THE SELLER: DIRECT DAMAGES NOT EXCEEDING THE PURCHASE PRICE OF THE PRODUCT OR REPLACEMENT OF THE PRODUCT. TO THE EXTENT ALLOWED BY APPLICABLE LAW, LOVELAND PRODUCTS, INC. AND THE SELLER SHALL NOT BE LIABLE TO THE BUYER OR USER OF THIS PRODUCT FOR ANY CONSEQUENTIAL, SPECIAL, OR INDIRECT DAMAGES, OR DAMAGES IN THE NATURE OF A PENALTY.

FORMULATED FOR

Loveland PRODUCTS INC.

P.O. BOX 1286, GREELEY, COLORADO 80632-1286

MATERIAL SAFETY DATA SHEET

MALATHION 8-E INSECTICIDE

FOR CHEMICAL EMERGENCY, SPILL, LEAK, FIRE, EXPOSURE OR ACCIDENT, CALL CHEMTREC - DAY OR NIGHT 1-800-424-9300

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

FORMULATED FOR:

LOVELAND PRODUCTS, INC.
P.O. Box 1286 • Greeley, CO 80632-1286

24-Hour Emergency Phone: 1-800-424-9300
Medical Emergencies: 1-800-301-7976
U.S. Coast Guard National Response Center: 1-800-424-8802

PRODUCT NAME: MALATHION 8-E INSECTICIDE
CHEMICAL NAME: Malathion; (O-O-Dimethyl phosphorodithioate of diethyl mercaptosuccinate)
CHEMICAL FAMILY: Organophosphate Insecticide
EPA REG. NO.: 34704-452
MSDS Number: 000452-06-LPI **MSDS Revisions:** New **Date of Issue:** 06/08/06 **Supersedes:** New

2. HAZARDS IDENTIFICATION SUMMARY

KEEP OUT OF REACH OF CHILDREN – CAUTION – Harmful if swallowed or absorbed through skin. Causes eye irritation. Avoid contact with eyes, skin, or clothing. May cause sensitization following repeated contact with skin. If sensitization reactions result, contact a physician.

This product is straw to amber colored liquid with a mild petroleum odor. Primary routes of entry are Inhalation, eye contact and skin contact.

Warning Statements:

NOTE TO PHYSICIAN: This product is an organophosphate (cholinesterase-inhibiting) insecticide. Atropine is antidotal and should be given in multiple doses as necessary until the patient is atropinized. In severe cases 2-PAM may be given provided therapy begins within 24 hours of exposure. Monitor serum and RBC cholinesterase. Administer intravenous fluids cautiously, if needed, to correct dehydration. Symptoms of cholinesterase inhibition include salivation, gastrointestinal hypermotility, abdominal cramping, nausea, diarrhea, sweating, miosis, tearing, blurred vision, headache, dizziness, ataxia, bradycardia, dyspnea, cyanosis, and muscle twitching or tremors. In extreme cases, tetany, mental confusion, incontinence, weakness, collapse, paralysis, convulsive seizures, and even death, can occur.

3. COMPOSITION, INFORMATION ON INGREDIENTS

Chemical Ingredients:	Percentage by Weight:	CAS No.	TLV (Units)
Malathion	79.50	121-75-5	15 mg/m^3 (Skin)
Inert Ingredients, including	20.50		
Aromatic hydrocarbons, contains		64742-94-5	not listed
Naphthalene		91-20-3	52 mg/m^3 (Skin)

4. FIRST AID MEASURES

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If in eyes: Hold eye open and rinse slowly and gently with water 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

FOR A MEDICAL EMERGENCY INVOLVING THIS PRODUCT CALL: 1-800-301-7976. Have the product label or container with you when calling a poison control center or doctor, or going for treatment.

5. FIRE FIGHTING MEASURES

FLASH POINT (°F/Test Method): 175°F/79.4°C (TCC)
FLAMMABLE LIMITS (LFL & UFL): None established
EXTINGUISHING MEDIA: Dry chemical, carbon dioxide, foam, water spray or fog.
HAZARDOUS COMBUSTION PRODUCTS: Thermal decomposition products include oxides of sulfur and phosphorus-containing compounds.
SPECIAL FIRE FIGHTING PROCEDURES: Wear self-contained breathing apparatus with full protective clothing. Fight fire from upwind and keep all non-essential personnel out of area.
UNUSUAL FIRE AND EXPLOSION HAZARDS: None known.

6. ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED:

For small spills, absorb with an absorbent material such as pet litter. Sweep up and transfer to containers for possible land application according to label use or for proper disposal. Check local, state and federal regulations for proper disposal. Flush the area with water to remove any residue.

CAUTION: Keep spills and cleaning runoff out of municipal sewers and open bodies of water.

MATERIAL SAFETY DATA SHEET — MALATHION 8-E INSECTICIDE

7. HANDLING AND STORAGE

HANDLING: Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. This product is combustible. Do not use near heat or open flame.

STORAGE: Store in a safe manner. Store in original container only. Store in a cool, dry place. Keep container tightly closed when not in use. Do not store near heat or open flame. Do not contaminate water, food, or feed by storage or disposal.

Personal Protective Equipment: Applicators and other handlers must wear: long sleeved shirt and long pants, chemical-resistant gloves, such as barrier laminate, butyl rubber, nitrile rubber or Viton®, shoes plus socks, and protective eyewear. Follow manufacturer's instructions for cleaning and maintaining PPE. If no instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS: When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets with requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

RESPIRATORY PROTECTION: Not normally required, if vapors or mists exceed acceptable levels, wear a NIOSH approved pesticide respirator.

EYE PROTECTION: Chemical goggles or shielded safety glasses.

SKIN PROTECTION: Wear protective clothing: long-sleeved shirts and pants, shoes with socks. Wear chemical-resistant gloves.

	OSHA PEL 8 hr TWA	ACGIH TLV-TWA
Malathion	15 mg/m^3 (Skin)	1 mg/m^3 (Inhalable fraction of aerosol)
Naphthalene	50 mg/m^3	52 mg/m^3 (Skin)

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AND ODOR: Straw to amber liquid with mild petroleum odor.
SPECIFIC GRAVITY (Water = 1): 1.177 g/ml
BULK DENSITY: 9.82 lbs/gal.
SOLUBILITY: Emulsifies
VAPOR PRESSURE: 31.0 torr @ 25°C
BOILING POINT: Not established
pH: 3.6 (5% solution)
PERCENT VOLATILE (by volume): Not established
EVAPORATION RATE: Not established

Note: These physical data are typical values based on material tested but may vary from sample to sample. Typical values should not be construed as a guaranteed analysis of any specific lot or as specification items.

10. STABILITY AND REACTIVITY

STABILITY: Stable
CONDITIONS TO AVOID: Excessive heat, open flame or extreme cold.
INCOMPATIBILITY: Strong bases, acids, and oxidizers.
HAZARDOUS DECOMPOSITION PRODUCTS: Thermal decomposition – oxides of sulfur and phosphorus-containing compounds.
HAZARDOUS POLYMERIZATION: Will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Oral LD_{50} (rat): 370 mg/kg (Technical)
Acute Dermal LD_{50} (rabbit): 4100 mg/kg
Eye Irritation (rabbit): Moderate irritant
Skin Irritation (rabbit): Slight irritant
Inhalation LC_{50} (rat): >5.12 mg/L (4 hr)
Skin Sensitization (Guinea Pig): Possible sensitizer.
Carcinogenic Potential: None listed in OSHA, NTP, IARC or ACGIH

12. ECOLOGICAL INFORMATION

This pesticide is toxic to fish, aquatic invertebrates, and aquatic life stages of amphibians. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash waters. This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

13. DISPOSAL CONSIDERATIONS

Do not reuse containers. **Metal:** Triple rinse (or equivalent), then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by local, state and federal regulations. **Plastic:** Triple rinse (or equivalent), then offer for recycling at an ACRC site (go to http://www.acrecycle.org/ for locations) or by reconditioning, or puncture and dispose of in a sanitary landfill, or, incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal laws. Do not contaminate water, food, or feed by storage or disposal.

MATERIAL SAFETY DATA SHEET

MALATHION 8-E INSECTICIDE

14. TRANSPORT INFORMATION

DOT Shipping Description: LESS THAN 12.8 GALLONS NOT REGULATED BY USDOT.
DOT Shipping Description: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S., 9, UN3082, III (MALATHION) RQ ERG GUIDE 171
U.S. Surface Freight Classification: INSECTICIDES, INSECT REPELLENTS, NOI, OTHER THAN POISON (NMFC 102120, CLASS: 60)
Consult appropriate ICAO/IATA and IMDG regulations for shipment requirements in the Air and Maritime shipping modes.

15. REGULATORY INFORMATION

NFPA & HMIS Hazard Ratings:

NFPA				HMIS	
2	Health	0	Least	2	Health
2	Flammability	1	Slight	2	Flammability
0	Instability	2	Moderate	0	Reactivity
		3	High	H	PPE
		4	Severe		

SARA Hazard Notification/Reporting
SARA Title III Hazard Category:

Immediate	Y	Fire	N	Sudden Release of Pressure	N
Delayed	Y	Reactive	N		

Reportable Quantity (RQ) under U.S. CERCLA: Malathion (CAS: 121-75-5): 100 pounds; Naphthalene (CAS: 91-20-3) 100 pounds
SARA, Title III, Section 313: Malathion (CAS: 121-75-5) 79.50%; Naphthalene (CAS: 91-20-3) 0.82%
RCRA Waste Code: Not listed
CA Proposition 65: WARNING: This product contains chemicals known to the State of California to cause cancer or birth defects or other reproductive harm.

16. OTHER INFORMATION

MSDS STATUS: New
PREPARED BY: Registrations and Regulatory Affairs
REVIEWED BY: Environmental/ Regulatory Services

®Viton is a registered trademark of DUPONT DOW ELASTOMERS L.L.C.

AHETF Study No. AHE55

Risk of Toxicity from Pesticide Product Handled (Must be attached to the Informed Consent Form)

The product you will handle is identified as follows:

Name: Fyfanon® 8 lb. Emulsion (EPA Registration No. 5905-250-ZA)

Active Ingredient (AI): Malathion (insecticide, CAS No. 00121-75-5)

Formulation and Packaging: 8 lbs AI/gallon Emulsifiable Concentrate in 1 or 2.5 gallon plastic jugs

You may handle up to: 12.5 gallons of product

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This malathion product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include moderate eye irritation, slight skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 2005
MSDS date: 1-5-05

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Version date: 1-24-08 DRAFT

FYFANON, THE PREMIUM GRADE MALATHION

Helena Chemical Company
PH: 901-761-0050
CHEMTREC: 800-424-9300
Effective Date: 05-OCT-2005
Product: FYFANON, THE PREMIUM GRADE MALATHION

I. IDENTIFICATION

Chemical Name: MALATHION
Chemical Family: ORGANOPHOSPHATE PESTICIDES
Formula: C10-H19-O6-PS2 (ACTIVE INGREDIENT)
Synonyms: MALATHION
CAS Number: SEE INGREDIENT STATEMENT, SECTION III.
EPA Number: 5905-196

II. PHYSICAL DATA

Boiling Point: 290 TO 300 DEG F.
Freezing Point: <0 DEGREES C.
Spec Gravity: 1.065 GMS/CC
Vapor Pressure: 9 MM HG
Vapor Density: 3.6
Solubility: 0.01%
Volatiles: 35-40%
Evaporation: NOT DETERMINED
Melting Point: NOT APPLICABLE
Appearance: CLEAR/YELLOW LIQUID, CHARACTERISTIC ODOR

III. INGREDIENTS

Material	CAS Number	Percent	TLV	Hazard
MALATHION	00121-75-5	56.44	10 MG/M3	MODERATELY TOXIC
PETROLEUM DISTILLATES		37.60	100 PPM (SKIN)	SKIN & EYE IRRITANT
INERT INGREDIENTS		5.96	NOT APPLICABLE	NONHAZARDOUS

IV. FIRE AND EXPLOSION HAZARD

Flash Point: >140 DEGREES F.
Autoignition Temp: 700 DEG F (ESTIMATE)
Flammable Limit: LOWER -1, UPPER -7
Extinguishing Media: DRY CHEMICAL OR CARBON DIOXIDE FOR SMALL FIRES.
WATER SPRAY OR FOAM FOR LARGE FIRES.
Special Fire Fight Proc: WEAR SELF-CONTAINED BREATHING APPARATUS AND FULL FIRE FIGHTING CLOTHING. USE AS LITTLE WATER AS POSSIBLE. DIKE AREA TO PREVENT PESTICIDE RUNOFF. USE SPRAY OR FOG. CONDUCT FIRE FIGHTING UPWIND.
Fire and Expl Hazard: ALERT MEDICAL PERSONNEL TO BE READY TO TREAT FOR PESTICIDE POISONING, SHOULD TREATMENT BE NECESSARY.

V. HEALTH HAZARD

Carcinogen Information: NONE CURRENTLY LISTED.
ACUTE EFFECTS OF OVER EXPOSURE
Swallowing: SLIGHTLY TOXIC; THE ACUTE ORAL LD50 (RABBIT) IS 3.4 G/KG, EPA CATEGORY III.
Skin Absorption: SLIGHTLY TOXIC; THE ACUTE DERMAL LD50 (RABBIT) IS 2.0 G/KG, EPA CATEGORY III.
Inhalation: THE ACUTE INHALATION LC50 IS 4.9 MG/L AIR, EPA CATEGORY III, SLIGHTLY TOXIC.
Skin contact: SLIGHTLY IRRITATING, EPA CATEGORY III.
Eye Contact: MODERATELY IRRITATING, EPA CATEGORY II.
Chronic Effects: CHOLINESTERASE INHIBITION, OVEREXPOSURE MAY CAUSE ACUTE EFFECTS.
Other Hazard: NONE CURRENTLY KNOWN.
EMERGENCY AND FIRST AID PROCEDURES
Swallowing: DRINK ONE OR TWO GLASSES OF WATER TO DILUTE. INDUCE VOMITING ONLY IF INSTRUCTED TO DO SO BY A DOCTOR OR POISON CONTROL CENTER. CALL A PHYSICIAN OR POISON CONTROL CENTER.
Skin: REMOVE CONTAMINATED CLOTHING AT ONCE, WASH SKIN THOROUGHLY WITH SOAP AND WATER. OBTAIN MEDICAL ATTENTION IMMEDIATELY.
Inhalation: REMOVE PERSON FROM EXPOSURE. APPLY ARTIFICIAL RESPIRATION IF INDICATED. OBTAIN MEDICAL ATTENTION IMMEDIATELY.
Eyes: FLUSH EYES WITH WATER FOR 15 MINUTES, HOLDING EYELIDS OPEN. IF IRRITATION DEVELOPS, OBTAIN MEDICAL ATTENTION IMMEDIATELY.
Notes to Physician: PARASYMPATHOMIMETIC AGENT. ERYTHROCYTE CHOLINESTERASE ACTIVITY SHOULD BE MEASURED. SIGNS AND SYMPTOMS INCLUDE, PROGRESSIVELY: HEADACHE, LIGHT-HEADEDNESS, MIOSES WITH LOSS OF ACCOMMODATION, NAUSEA, VOMITING, HYPERHIDROSIS, MUSCLE FASCICULATIONS, SPHINCTER FAILURE, COMA, AND DEATH. IF SIGNS AND SYMPTOMS ARE PRESENT, GIVE ATROPINE, 4 MG, I.V. REPEAT EVERY 10 MINUTES UNTIL ATROPINIZED. OBSERVE FOR AT LEAST 48 HOURS. OPIATES AND PHENOTIAZINE TRANQUILIZERS ARE CONTRAINDICATED. IF RECENTLY INGESTED, EVACUATE STOMACH BY INTUBATION.

VI. REACTIVITY

Stability: Stable
Conditions to Avoid: AVOID CONTACT WITH IRON AND STRONG ALKALIES AND STORAGE ABOVE 120 DEGREES F.
Polymerization: Will Not Occur
Conditions to Avoid: NONE CURRENTLY KNOWN
Incompatibility material: IRON, STRONG ALKALIES, AND STRONG OXIDIZERS.
Hazardous Combustion: THERMAL DECOMPOSITION MAY PRODUCE ISOMALATHION, HYDROGEN SULFIDE, SULFUR, OXIDES OF CARBON AND PHOSPHORUS.

VII. SPILL OR LEAK PROCEDURES

Spill or Leak Proc: ABSORB IN CLAY OR SODA ASH; SWEEP UP AND PLACE IN WASTE DISPOSAL CONTAINER. TREAT CONTAMINATED AREA WITH FULL-STRENGTH LIQUID CHLORINE BLEACH. LET STAND FOR 15 MINUTES, AND REPEAT PROCEDURE. FLUSH AREA WITH WATER. COLLECT WASHWATERS AND STORE IN CHEMICAL WASTE CONTAINER FOR PROPER DISPOSAL.
Waste Disposal Method: THIS MATERIAL MUST BE DISPOSED OF ACCORDING TO FEDERAL, STATE, OR LOCAL PROCEDURES UNDER THE RESOURCE CONSERVATION AND RECOVERY ACT.

VIII. SPECIAL PROTECTION INFORMATION

Respiration: USE ONLY NIOSH/MSHA CARTRIDGE TYPE RESPIRATOR APPROVED FOR ORGANOPHOSPHATE PESTICIDE VAPORS.
Ventilation: MECHANICAL (GENERAL) SPARK PROOF
Gloves: IMPERVIOUS
Eyes: CHEMICAL SPLASH GOGGLES.
Other: EMERGENCY SHOWER, EYE WASH STATION, IMPERVIOUS APRON AND FOOTWEAR.

IX. SPECIAL PRECAUTIONS

Special precaution: KEEP OUT OF REACH OF CHILDREN. DO NOT STORE WITH FOOD, FEED, OR OTHER MATERIAL TO BE USED OR CONSUMED BY HUMANS OR ANIMALS. DO NOT CONTAMINATE WATER SUPPLIES, LAKES, STREAMS, OR PONDS. STORE IN A SECURE, DRY, WELL-VENTILATED AREA, SEGREGATED FROM OXIDIZERS AND INCOMPATIBLE MATERIALS. PROTECT FROM MOISTURE.
Other precaution:
A) RCRA HAZARDOUS CLASSIFICATION: NOT LISTED
B) SARA TITLE III, SECTION 313: MALATHION (56.44%)
C) SARA THRESHOLD PLANNING QUANTITY: NOT LISTED
D) CERCLA REPORTABLE QUANTITY: 20 GALLON
E) 49 CFR 171.101, APPENDIX A: HAZARDOUS SUBSTANCE
F) 49 CFR 172.101, APPENDIX B: MARINE POLLUTANT

X. SHIPPING INFORMATION

Shipping name: RQ, ORGANOPHOSPHORUS PESTICIDES, LIQUID, TOXIC, (MALATHION), 6.1, UN3018, PG III "ERG # 152"
Hazard Class: CLASS 6.1
Identification No: UN3018
Labels Required: POISON (6) or PG III (6)
Placarding: POISON (6)
Freight Class: INSECTICIDES, AGRICULTURAL, LIQUID, NOIBN (NMFC ITEM 102120, CLASS 60)

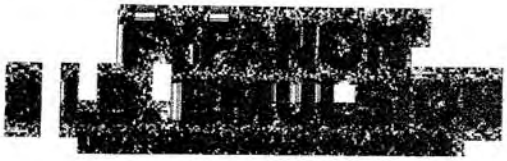
Chemical Name	Equivalent R.Q.
MALATHION	100 LB/(45.4 KG)

XI. GENERAL PRODUCT INFORMATION

National Fire Protection Association Rating: (Rating level: 4-Extreme, 3-High, 2-Moderate, 1-Slight, 0-Minimum)
Health: 2
Fire: 2
Reactivity: 0
S.A.R.A. Title III Hazard Classification: (Yes/No)
Immediate (Acute) Health: Y
Delayed (Chronic) Health: N
Sudden Release of pressure: N
Fire: Y
Reactive: N

Mail inquiries to: 225 Schilling Blvd., Suite 300 Collierville, TN 38017
Helena Chemical Company believes that the data contained herein is factual. This data is not to be taken as a warranty or representation of legal responsibility. It is offered solely for your consideration, investigation and verification. VID 10.5.05

SPECIMEN LABEL



ACTIVE INGREDIENT:
Malathion: O,O-dimethyl phosphorodithioate of diethyl mercaptosuccinate.....81.43%
INERT INGREDIENTS:.....18.57%
TOTAL.....100.00%
This product contains 8 lbs. of malathion per gallon.

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION
Harmful is swallowed, inhaled or absorbed through the skin. Causes eye irritation. Avoid breathing spray mist. Do not get in eyes, on skin or clothing.

FIRST AID

Organophosphate

IF SWALLOWED:	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth. • Call a poison control center or doctor for further treatment advice
IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. In case of emergency, call 1-800-424-9300.

NOTE TO PHYSICIAN

This product may cause cholinesterase inhibition. Atropine is antidotal. 2PAM may be effective as an adjunct to atropine.

SEE INSIDE PANEL FOR ADDITIONAL PRECAUTIONS AND DIRECTIONS FOR USE

SN 0105/1205
EPA REG. NO. 5905-250-ZA

NET CONTENTS: □ 1 Gal. (3.785 Liters)
□ 2.5 Gal. (9.46 Liters)
□ 30 Gal. (113.55 Liters)

EPA EST. NO.: First letters of product batch code indicate producing establishment.
5905-IA-1=DI • 5905-GA-1=CG • 5905-AR-1=WH • 5905-CA-1=KC

"RQ", Orgaonophosphorus, Liquid, Toxic (Malathion), UN3018

MANUFACTURED FOR
HELENA CHEMICAL COMPANY
225 SCHILING BOULEVARD, SUITE 300
COLLIERVILLE, TENNESSEE 38017

PERSONAL PROTECTIVE EQUIPMENT
Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category F on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear:
Long-sleeved shirt and long pants
Chemical-resistant gloves, such as barrier laminate, butyl rubber, nitrile rubber, or viton
Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

When handlers used closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS
Users should:
- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS
This pesticide is toxic to fish, aquatic invertebrates, and aquatic life stages of amphibians. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal

Disclaimer: Always refer to the label on the product before using Helena or any other product.

SPECIMEN LABEL

areas below the mean high water mark. Drift and runoff may be hazardous to aquatic organisms in areas near the application site. Do not contaminate water when disposing of equipment washwaters. This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

PHYSICAL OR CHEMICAL HAZARDS
Do not use or store near heat or open flame.

CHEMIGATION PROHIBITION
Do not apply this product through any type of irrigation system.

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read directions carefully. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS
Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and the handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.
Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.
Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.
Exception: If the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.
PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:
Coveralls
Chemical-resistant gloves, such as barrier laminate, butyl rubber, nitrile rubber, or viton
Shoes plus socks

STORAGE AND DISPOSAL
Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved disposal facility.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

GENERAL INFORMATION
Pour specified amount of this product into nearly filled spray tank. Add balance of water to filled tank. Keep agitator running during filling and spraying operations. If mixture does not mix readily, but tends to separate as an oily layer, do not use as injury to plants may result. Do not combine with wettable powders unless previous use of this mixture has proven physically compatible and safe to plants. Always thoroughly emulsify this product with at least half of total water before adding wettable powder.
SUGGESTED WATER RATES FOR AIRCRAFT AND GROUND APPLICATION: (The actual rate required to provide thorough, uniform coverage varies with plant growth at time of application. Except as specified for certain uses, the following rates are therefore intended to cover a broad range of conditions.)

CROP	GAL. WATER/ACRE	
	AIRCRAFT	GROUND
Vegetable and Field Crops	1 - 20	5 - 125
Orchard, Grapes	5 – 25	
Orchard Crops (see exceptions below)		300-800
Citrus		500-3000
Grapes		100-200

RECOMMENDATIONS
Unless otherwise indicated, dosages are given in pints of **FYFANON® 8 LB.** per acre in sufficient water to provide thorough coverage of vegetable and field crops and pints of **FYFANON® 8 LB.** per 100 gallons of water for thorough coverage sprays of fruit crops. Begin applications when insects first appear and repeat at 7-10 day intervals as needed to maintain control, but observe use limitation given for specific crops. Maximum permissible rate per acre, expressed as **FYFANON® 8 LB.** given in parenthesis, () , after each crop claim.

CROP USES
TREE FRUIT CROPS
APRICOTS: Aphids, Codling Moth, European Lecanium Scale, Orange Tortrix, Soft Brown Scale - 1¼ pints. Do not apply within 7 days of harvest. (10 pints)

CHERRIES: Black Cherry Aphid, Bud Moth, Cherry Fruit Fly, Fruit Tree Leaf Roller, Lesser Peach Tree Borer (apply to trunks and scaffold limbs at 21 day intervals beginning with emergence). **Forbes and San Jose Scales** (apply 3 weeks before and immediately after harvest) - 1 pint. Do not apply within 3 days of harvest. Caution: May cause injury on certain varieties of sweet cherries in the Northeast. (8 pints)

CITRUS (Oranges, Grapefruit, Kumquats, Lemons, Limes, Tangerines): California Red Scale, Yellow Scale, Purple Scale, Black Scale, (Single and Off-Brooded) Soft Scale, Thrips, Citricola Scale, Aphids - 1 pint. Do not apply within 7 days of harvest. Make no application when trees are in bloom. California - Do not apply unless parasite activity in the scale is at a low level or absent. (25 pints)

Disclaimer: Always refer to the label on the product before using Helena or any other product.

SPECIMEN LABEL

GRAPES: European Fruit Lecanium, Grape Leafhopper, Mealybug, Spider Mites - 1 pint. Do not apply within 3 days of harvest. Injury may occur to Ribler, Cardinal and Almeria varieties when applications are made after the clusters appear. (2¾ pints)

PEACHES: Black Cherry Aphids, Black Peach Aphid, Green Peach Aphid, Japanese Beetle, Rusty Plum Aphid - ¾ pint. **Oriental Fruit Moth, Plum Curculio and Scales (European Fruit Lecanium, Terrapin, Cottony Peach)** - 1¼ pints. Do not apply within 7 days of harvest. (9 pints)

VEGETABLE AND FIELD CROPS

ALFALFA, CLOVER: Alfalfa Weevil Larvae, Aphids, Armyworms, Clover Leaf Weevil, Grasshoppers, Lygus Bugs, Pea Aphid, Potato Leafhoppers, Spider Mites, Spittlebugs, Vetch Bruchid – 1- 1½ pints. Use higher rate for **Armyworm** control. For hard to control insects, use up to 2 pints per acre. Apply to alfalfa in bloom only in the evening or early morning when bees are not working in the fields or are not hanging on the outside of hives. May be applied on day of harvest or grazing up to 1½ pints rate; when using 2 pint rate, do not apply within 7 days of harvest or grazing.

ALFALFA, CLOVER, AND VETCH GROWN FOR SEED (Not for use on Vetch in California): Aphids, Leafhoppers, Lygus Bugs – 1 - 1 ¼ pints. Apply to plants in bloom only in the evening or early morning when bees are not working in the fields or are not hanging outside the hives. May be applied on the day of harvest.

BEANS: Aphids, Cucumber Beetle, Japanese Beetle, Mexican Bean Beetle, Nitidulid Beetle, Pea Leaf Weevil, Potato Leafhopper, Spider Mites - 1½ pints. **Lygus Bugs (on dry beans in California)** - 1 - 1½ pints. Do not apply within 1 day of harvest. Do not graze or feed treated crop foliage to livestock.

BEETS, GARDEN (Seed Crop): Lygus - 1¼ pints. Apply in seedball to hand seed stage. Repeat as needed. Do not apply within 7 days of harvest. (No limitation.)

BEETS, TABLE: Aphids, Beet Armyworm, Blister Beetles, Flea Beetle - 2½ pints. Do not apply within 7 days of harvest. (2½ pints.)

BERRIES (Blackberry, Blueberry, Boysenberry, Dewberry, Loganberry, Raspberry): Aphids, Japanese Beetle, Rose Leafhopper, Rose Scale, Two-Spotted Spider Mites, Sap Beetle - 2 pints. Do not apply within 1 day of harvest.

CELERY: Aphids, Leafhoppers, Spider Mites, Whiteflies - 1½ pints. Do not apply within 7 days of harvest. (1½ pints.)

COLE CROPS (Broccoli, Brussels Sprouts, Cabbage, Kale, Mustard,Turnips): Aphids, Cabbage Loopers, Imported Cabbage Worm - 1½ - 2 pints. Use higher rate for **loopers** and **worms**. Do not apply within 3 days of harvest on **Broccoli** and **Turnips**, 7 days on others.

CORN: Aphids, Corn Rootworm Adults, Sap Beetles, Thrips, Young Grasshoppers - 1¼ pints. Do not apply within 5 days of harvest for forage use. **Caution:** Injury may occur in the whorl and silk stages with emulsifiable liquids. (1¼ pints.)

COTTON: Brown Cotton Leafworm, Cotton Aphid, Cotton Leafworm, Cotton Leafperforator, Spider Mite, Leafhoppers, Lygus Bugs, Thrips, Whiteflies - ¾-1 pt. **Fall Armyworms, Boll Weevil, Grasshoppers, Garden Webworms, Lygus** - 1¼-2 pts. **Cotton Fleahoppers** - ¾-1 pt. May be applied on the day of harvest. Consult local agricultural authorities for exact time of application.

CUCURBITS (Cucumbers, Squash): Spider Mites, Squash Vine Borer, Thrips - 1¾ pints.
Do not apply on **Cucumbers** and **Squash** unless plants are dry or within 1 day of harvest. (1¾ pints.)

EGGPLANT: Aphids, Lace Bug, Spider Mites - 1¼ - 2 pints. Use higher rate for **Lace Bugs**. Do not apply within 3 days of harvest.

GRASS AND CEREAL CROPS (Barley, Corn, Wheat, Barn Grass, Canary Grass, Fescue, Orchard Grass, Red Top, Timothy and Yellow Foxtail): Cereal Leaf Beetle - ¾ - 1¼ pints. Do not apply within 7 days of harvest or forage use on **Barley** and **Wheat**; 5 days on **Corn. Grass, Grass Hay Pastures and Range Land: Aphids, Leafhoppers** - 1-1¼ pints, repeat application as necessary. (**Grasses** 1¼ pints; **Corn** 1 pint, other **cereals** 1¼ pints.)

HOPS: Aphids, Mites - 1¼ pints. Do not apply within 7 days of harvest. (1¼ pints)

HORSERADISH: Aphids, Diamond Back Moth, Flea Beetle, and Leafhoppers. Do not apply within 7 days of harvest. (2½ pints.)

LETTUCE, ENDIVE: Aphids, Alfalfa Looper, Cabbage Looper, Leafhoppers, Mites - 2 pints. Do not apply within 14 days of harvest on leaf lettuce; 7 days on endive and head lettuce. (2 pints.)

MINT: Aphids, Flea Beetle Adults, Spider Mites - 1 pint. Do not apply within 7 days of cutting. (1 pint.)

ONIONS: Onion Maggots, Thrips - 2 pints. For **Onion Maggots** apply when flies first appear and repeat every 4 days. Do not apply within 3 days of harvest on **Green Onions.** (2 pints)

PARSNIPS - Aphids, Diamond Back Moth, Flea Beetle, Leafhoppers - 2 pints. Do not apply within 7 days of harvest.

PEAS: Aphids, Pea Weevils - 1¼ pints. Do not apply within 3 days of harvest. Do not graze or feed treated crop foliage to livestock

PEPPERS: Aphids, Pepper Maggots - 1½ pints. Do not apply within 3 days of harvest. (1½ pints)

POTATOES: False Chinch Bugs, Leafhoppers, Mealy Bugs - 1 pint. **Aphids, Blister Beetles** - 2½ pints.

RADISHES: Aphids and Diamond Back Moth. Do not apply within 7 days of harvest. (2 pints)

Disclaimer: Always refer to the label on the product before using Helena or any other product.

SPECIMEN LABEL

RICE: Leafminers - 1½ pts. Make first application when first rice blades appear on the surface of the water and repeat if necessary. **Stink Bugs** - 1 pint in a minimum of 2 gallons of water applied by aircraft during the early milk and dough stages of growing rice. Do not apply within 7 days of harvest. (1½ pints.) Broadcast use only over intermittently flooded areas. Application may not be made around bodies of water where fish or shellfish are grown and/or harvested commercially.

SALSIFY: Aphids, Diamond Back Moth, Flea Beetle, and Leafhoppers - Do not apply within 7 days of harvest. (2 pints).

SMALL GRAINS (Barley, Rye, Wheat): Armyworms, English Grain Aphids, Grasshoppers, Greenbugs - 1 - 1¼ pints. Do not apply within 7 days of harvest. (1¼ pints.)

SPINACH: Aphids - 1½ pints. Do not apply within 7 days of harvest.

STRAWBERRIES: Aphids (use at rate of 2 pints), **Field Crickets, Lygus Bugs, Potato Leafhopper, Spider Mites, Spittlebugs, Strawberry Leafroller, Strawberry Root Weevil, Thrips, Whiteflies** - 1½-2 pints. Do not apply within 3 days of harvest. (2 pints.)
SWISS CHARD: Aphids, Blister Beetle - 2 pints. Do not apply within 7 days of harvest. (2 pints.)

TOMATOES: Aphids, Spider Mites - 1½ pints. **Drosophila Flies** - 2 pints in full coverage application to fruit and foliage. Do not apply within 1 day of harvest. At rates over 2 pints up to 3½ pints, do not apply within 5 days of harvest. **California only:** These higher rates may be applied up to 3 days of harvest. (3½ pints)

PASTURE AND RANGE LAND: Aphids, Grasshoppers, Leafhopper - 1¼ pints. Or use 1¼ pints in 1 gallon diesel fuel oil by means of airplane or a turbine blower type sprayer. May be applied on day of harvest or grazing. (1¼ pints.)

WASTELANDS, ROADSIDES, SOIL-BANK LANDS (Not Grazed): Grasshoppers - 1 - 2 pints in 1 gallon fuel oil by means of an airplane or a turbine-blower type sprayer.

STORAGE PEST PROTECTION
For protection against: Cereal Leaf Beetles, Confused Flour Beetle, Indian Meal Moth, Flat Grain Beetle, Granary Weevil, Lesser Grain Borer, Red Flour Beetle, Rice Weevil, Rusty Grain Beetle, Sawtoothed Grain Beetle.

GRAINS (Barley, Corn, Oats, Rye, Wheat)-RESIDUAL SPRAY - BEFORE STORING:
(For walls, floors, and machinery in grain elevators, in treating truck beds, boxcars, and ships holds before loading grain): Use 5 pints per 25 gallons of water. Make thorough application. Before applying spray, clean elevators, boxcars, truck beds, etc. thoroughly. Remove and burn all sweepings and debris.

ORNAMENTALS
Dosages given are for use in 100 gallons of dilute spray -

Aphids, European Pine Shoot Moth, Four-Lined Leaf Bug, Japanese Beetle Adult, Mealybugs, Millipedes, Potato Leafhopper, Rosa Leafhopper, Scurfy Scale, Spider Mites, Springtails, Sowbugs, Tarnished Plant Bug, Thrips, Whitefly, Eunoymus Scale, Lace Bugs, Oyster Shell Scale
.....1 pint
Azalea Scale, Bagworms, Birch Leafminer, Boxwood Leafminer, Fletcher Scale, Florida-Red Scale, Juniper Scale, Magnolia Scale, Oak Kermes, Pine Leaf Scale, Tent Caterpillar
.....1¼ pints
Black Scale Crawlers, Monterey Pine Scale.....1 3/5 pints
Pine Needle Scale, Wax Scale .....2 pints
For Oyster Shell, Fletcher, Juniper, Oak Kermes and Pine Needle Scales, apply when scale crawlers have settled on foliage.
CAUTION: Avoid use on certain ferns including Boston, Maidenhair and Pteris, as well as some species of Crassula and Canaetri Juniper.

FLY CONTROL
For use around the outside of buildings which house domestic animals, around the outside of homes, around yards, and the outside of meat and food processing plants.

STRAIGHT FYFANON® SPRAYS
FYFANON® SPRAYS

Amount of Spray	Amount of Sugar Molasses or	Unsulfurized **FYFANON® 8-E** Bait Spray	Amount of **FYFANON® 8-E** (or)	Corn Syrup	Amount
2 ½ gals.	¾ cup	2 ½ gals.	¾ cup	1 cup	1 cup
12 gals.	1 ¼ pts.	12 gals.	1 ¼ pts.	2 ½ lbs.	1 qt.
100 gals.	1 ¼ gals.	100 gals.		1 ¼ gals.	20 lbs. 2 gals.

Apply spray at rate of 1 gallon per 1,000 square feet on painted surfaces and 2 gallons per 1,000 square feet on unpainted surfaces where flies alight or congregate. In most cases, adding molasses or sugar to the spray prolongs the insecticidal activity and serves as a fly attractant.

CAUTION: Avoid contamination of milk, milk equipment and water. Avoid contamination of feed and food products; also drinking fountain and feed troughs.

DROSOPHILA FLIES and DRIED FRUIT BEETLES: On or around cull fruit and vegetable dumps. Mix 7½ pints in 100 gallons of water and apply as a drench, using 8-10 gallons of spray per 100 square feet (for best results, dumps should not be over 18 inches deep). Do not feed treated fruit and vegetables.

MOSQUITO CONTROL
MOSQUITOES, FLIES AND SMALL FLYING INSECTS: (Broadcast use only over intermittently flooded areas. Application may not be made around bodies of water where fish or shellfish are grown and/or harvested commercially.) For use by trained personnel as a 2-5% fog, aerosol or space spray. To make a 2% solution dilute 1 part in 45 parts of water, fuel oil or diesel

oil. When using kerosene-type solvent as carrier, dilute 1 part in 45 parts of a mixture consisting of 4 parts kerosene-type solvent and 1 part aromatic hydrocarbon-type solvent. For a 5% solution, dilute 1 part in 18 parts of mixture using similar solvents.

MOSQUITO LARVAE IN STANDING WATER: (Broadcast use only over intermittently flooded areas. Application may not be made around bodies of water where fish or shellfish are grown and/or harvested commercially.) Apply at the rate of 8 fluid ounces (approximately ½ pint) per acre. Mix in sufficient water or oil to obtain even coverage when applied by air or ground. Repeat applications as necessary. Avoid applying oil-based formulations to valuable ornamental plants as injury may occur. Keep out of any fish bearing waters.

ADULT MOSQUITO AND FLY CONTROL

Apply 2.4 to 4.8 fluid ozs. per acre for control of Adult Mosquitoes and 7.2 to 9.6 fluid ozs. per acre for control of **Adult Flies** and **Mosquitoes**. Repeat as necessary. Can be applied to **Alfalfa, Clover, Pasture and Range Grass, Grass and Grass Hay, Grain Crops (Barley, Corn, Oats, Rye, & Wheat), Beans, Rice, and Nonagricultural Lands.** Do not apply within 7 days of harvest on **Grain Crops (Barley, Oats, Rye & Wheat) and Rice**; 5 days of harvest on **Corn**; 1 day of harvest on **Beans**. No time limitation on **Alfalfa, Clover, Pasture and Range Grass, Grass and Grass Hay**. Do not apply to **Alfalfa** and **Clover** in bloom. Do not use on seed **Alfalfa**. Treat shrubbery and vegetation where mosquitoes may rest.

(Broadcast use only over intermittently flooded areas. Application may not be made around bodies of water where fish or shellfish are grown and/or harvested commercially.) Shrubbery and vegetation around stagnant pools, marshy areas, ponds, and shorelines may be treated.

Mist blowers and boom sprayer utilizing a controlled airflow to facilitate particle size and spray deposition may be used at a vehicle speed of 4 to 10 m.p.h.

Mist blowers with a pump capable of producing up to 40 psi and blower speeds of 2600 r.p.m. are satisfactory. Use flat fan nozzles, 8001 to 8002, placed 30o into air blast or rotary atomizers into the air blast that produce an efficient spray particle with a mass medium diameter of 40 to 100 microns.

Swath widths should not exceed 30 feet, and applications should not be made when winds exceed 5 m.p.h.
Repeat applications should be made as necessary unless otherwise specified.

CONDITIONS OF SALE - LIMITED WARRANTY AND LIMITATIONS OF LIABILITY AND REMEDIES
Read the Conditions of Sale - Warranty and Limitations of Liability and Remedies before using this product. If the terms are not acceptable, return the product, unopened, and the full purchase price will be refunded.

The directions on this label are believed to be reliable and should be followed carefully. Insufficient control of pests and/or injury to the crop to which the product is applied may result from the occurrence of extraordinary or unusual weather conditions or the failure to follow the label directions or good application practices, all of which are beyond the control of Helena Chemical Company (the "Company") or seller. In addition, failure to follow label directions may cause injury to crops, animals, man or the environment. The Company warrants that this product conforms to the chemical description on the label and is reasonably fit for the purpose referred to in the directions for use subject to the factors noted above which are beyond the control of the Company. The Company makes no other warranties or representations of any kind, express or implied, concerning the product, including no implied warranty of merchantability or fitness for any particular purpose, and no such warranty shall be implied by law.

The exclusive remedy against the Company for any cause of action relating to the handling or use of this product shall be limited to, at Helena Chemical Company's election, one of the following:

1. Refund of the purchase price paid by buyer or user for product bought, or
2. Replacement of the product used

To the extent allowed by law, the Company shall not be liable and any and all claims against the Company are waived for special, indirect, incidental, or consequential damages or expense of any nature, including, but not limited to, loss of profits or income. The Company and the seller offer this product and the buyer and user accept it, subject to the foregoing conditions of sale and limitation of warranty, liability and remedies.

Disclaimer: Always refer to the label on the product before using Helena or any other product.

AHETF Study No. AHE55

Risk of Toxicity from Pesticide Product Handled (Must be attached to the Informed Consent Form)

The product you will handle is identified as follows:

Name: Fyfanon® (EPA Registration No. 5905-196)

Active Ingredient (AI): Malathion (insecticide, CAS No. 00121-75-5)

Formulation and Packaging: 5 lbs AI/gallon Emulsifiable Concentrate in [redacted]

You may handle up to: 20 gallons of product

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves and protective eyewear. The gloves and protective eyewear must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This malathion product is classified as moderate toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include moderate eye irritation, slight skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 2005 MSDS date: 10-5-05

_____ _____

Signature of Subject Date

_____ _____

Signature of Witness Date

Version date: 1-25-08 DRAFT

SPECIMEN LABEL

FYFANON®

THE PREMIUM GRADE MALATHION

ACTIVE INGREDIENT:

Malathion: O,O-dimethyl phosphorodithioate of diethyl mercaptosuccinate 56.44%

INERT INGREDIENTS

.....43.56%

TOTAL.....100.00%

* Contains xylene range aromatic solvent.

(ONE GALLON OF FYFANON CONTAINS 5 POUNDS OF MALATHION)

KEEP OUT OF REACH OF CHILDREN

WARNING – AVISO

Si Usted no entiende la etiqueta, busque a alguien para que se la explique a Usted en detalle. (If you do not understand the label, find someone to explain it to you.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING-AVISO

May be harmful if swallowed, inhaled or absorbed through skin. Causes substantial but temporary eye injury. Do not take internally. Avoid contact with eyes, skin and clothing. Avoid breathing vapors, dust, or spray mist. Flush contaminated eyes with plenty of water and get medical attention if irritation persists.

FIRST AID

Organophosphate

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor.
- Do not give anything by mouth to an unconscious or convulsing person.

IF INHALED:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
- Call a poison control poison center or doctor for further treatment advice.

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING:

- Take off contaminated clothing
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment

Have the product container with you when calling a poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN

Contains an organophosphate that inhibits cholinesterase.

SEE INSIDE BOOKLET FOR ADDITIONAL PRECAUTIONS AND DIRECTIONS FOR USE.

SN 1201/0105 NET CONTENTS:

EPA REG. NO. 5905-196

EPA EST. NO. First letters of batch code indicate producing establishment::

5905-GA-1=CG • 5905-AR-1=WA • 5905-IA-1=DI • 5905-CA-1=KC

"RQ", Organophosphorus Pesticide, Liquid, Toxic (Matlathion), UN3018

®Registered Trademark of Cheminova

MANUFACTURED FOR
HELENA CHEMICAL COMPANY
225 SCHILLING BOULEVARD, SUITE 300
COLLIERVILLE, TENNESSEE 38017

PERSONAL PROTECTIVE EQUIPMENT

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category **F** on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear:

Long-Sleeved shirt and long pants
Chemical-resistant gloves, such as Barrier Laminate, Butyl Rubber, Nitrile Rubber or Viton.
Shoes plus socks
Protective Eyewear
Chemical-resistant headgear for overhead exposure

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should:

Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

ENVIRONMENTAL HAZARDS

Disclaimer: Always refer to the label on the product before using Helena or any other product.

SPECIMEN LABEL

This pesticide is toxic to fish, aquatic invertebrates, and aquatic life stages of amphibians. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to aquatic organisms in areas near the application site. Do not contaminate water when disposing of equipment washwaters.

This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

CHEMIGATION: Refer to supplemental labeling entitled "Instructions for Application Through Irrigation Systems for Watercress Only." Do not apply this product through any irrigation system unless the supplemental labeling on chemigation is followed.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours, with the exception of treated areas of slash pine – where a restricted entry interval (REI) of 24 hours is indicated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralls
Chemical-resistant gloves such as Barrier Laminate, Butyl Rubber, Nitrile Rubber or Viton.
Shoes plus socks
Protective Eyewear
Chemical-resistant headgear for overhead exposure

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses. Keep children and pets out of treated area until sprays have dried.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

STORAGE: Store in a dry place.
PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved disposal facility.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

USE DIRECTIONS

BEANS (Lima, Green, Snap, Navy, Red Kidney, Wax, Cowpeas, Blackeyed Peas): Mexican Bean Beetle - 1 1/2 pts. **Spider Mites** - 1 1/2 pts. **Japanese Beetle*** - 1 1/2 - 2 pts. **Aphids, Cucumber Beetle, Potato Leafhoppers, Lygus Bugs** - 2 pts. *Make 2 or more applications as needed. Do not apply within 1 day of harvest. Note: Do not graze or feed treated crop foliage to livestock.

DRY BEANS (California and Northwestern U.S.): Lygus Bugs - 1 1/2 - 2 pts. Do not apply within 1 day of harvest. Note: Do not graze or feed treated crop foliage to livestock.

COLE CROPS AND LEAFY VEGETABLES: [Broccoli, Turnips (Do not apply within 3 days of harvest), **Brussels Sprouts, Cabbage, Collards, Dandelions, Kale, Kohlrabi, Mustard Greens, Swiss Chard, Watercress** (Do not apply within 7 days of harvest), **Parsley** (Do not apply within 21 days of harvest)], **Harlequin, Cabbage Bug (on Collards only)** - 1 pt. **Imported Cabbage Worm, Cabbage Looper, and Diamondback Moth** - For control of cabbage loopers, worms, and diamondback moths, **FYFANON®** should be used in combination with other recommended insecticides.

CELERY (Sweet Anise* and Fresh Leaves and Stalks Only): Aphids, Spider Mites - 1 1/2 pts. *Not for use on seed and oil crop. Do not apply within 7 days of harvest.

LETTUCE: Leafhoppers, Aphids, Spider Mites - 2 pts. **Cabbage Looper** - 3 pts. Do not apply to leaf lettuce within 14 days of harvest; do not apply to head lettuce within 7 days of harvest.

SPINACH: Aphids - 2 pts. Do not apply within 7 days of harvest.

CORN (Sweet): Japanese Beetle - 2 pts. Do not apply within 5 days of harvest. Injury may occur in the whorl or to the silks.

CORN (Grain or Forage): Aphids, Corn Earworm, Corn Rootworm Adults, Grasshoppers, Sap Beetle, Thrips - 1-1/2 pts. For control of corn earworm and sap beetles, begin treatments when 10% of the ears show silk. Repeat applications at 3-5 day intervals until 4-5 applications have been made. Do not apply within 5 days of harvest or forage use. **Armyworms** - 1-1/2 - 2 pts. Injury may occur in the whorl and silk stages with **FYFANON®.**

Disclaimer: Always refer to the label on the product before using Helena or any other product.

SPECIMEN LABEL

CUCURBITS (Cucumbers): Aphids, Spider Mites, Pickleworm - 1 1/2 pts. **Cucumber Beetle, Leafminer** - 2 pts. **Squashvine Borer** - 3 pts. Do not apply unless plants are dry. Apply uniformly over soil around base of plants. Do not apply within 1 day of harvest.

ENDIVE: Cowpea Aphid, Pea Aphid - 1-1/2 - 2 pts. Do not apply within 7 days of harvest.

SQUASH: Alfalfa Loopers - For control of loopers, **FYFANON®** should be used in combination with other recommended insecticides. **Aphids, Spider Mites** - 1 1/2 pts. **Pickleworm** - 2 pts. **Squash Vine Borers, Cucumber Beetles** - 3 pts. Do not apply unless plants are dry. Do not apply within 1 day of harvest.

EGGPLANT: Aphids, Spider Mites - 1 pt. **Lace Bug** - 3 pts. Apply uniformly over soil around base of plant. Do not apply within 3 days of harvest.

COTTON: Brown Cotton Leafworm, Cotton Aphid, Cotton Leafworm, Cotton Leaf Perforators, Desert Spider Mite, Leafhoppers, Lygus Bugs, Thrips, Whitefilies - 1/2 - 2 pts. **Boll Weevil** -2-4 pts. **Cotton Fleahoppers** -1 - 1 1/2 pts. May be applied on the day of harvest. Consult local agricultural authorities for exact time of application. **Fall Armyworms, Garden Webworms, Grasshoppers** - 1-1/2 - 3 pts. May be applied on the day of harvest. **Lygus Bugs, Thrips** - 1 - 4 pts. Note: Do not graze or feed treated crop foliage to livestock.

MINT: Aphids, Spider Mites, Leafhopper, Adult Flea Beetles, Caterpillars - 1 1/2 pts. Do not apply within 7 days of harvest.

RICE: Rice Leaf Miner - 2 1/2 pts. Make first application shortly after the first rice blades appear on the surface of the water and repeat if necessary. Do not apply within 7 days of harvest. **Rice Stink Bug** - 1 - 1 1/2 pts. Do not apply within 7 days of harvest. Broadcast use only over intermittently flooded areas. Application may not be made around bodies of water where fish or shellfish are grown and/or harvested commercially.

TOMATOES (outdoor): Spider Mites - 1-1/2 pts. Do not apply within 1 day of harvest. **Aphids** - 1 pt. Do not apply within 1 day of harvest. **Drosophila** - 2-1/2 pts. Do not apply within 1 day of harvest. **Armyworm, Fruit worms (California only)** - 2-3/4 qts. Do not apply within 3 days of harvest.

VETCH: Pea Aphid, Vetch Bruchid - 1 1/2 - 2 pts. Do not apply within 7 days of harvest or pasturing.

ALFALFA: Aphids, Potato Leafhopper, Spider Mites, Alfalfa Weevil Larvae, Spittlebug, Grasshoppers, Lygus Bug, Spotted Alfalfa Aphid, Stink Bugs - 1 1/2 - 2 pts. **Clover Leaf Weevil** - 1 1/2 pts. **Pea Aphid** - 1 pt. **Armyworms** - 2 pts. **Vetch Bruchid** - 2 - 2-1/2 pts. Apply to alfalfa in bloom only in the evening or early morning when bees are not working in the field or are not hanging on outside of hives. May be applied on the day of harvest.

CLOVER: Alfalfa Weevil Larvae, Aphids, Spider Mites, Lygus Bugs, Grasshoppers, Potato Leafhoppers, Spittlebugs - 1 1/2 - 2 pts **Clover Leaf Weevil** - 1 1/2 pts. **Armyworms** - 2 pts. Do not apply to clover in bloom. May be applied on day of harvest.

Disclaimer: Always refer to the label on the product before using Helena or any other product.

SORGHUM: Greenbugs - 1-1/2 pts. Do not apply within 7 days of harvest. Note: Do not graze or feed treated crop foliage to livestock.

GRASS CROPS

Grass & Grass Hay: Grasshoppers, Aphids, Leafhoppers - 1 1/2 - 2 pts. or 1 1/2 pts. in 1 gal. diesel fuel oil*. **Armyworms** - 2 pts. OR 1 1/2 pts. in 1 gal. diesel fuel oil*. *Apply by aircraft or turbine-blower sprayer.

Pasture & Range Grass: Grasshoppers, Aphids, Leafhoppers - 1 1/2 - 2 pts. OR 1 1/2 pts. in 1 gal. diesel fuel oil*. *Apply by aircraft or turbine-blower sprayers.

Barn Grass, Canary Grass, Fescue, Orchard Grass, Red Top, Timothy, Yellow Foxtail: Cereal Leaf Beetle - 1 - 1 1/2 pts. May be applied on day of harvest or grazing.

NON-AGRICULTURAL LANDS (Wasteland, Roadsides, Soil Bank, Land not to be Grazed): Grasshoppers - 1 1/2 - 3 pts. OR 1 1/2 - 3 pts. in 1 gal. diesel fuel oil*. *Apply by aircraft or turbine-blower sprayer. Repeat applications may be needed after hatching and before movements to crops take place.

GRAIN CROPS

Barley, Corn, Wheat: Cereal Leaf Beetle - 1-1/2 pts.
Barley, Rye, Wheat, Oats: English Grain Aphid, Greenbugs, Grasshoppers* - 1-1/2 pts. *Make full coverage to hatching areas when nymphs are young. **Armyworms** - 2 pts.

GRAINS (Corn, Barley, Oats, Rye, & Wheat) - RESIDUAL SPRAY BEFORE STORING: For walls, floors, and machinery in grain elevators, in treating truck beds, box cars, and ship holds before loading grain, use 1 gallon per 25 gallons of water. Make thorough application. Before applying spray, clean elevators, boxcars, truck beds, etc. thoroughly. Remove and burn all sweepings and debris.

GARLIC, LEEKS, SHALLOTS: Aphids, Thrips - 1 1/2 - 2 pts. Apply uniformly over soil around base of plant. Do not apply within 3 days of harvest.

LENTILS: Cowpea Aphid, Pea Aphid - 1 1/2 pts. Do not apply within 3 days of harvest. Note: Do not graze or feed treated crop foliage to livestock.

MUSHROOMS: Mites - 2 1/2 pts. per 130 gals. OR 1 tbs. per 100 sq. ft. of bed. **Phorid and Sciarid Flies** - 2 1/2 pts. per 130 gals. or 1 tbs. per 100 sq. ft. of bed. Make thorough application as soon as possible after picking. Repeat applications as necessary, usually twice a week. Do not apply within 1 day of harvest.

ONION: Thrips - 1 1/2 pts. **Onion Maggots** - 2 1/2 pts. Do not apply within 3 days on Green Onions.

PEAS: Alfalfa Loopers, Celery Loopers - For Control of Loopers, **FYFANON®** should be used in combination with other recommended insecticides. Do not apply within 3 days of harvest. Note: Do not graze or feed treated crop foliage to livestock.

SPECIMEN LABEL

OKRA: Aphids - 1 1/2 pts. **Japanese Beetle** - 2 pts. Do not apply within 1 day of harvest.

PEPPERS: Aphids - 1 pt. **Pepper Maggots** - 2 1/2 pts. Do not apply within 3 days of harvest.

POTATOES: Aphids, Mealybugs, Leafhoppers - 2 pts . **False Chinch Bugs** - 1 1/2 pts. **Mealybugs** - 2 - 2-1/2 pts. May be applied on the day of harvest.

BEETS (Table & Garden): Aphids - 1 1/2 pts. - 2 pts. If tops are to be used as feed, do not apply within 7 days of harvest.

HORSERADISH, PARSNIPS: Aphids - 1 1/2 - 2 pts. Apply uniformly over soil around base of plants.

RADISH, SALSIFY: Aphids - 1 1/2 - 2 pts. Do not apply within 7 days of harvest.

RUTABAGAS: Aphids - 1 1/2 pts. Do not apply within 3 days of harvest.

SWEET POTATOES: Leafhoppers - 1 1/2 - 2 pts. **Morninglory leafminers** - 2 1/2 - 3 pts. Do not apply within 3 days of harvest.

APRICOTS: Codling Moth, Orange tortrix, Terrapin Scale, Soft Brown Scale, Aphids - 1 1/2 - 2 pts. Do not apply within 7 days of harvest.

AVOCADOS: Latania Scale, Greenhouse Thrips, Omnivorous Looper, Orange Tortrix, Soft Brown Scale - 1 1/2 pts. Do not apply within 7 days of harvest.

CHERRIES: Black Cherry Aphids, Fruit Tree Leaf Roller - 1 1/2 pts. **Cherry Fruit Fly, Bud Moth** - 1 pt. Injury may occur on certain varieties of sweet cherries particularly in the northwest. Do not apply within 3 days of harvest. May injure foliage on some varieties.

CITRUS - (CONSULT LOCAL SPRAY SCHEDULES FOR RECOMMENDED VOLUMES OF SPRAY PER ACRE.) Grapefruit, Lemons, Limes, Oranges, Tangerines, Tangelos, Kumquats: California Red Scale, Yellow Scale, Purple Scale, Black Scale (single and off brooded), Soft Scale, Citricola Scale - 1 - 1 1/2 pts. Do not apply within 7 days of harvest.

FIGS: Dried Fruit Beetles, Vinegar Beetles - 2 qts. plus 1-2 gals. unsulfurized molasses per acre. Do not apply within 3 days of harvest.

NURSERY STOCK, GRAPE VINES: Overwintering Grape Phylloxera. For the control of overwintering grape phylloxera on nursery stock grape vines, remove excess soil from the roots and dip in a solution made up of 1 to 1 1/2 pts. of **FYFANON®** emulsifiable liquid in 50 gallons of water. Submerge the entire root system in the solution for 5 minutes. Keep the solution agitated at all times. Fifty gallons of solution will treat approximately 500 nursery stock grape vines. Do not apply within 3 days of harvest. Emulsion may cause injury to foliage on some varieties.

NECTARINES: Plum Curculio - 2 pts. **Mites** 1-2 pts. Application of this mixture should be made only in the petal fall period. Do not apply within 7 days of harvest.

PEACHES: Oriental Fruit Moth, Plum Curculio, Terrapin Scale, Cottony Peach Scale - 2 pts. **Green Peach Aphid, Black Cherry Aphid, Black Peach Aphid, Rusty Plum Aphid, Japanese Beetle** - 1 pt. Do not apply within 7 days of harvest.

BLACKBERRIES, BOYSENBERRIES, DEWBERRIES, LOGANBERRIES, RASPBERRIES: Mites, Thrips, Leafhoppers, Japanese Beetle - 1 1/2 pts. **Aphids, Rose Scale** - 3 pts. Do not apply within 1 day of harvest.

RASPBERRIES: Sap Beetle - 1 1/2 - 2 pts. Do not apply within 1 day of harvest.

BLUEBERRIES: Blueberry Maggots in the Northeast - 1 pt. of **FYFANON®** plus 1 1/2 qts. of Staley's Sauce Base #7 in 100 gals. of water per acre and apply by ground or air equipment. Preharvest interval - 8 hours. **Japanese Beetle** - 1 1/2 pts.

STRAWBERRIES: Aphids, Spider Mites, Strawberry Root Weevil - 1 1/2 pts. **Lygus Bugs, Spittlebugs, Field Crickets, Thrips** - 1 1/2 - 3 pts. **Potato Leafhopper, Strawberry Leafroller, Whiteflies** - 1 1/2 - 2 1/2 pts. Do not apply within 3 days of harvest.

PECANS: Spider Mites, Aphids, Pecan Nut Casebearer, Pecan Phylloxera, Pecan Bud Moth - 1-2 pts.

ORNAMENTALS (Ornamental Flowering Plants, Ornamental Nursery Stock, Ornamental Woody Plant s, Pine Seed Orchards, Uncultivated Non-Agricultural Areas, Christmas Tree Plantations): Oyster Shell Scale, Lace Bug - 1 pt. **Euonymus Scale** - 1 - 1- 1/2 pts. **Aphids, Mealy Bugs, Spider Mites, Whitefly, Fourlined Leaf Bug, Japanese Beetle Adult, Potato Leafhopper, Tarnished Plant Bug, Thrips, Rose Leafhopper, European Pine Shoot Moth, Scurfy Scale** - 1 1/2 pts. Apply sufficient amount for good coverage. **Birch Leaf Miner, Boxweed Leaf Miner, Bagworms, Tent Caterpillars, Azalea Scale, Oak Kermes,Pine Leaf Scale, Magnolia Scale, Fletcher Scale, Florida Red Scale** - 2 pts. Apply when scale crawlers have settled on foliage. **Black Scale Crawlers, Monterey Pine Scale, Soft Scale** - 2 1/2 pts. **Pine Needle Scale** - 4 pts. **Wax Scale** - 2 qts. Apply in spring when crawlers are active. Repeat 1 or 2 full coverage applications at 10 days intervals. NOTE: Apply sufficient amount for good coverage.

GREENHOUSE (Around Greenhouses and Gardens): Millipedes, Springtails, Sowbugs - Mix 1 teaspoonful of **FYFANON®** in 1 gal. of water and apply to 150 square feet of soil surface or where insects congregate. Repeat at 7 to 10 day intervals as needed.

SLASH PINE (Ornamental Nursery Stock, Pine Seed Orchards, Christmas Tree Plantations): Slash Pine Flower Thrips - Apply 1 1/4 gallons **FYFANON®** per 100 gallons of water. Apply at a minimum rate of 3/4 gallon per tree on the smallest flowering trees. Mist blowers or airblast sprays may be used.

Aerial Application - Mix 2-1/2 quarts of **FYFANON®** in at least 5 gallons of water; apply at a minimum rate of 5 gallons per acre. Make two applications, the first when female flowers are twig bug

stage; the second one week prior to maximum flower receptivity to pollen.

Do not allow workers to reenter fields to engage in any activity requiring substantial contact with treated foliage for one day (24 hours) following application. Do not harvest trees within 24 hours of application.

MOSQUITOES (OUTDOOR ADULT MOSQUITO CONTROL): For control of mosquitoes outdoors, use a 2% to 5% Malathion area or fog spray. For a 2% spray, dilute 1 part of **FYFANON®** with 28 parts of water; for 5%, dilute 1 to 11. Repeat as necessary. Treat shrubbery and vegetation where mosquitoes may rest. Shrubbery and vegetation around stagnant pools, marshy areas, ponds, and shore lines may be treated.

MOSQUITO LARVAE CONTROL: For control of mosquito larvae in standing water, intermittently flooded areas, stagnant water, and temporary rain pools, apply 13 ounces of **FYFANON®** per acre. Mix in sufficient water or oil to obtain even coverage when applied by air or ground equipment. NOTE: BROADCAST USE ONLY OVER INTERMITTENTLY FLOODED AREAS. APPLICATION MAY NOT BE MADE AROUND BODIES OF WATER WHERE FISH OR SHELLFISH ARE GROWN AND/OR HARVESTED COMMERCIALLY. CONTAMINATION OF SHALLOW, FISH-BEARING WATERS MAY KILL FISH.

FLIES: For the control of flies around buildings which house domestic animals, around yards and around homes, apply a spray containing 2 gallons of **FYFANON®** in 100 gallons of water. Apply the spray at the rate of one gallon per 1,000 square feet on painted surfaces and two gallons per 1,000 square feet on unpainted surfaces where flies alight or congregate, such as outside walls, stanchions, windows outside dairy barns, fences, around garbage cans, etc. Repeat applications as necessary. For a bait spray, use 2 gallons of **FYFANON®** with two gallons of unsulfurized molasses or corn syrup, or 20 pounds of sugar per 100 gallons of water. Use 3 gallons of this product with 40 pounds of sugar per 100 gallons if the fly population is severe. Repeat applications as necessary. Do not use inside buildings.

CONDITIONS OF SALE - LIMITED WARRANTY AND LIMITATIONS OF LIABILITY AND REMEDIES
Read the Conditions of Sale - Warranty and Limitations of Liability and Remedies before using this product. If the terms are not acceptable, return the product, unopened, and the full purchase price will be refunded.

The directions on this label are believed to be reliable and should be followed carefully. Insufficient control of pests and/or injury to the crop to which the product is applied may result from the occurrence of extraordinary or unusual weather conditions or the failure to follow the label directions or good application practices, all of which are beyond the control of Helena Chemical Company (the "Company") or seller. In addition, failure to follow label directions may cause injury to crops, animals, man or the environment. The Company warrants that this product conforms to the chemical description on the label and is reasonably fit for the purpose referred to in the directions for use subject to the factors noted above which are beyond the control of the Company. The Company makes no other warranties or representations of any kind, express or implied, concerning the product, including no implied warranty of merchantability or fitness for any particular purpose, and no such warranty shall be implied by law.

The exclusive remedy against the Company for any cause of action relating to the handling or use of this product shall be limited to, at Helena Chemical Company's election, one of the following:

1. Refund of the purchase price paid by buyer or user for product bought, or
2. Replacement of the product used

To the extent allowed by law, the Company shall not be liable and any and all claims against the Company are waived for special, indirect, incidental, or consequential damages or expense of any nature, including, but not limited to, loss of profits or income. The Company and the seller offer this product and the buyer and user accept it, subject to the foregoing conditions of sale and limitation of warranty, liability and remedies.

Disclaimer: Always refer to the label on the product before using Helena or any other product.

MATERIAL SAFETY DATA SHEET UPDATES AVAILABLE AT WWW.GREENBOOK.NET 1

FYFANON 8 LB. EMULSION

Helena Chemical Company
PH: 901-761-0050
CHEMTREC: 800-424-9300
Effective Date: 05-JAN-2005
Product: FYFANON 8 LB. EMULSION

I. IDENTIFICATION

Chemical Name: MALATHION
Chemical Family: ORGANOPHOSPHATE PESTICIDE
Formula: C10H19O6PS2, ACTIVE INGREDIENT.
Synonyms: 8 LB. MALATHION
CAS Number: SEE INGREDIENT STATEMENT, SECTION III.
EPA Number: 5905-250

II. PHYSICAL DATA

Boiling Point: 290 TO 300 DEG F.
Freezing Point: <0 DEGREES C.
Spec Gravity: 1.180 GMS/CC
Vapor Pressure: 10 MM HG
Vapor Density: 3.6
Solubility: 0.01%
Volatiles: 35-40%
Evaporation: NOT ESTABLISHED
Melting Point: NOT APPLICABLE
Appearance: CLEAR/YELLOW LIQUID, CHARACTERISTIC ODOR

III. INGREDIENTS

Material	CAS Number	Percent	TLV	Hazard
MALATHION	00121-75-5	81.43	10 MG/M3	MODERATELY TOXIC
PETROLEUM DISTILLATES		10.57	100 PPM (SKIN)	SKIN & EYE IRRITANT
INERT INGREDIENTS		8.00	NOT ESTABLISHED	NONHAZARDOUS

IV. FIRE AND EXPLOSION HAZARD

Flash Point: >150 DEGREES F.
Autoignition Temp: NOT DETERMINED
Flammable Limit: LOWER -1, UPPER -7
Extinguishing Media: DRY CHEMICAL OR CARBON DIOXIDE FOR SMALL FIRES, WATER SPRAY OR FOAM FOR LARGE FIRES.
Special Fire Fight Proc: WEAR SELF-CONTAINED BREATHING APPARATUS AND FULL FIRE FIGHTING CLOTHING. USE AS LITTLE WATER AS POSSIBLE. DIKE AREA TO PREVENT PESTICIDE RUNOFF. USE SPRAY OR FOG. CONDUCT FIRE FIGHTING UPWIND.
Fire and Expl Hazard: ALERT MEDICAL PERSONNEL TO BE READY TO TREAT FOR PESTICIDE POISONING, SHOULD TREATMENT BE NECESSARY.

V. HEALTH HAZARD

Carcinogen Information: NONE CURRENTLY LISTED.
ACUTE EFFECTS OF OVER EXPOSURE
Swallowing: SLIGHTLY TOXIC; THE ACUTE ORAL LD50 (RATS) 3,210 MG/KG, EPA CATEGORY III.
Skin Absorption: MODERATELY TOXIC; THE ACUTE DERMAL LD50 (RABBITS) >2,020 MG/KG, EPA CATEGORY III.
Inhalation: THE ACUTE INHALATION LC50 (RATS) 7.03 MG/L AIR, SLIGHTLY TOXIC, EPA CATEGORY III.
Skin contact: SLIGHTLY IRRITATING, EPA CATEGORY IV.
Eye Contact: MODERATELY IRRITATING, EPA CATEGORY II.
Chronic Effects: CHOLINESTERASE INHIBITION, OVER-EXPOSURE MAY CAUSE ACUTE EFFECTS.
Other Hazard: NONE CURRENTLY KNOWN.
EMERGENCY AND FIRST AID PROCEDURES
Swallowing: CALL A POISON CONTROL CENTER OR DOCTOR IMMEDIATELY FOR TREATMENT ADVICE. SIP A GLASS OF WATER, IF ABLE TO SWALLOW. DO NOT INDUCE VOMITING UNLESS TOLD TO DO SO BY A POISON CONTROL CENTER OR DOCTOR. DO NOT GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON.
Skin: REMOVE CONTAMINATED CLOTHING AT ONCE. WASH SKIN THOROUGHLY WITH SOAP AND WATER OR RINSE WITH CLEAN WATER FOR 15 TO 20 MINUTES. OBTAIN MEDICAL ATTENTION IMMEDIATELY.
Inhalation: MOVE TO FRESH AIR. IF NOT BREATHING, CALL 911 OR AN AMBULANCE, THEN GIVE ARTIFICIAL RESPIRATION, PREFERABLY MOUTH TO MOUTH. CALL A POISON CONTROL CENTER OR DOCTOR FOR FURTHER TREATMENT ADVICE.
Eyes: FLUSH EYES WITH WATER FOR 15 MINUTES, HOLDING EYELIDS OPEN. REMOVE CONTACT LENSES, IF PRESENT, AFTER THE FIRST 5 MINUTES, THEN CONTINUE RINSING. CALL A POISON CONTROL CENTER OR DOCTOR FOR TREATMENT ADVICE.
Notes to Physician: FYFANON 8 LB. EMULSION IS AN ORGANOPHOSPHATE PESTICIDE. THIS PRODUCT MAY CAUSE CHOLINESTERASE INHIBITION. ATROPINE IS ANTIDOTAL. 2-PAM MAY BE EFFECTIVE AS AN ADJUNCT TO ATROPINE.

VI. REACTIVITY

Stability: Stable
Conditions to Avoid: CONTACT WITH IRON AND STRONG ALKALIES AND STORAGE ABOVE 120 DEGREES F.
Polymerization: Will Not Occur
Conditions to Avoid: NONE CURRENTLY KNOWN
Incompatibility material: IRON, STRONG ALKALIES, AND STRONG OXIDIZERS.
Hazardous Combustion: THERMAL DECOMPOSITION MAY PRODUCE ISO-MALATHION, HYDROGEN SULFIDE, SULFUR, OXIDES OF CARBON, AND PHOSPHORUS.

VII. SPILL OR LEAK PROCEDURES

Spill or Leak Proc: ABSORB IN CLAY OR SODA ASH. SWEEP UP AND PLACE IN WASTE DISPOSAL CONTAINER. TREAT CONTAMINATED AREA WITH FULL-STRENGTH LIQUID CHLORINE BLEACH. LET STAND FOR 15 MINUTES, AND REPEAT PROCEDURE. FLUSH AREA WITH WATER.
Waste Disposal Method: THIS MATERIAL MUST BE DISPOSED OF ACCORDING TO FEDERAL, STATE, OR LOCAL PROCEDURES UNDER THE RESOURCE CONSERVATION AND RECOVERY ACT.

VIII. SPECIAL PROTECTION INFORMATION

Respiration: USE ONLY NIOSH/MSHA CARTRIDGE TYPE RESPIRATOR APPROVED FOR ORGANOPHOSPHATE PESTICIDE VAPORS.
Ventilation: LOCAL EXHAUST SUFFICIENT.
Gloves: IMPERVIOUS
Eyes: CHEMICAL SPLASH GOGGLES.
Other: EMERGENCY SHOWER, EYE WASH STATION, IMPERVIOUS APRON AND FOOTWEAR.

IX. SPECIAL PRECAUTIONS

Special precaution: KEEP OUT OF REACH OF CHILDREN. DO NOT STORE WITH FOOD, FEED, OR OTHER MATERIAL TO BE USED OR CONSUMED BY HUMANS OR ANIMALS. DO NOT CONTAMINATE WATER SUPPLIES, LAKES, STREAMS, OR PONDS. STORE IN A SECURE, DRY, WELL-VENTILATED AREA, SEGREGATED FROM OXIDIZERS AND INCOMPATIBLE MATERIALS. PROTECT FROM MOISTURE.
Other precaution:
A) RCRA HAZARDOUS WASTE NUMBER: NOT LISTED
B) SARA TITLE III, SECTION 313: MALATHION (81.43%), 01/01/95
C) SARA THRESHOLD PLANNING QUANTITY: NOT LISTED
D) CERCLA REPORTABLE QUANTITY: 12.5 GALLONS
E) 49 CFR 172.101, APPENDIX A: HAZARDOUS SUBSTANCE
F) 49 CFR 172.101, APPENDIX B: MARINE POLLUTANT

X. SHIPPING INFORMATION

Shipping name: RQ, ORGANOPHOSPHORUS PESTICIDES, LIQUID, TOXIC, (95% MALATHION), 6.1, UN 3018, PG III "ERG #152"
Hazard Class: KEEP FROM FOOD (6)
Identification No: UN 3018
Labels Required: KEEP FROM FOOD (6)
Placarding: KEEP FROM FOOD (6)
Freight Class: INSECTICIDES, AGRICULTURAL, LIQUID, NOIBN (NMFC ITEM 102120, CLASS 60)

Chemical Name	Equivalent R.Q.
MALATHION	100 LB/(45.4 KG)

XI. GENERAL PRODUCT INFORMATION

National Fire Protection Association Rating: (Rating level: 4-Extreme, 3-High, 2-Moderate, 1-Slight, 0-Minimum)
Health: 2
Fire: 2
Reactivity: 0
S.A.R.A. Title III Hazard Classification: (Yes/No)
Immediate (Acute) Health: Y
Delayed (Chronic) Health: N
Sudden Release of pressure: N
Fire: Y
Reactive: N

Mail inquiries to: 225 Schilling Blvd., Suite 300 Collierville, TN 38017
Helena Chemical Company believes that the data contained herein is factual. This data is not to be taken as a warranty or representation of legal responsibility. It is offered solely for your consideration, investigation and verification. VID 1.6.05

LS Consulting

From: LS Consulting [lsconsulting@oh.rr.com]
Sent: Friday, February 29, 2008 5:48 PM
To: Robert Roogow (rroogow@iirb.com)
Subject: AHE55 Protocol Tracked Revisions and SOP update
Attachments: AHE55 Protocol TF 2-27-08 rev 2-29-08.doc

Robert,

Attached find the tracked revisions to the AHE55 protocol. Of course the TOC looks a mess with an added section. I think I captured the changes you and I discussed. If not, please call me with your comments.

In re the SOPs, the task force believes it best if we include the references to specific SOPs. I've prepared a list of all SOPs cited in the protocol and requested copies of these from the AHETF QA officer. Quite a few are new or modified and still require signature. As soon as I receive the copies, I'll forward to you in pdf. Those requiring signature will be signed over the weekend by appropriate AHETF officers and forwarded to you on Monday. I hope this works for you and understand it is necessary for you to be able to review the SOPs and have signed copies before the board review of the protocol.

Call or email me if you additional information, have questions or additional revision suggestions.

Larry

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, OH 44060
440/255-1954

AGRICULTURAL HANDLERS EXPOSURE TASK FORCE (AHETF)

STUDY No. AHE55

Study Title: Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

PROTOCOL AUTHORIZATION

Read and Approved by:

AHETF Sponsor Representative: David R. Johnson, Ph.D.

Signature _____

Date _____

Study Director: Larry D. Smith, Ph.D.

Signature _____

Date _____

TABLE OF CONTENTS

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1.0 GENERAL INFORMATION

1.1 Study Title

Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

1.2 Study No. AHE55

1.3 Objective

The objective of this study is to develop data to determine the potential exposure for workers making closed cab airblast applications.

1.4 Timeline

Proposed Experimental Start Date: August, 2008

Proposed Experimental Termination (Field Phase) Date: April, 2009

Proposed Experimental Termination (Analytical Phase) Date: October, 2009

Proposed Final Report Issue Date: December, 2009

1.5 Good Laboratory Practice

This study will be conducted in compliance with the US EPA FIFRA Good Laboratory Practice (GLP) Standards (40 CFR 160) and will adhere to applicable AHETF and/or field facility standard operating procedures (SOPs) and field work practices.

1.6 Pesticide Assessment Guideline

This study is based upon EPA's guidance documents for dermal and inhalation exposure measurement under Series 875: Occupational and Residential Exposure Test Guidelines. Data reporting will follow the requirements defined in these guidelines.

1.7 Institutional Review Board

Independent Investigational Review Board (IIRB)
6738 West Sunrise Blvd. Suite 102
Plantation, FL 33313
Telephone: 954-327-0778
E-mail: info@IIRB.com

1.8 Testing Facility, Sponsor's Representative and Sponsor

Agricultural Handlers Exposure Task Force, LLC
c/o David R. Johnson, Ph.D.
1720 Prospect Dr.
Macon, MO 63552
(660) 395-9590
davejohn@marktwain.net

1.9 Study Director

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, OH 44060
(440) 255-1954
lsconsulting@oh.rr.com

1.10 Principal Field Investigators

Principal Field Investigators may include:

Brian Lange
Access Research and Consulting, Inc.
4720 W. Jennifer Ave., Suite 106
Fresno, CA 93722
Principal Field Investigator:
Phone: 559-277-5272
brian@accessrc.com

Tami Belcher
Grayson Research, LLC
1040 Grayson Farm Road
Creedmoor, NC 27522
Phone: 919-528-5508
tbelcher@graysonfarm.com

Aaron Rotondaro
Paragon Research Services, Inc.

6773 Woodcliff Circle
Zionsville, IN 46077
Phone: 317-733-1243
arotondaro@indy.rr.com

During the consent process, each study participant will be informed of which of the above researchers will be involved with monitoring his/her exposure.

1.11 Field Facilities

Southeast Ag Research
86 Jim Moore Rd.
Chula, GA 31733
Phone: 229-386-8989
smith@seagr.com

1.12 Principal Analytical Investigator and Analytical Facility

To be determined and amended to the protocol prior to initiation of the field phase of the study.

1.15 Quality Assurance Unit

Compliance Assessment and Training, Inc.
Randy Fuller
2309 Patton Ct.
Lexington, KY 40509
Phone: 859-264-8844
randyfuller@windstream.net

2.0 ETHICAL CONSIDERATIONS

This study will be conducted in accordance with EPA's final regulation published at 40 CFR Part 26 that establishes requirements for the protection of subjects in human research. The protocol, informed consent form, and other required documentation for this study will be approved by an institutional review board (IRB) and submitted to the EPA as required by 40 CFR 26.1125. The report of the completed research is subject to 40 CFR 26.1303 requirements to document its ethical conduct.

The proposed research described by this protocol, the informed consent form, and all recruitment materials, such as handouts or visual aids, shall be reviewed and approved by Independent Investigational Review Board (IIRB) of Plantation, Florida. Complete records of the IRB review as required by 40 CFR 26.1125 will be submitted to EPA for review along with this protocol and other documents.

Researchers that participate in the study and interact with study participants must undergo ethics training (SOP AHETF-1.B). The training shall include successful completion of the course from the National Institutes of Health (NIH; Human Participant Protections Education for Research Teams) and/or the Basic Collaborative IRB Training Initiative Course (CITI; The Protection of Human Research Subjects). Copies of the certificates of completion for the ethics courses will be submitted to the IRB and stored in the respective personnel files (maintained by the AHETF and all contract facilities.)

2.1 Inclusion and Exclusion Criteria

AHETF has established the following inclusion and exclusion criteria for this closed cab airblast application study.

Participants in this study must meet the following inclusion criteria;

- Be freely willing to participate and to understand and sign the consent form
- Handle pesticides as part of their job
- Be trained in safe pesticide handling practices in accordance with the Worker Protection Standard (WPS), or be exempt from such training
- Have recent experience (within the last year) with making airblast applications using closed cab tractors and airblast sprayers (including the particular equipment to be used)
- Be at least 18 years old with a government-issued ID to verify age
- Consider themselves to be in good general health with no medical conditions that could impact their ability to participate in the study
- Be willing to follow all label and WPS requirements

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In addition, potential subjects who meet the following exclusion criteria will not be allowed to participate in this study:

- Are pregnant females
- Are nursing mothers
- Normally wear personal protective equipment (PPE) that is not required by the label, such as chemical-resistant clothing
- Don't understand Spanish or English
- Are employed by a pesticide manufacturer or a contractor to AHETF (except employees of the Local Site Coordinator)

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2.2 Remuneration of Subjects

During recruitment, workers will be offered an opportunity to take part in a group meeting with the Study Director or other designated member of the

study team (but without the workers' supervisors) to learn about participating in this study (Section 6.2). No remuneration is offered for this introductory meeting. Workers who are still interested will attend a private meeting with a researcher who will obtain the informed consent of the worker (Section 2.7). Workers will be paid $20 for their attendance right after the consent meeting, whether or not they decide to participate in the study. Workers who decide to participate in the study will be paid an additional $80 each time they suit up (i.e., put on the long underwear) to participate in the study. Usually, workers will participate in the study on only one day unless their participation is terminated due to weather or other unexpected occurrences. The additional $80 is provided in cash at the end of the monitoring period or at the time the volunteer withdraws from the study. All workers who participate will receive the payment, even if they withdraw or their participation is terminated by the study team.

2.3 Risks to Subjects

Six kinds of risks are associated with the conduct of the current exposure monitoring study. These are:

- The risk of heat-related illness
- The risk of exposure to surrogate chemicals
- The risk associated with scripting of field activities
- Psychological risks
- The risk of exposure to detergents
- The background risk of injury associated with agricultural work

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In this study risks to subjects are classified as "greater than minimal", primarily since agricultural work is considered a high risk occupation where the likelihood of harm or discomfort is greater than what is encountered in ordinary daily life. In particular, this study involves the operation of tractors and airblast sprayers which present risks of accidents and physical injury, as well as the use of chemicals (pesticides, fertilizers, additives, etc.) which presents a risk of adverse health effects. In addition, AHETF believes the risk of heat-related illness (resulting from wearing an extra layer of clothing to trap chemical) will at times be increased due to study participation. AHETF has adopted an extensive program to minimize these risks. All of the risk minimization procedures, as described in AHETF SOPs, will be followed during the conduct of the study.

2.3.1 Risk of Heat-Related Illness

This study involves the application of liquid sprays to citrus crops using airblast equipment and tractors with a closed cab. All airblast applications will be made outdoors and some locations and dates are likely to result in hot and/or humid conditions. AHETF expects most

tractors to be air conditioned, thus reducing the potential for heat-related illness. AHETF will not accept tractors without properly operating air conditioners. Researchers will inquire of the participants whether or not the air conditioner units function in their tractors. All participants in the study will be wearing an extra layer of clothing (i.e., long underwear under their WPS-required clothing) that they would not normally wear under such conditions. For these reasons, the study will likely involve an increased risk of heat-related illness due to study participation. AHETF researchers will therefore be vigilant in following the extensive educational and monitoring procedures designed to minimize the risk of heat-related illness that are detailed in SOP AHETF-11.G.

Since heat-related illness may occur during the conduct of the study, Study Directors shall have first aid training that includes recognition of signs and symptoms of heat-related illness. A copy of the certificate of completion of this training will be included in the Study Director's personnel file, maintained by the AHETF.

The following procedures will be followed by researchers to minimize the risk of heat-related illness in study participants:

- Ensure plenty of water and sports drinks are available for the workers.
- During worker orientation immediately before participation in the study, remind the workers of the risk of heat stress, suggest they drink some water before they start work, and let them know how/where they can get water during the monitoring period.
- Urge workers to drink water during the monitoring period and remind them that thirst does not give a good indication of how much water a person needs to drink.
- Observe workers during the monitoring period and be aware of the signs and symptoms of heat-related illness.
- Require workers to take rest breaks when early signs or symptoms of heat illness are present.
- Monitor the heat index (based on air temperature and relative humidity) at least hourly whenever ambient temperature is at or above 70 ºF.
- Stop the participant activity when the heat index (adjusted for direct sunlight, if applicable) reaches 120º F and resume only when more favorable conditions exist.
- Have a medical profession on site to observe for signs of heat-related illness
- Know the location of the nearest medical facility

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AHETF anticipates that applicators who participate in the study will spend the bulk of their time in the closed cab tractor; driving the tractor and making applications. This is a "sedentary" activity as defined by the North American Free Trade Association (NAFTA) Technical Working Group on pesticides (1998), so physical exertion is low which will reduce the likelihood of heat-related illness. However, each participant will be required to spray at least three loads of pesticide spray, so there will also be some time spent at a mixing/loading site waiting while another (non-study) worker prepares the next load. During these times, the study participant may exit the cab and be exposed to ambient temperatures and humidity which will increase the likelihood of heat-related illness. Applicators may also exit the cab periodically to adjust or repair equipment, if that becomes necessary.

Since workers may exit the cab, AHETF will monitor ambient conditions outside the cab to determine the heat index and base monitoring decisions on the external heat index. Workers in closed cabs that are not air conditioned will be subject to the heat index cutoff of 120º F as measured outside the cab (note that this situation reflects shaded conditions so the heat index is not adjusted for sunny conditions). However, when a subject is inside an air conditioned closed cab, the external heat index will not be applicable to that subject and exposure monitoring will not necessarily stop if the heat index cutoff is reached or exceeded. A worker will be allowed to exit the cab for short periods of time even if the heat index cutoff is exceeded; however, if the duration of exiting becomes prolonged (more than 30 minutes), the Study Director or other researcher shall stop the monitoring and/or move the worker to a cooler environment until monitoring can be resumed. For example, a worker who exits an air conditioned cab to adjust the airblast sprayer (e.g., nozzles, deflectors, pressure, etc.) might spend only a few minutes doing so and monitoring would not need to be stopped. On the other hand, if a worker exits to make a repair of the equipment, and it takes more than a half-hour, researchers will stop the monitoring and/or require the worker to move into a cooler environment (e.g., back into the air conditioned cab or into a cooler building).

In addition to the procedures discussed above, it is possible that some monitoring will take place at night or early in the morning to avoid excessively hot and humid conditions. Discussions with orchard airblast applicators in Florida and Georgia (July, 2007) indicate this is often preferred by workers since winds tend to be lower than during the day and temperatures tend to be cooler. AHETF will encourage this practice when daytime conditions are expected to approach the heat index cutoff of 120º F (adjusted for direct sun, if applicable).

2.3.2 Risk of Exposure to Surrogate Chemicals

The short duration of study participation for a subject (generally only one day) limits the risk of toxicity from surrogate chemicals to acute toxic effects (i.e., the potential for chronic effects is negligible). The active ingredients proposed for use in this study have been reviewed to determine the relative acute toxicity risks and status of reregistration at EPA. This study could involve either of two active ingredients: carbaryl or malathion.

The pesticide products containing these active ingredients and potentially used in this study are currently registered for airblast applications to citrus crops. AHETF will only monitor workers making applications in accordance with all label and Worker Protection Standard (WPS) requirements. Margins of Exposure (MOEs) are presented below for the highest amount of active ingredient that will be handled in this scenario (100 lb ai/day). For each of the active ingredients that may be used in this scenario the calculated MOEs greatly exceeded the required MOE for both the individual dermal and inhalation routes of exposure, as well as for the combined exposure, and their use is acceptable for this scenario.

Margins of Exposure for Closed-cab Airblast Application:

	Carbaryl	Malathion
Max. Daily Amount Handled	100 lb ai/day	100 lb ai/A
Dermal MOE	**3,308**	**4,885**
Inhalation MOE	**1,719**	**40,313**
Combined MOE	**1,130**	**4,400**

Level of concern (LOC) dermal = 100
LOC inhalation = 100 (carbaryl) or 1000 (malathion)
LOC combined = 100

The potential surrogates are listed below. All include minimal PPE requirements, especially the need for only a single layer of clothing. A summary of the signs and symptoms of acute overexposure to these products is presented in the following table. Additional detailed information is presented in the Product Risk Statements for these products (attached to the Informed Consent Form).

Product	Signal Word	Acute Toxicity Summary
Sevin® brand 80WSP Carbaryl Insecticide	CAUTION	• Slight eye irritation • Low toxicity for oral, dermal, and inhalation routes • Cholinesterase inhibition
Sevin® brand XLR Plus Carbaryl Insecticide	CAUTION	
Sevin® brand 4F Carbaryl Insecticide	CAUTION	
Fyfanon® 8 lb. Emulsion	CAUTION	• Moderate skin irritation • Moderate eye irritation • Possible allergic skin reactions • Low toxicity for oral, dermal, and inhalation routes • Cholinesterase inhibition
Fyfanon®	CAUTION	
Malathion 8-E	CAUTION	• Moderate eye irritation • Slight skin irritation • Possible allergic skin reaction • Low toxicity for oral, dermal, and inhalation routes • Cholinesterase inhibition
Gowan Malathion 8 Flowable	CAUTION	

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AHETF will make an effort to select growers who would normally be using one of these products regardless of their participation in the monitoring study. However, some growers might agree to use one of the listed surrogate products as a substitute for their usual product. In all cases, AHETF will ensure the workers are informed of the risks associated with the specific surrogate product during the informed consent process and prior to participation by reviewing the product label with the worker. In addition, attached to the informed consent form will be a Product Risk Statement that details the signs and symptoms of overexposure for the specific product that each worker will handle. This risk statement must be understood and signed by the subject during the consent process.

The risk of acute toxicity will be minimized by reminding workers of safe handling practices prior to participation in the study, ensuring that worker clothing meets WPS requirements prior to participation, and enforcing the use of label-specified PPE (especially the use of gloves outside the cab if contacting contaminated surfaces) during participation.

For this application study, participants will only be exposed to product that has been diluted in water. The closed cab will likely provide

significant protection from both dermal and inhalation exposure. In addition, dermal exposure potential will be reduced since the long underwear will intercept chemical that might otherwise reach the subject's skin. Therefore, the likelihood of acute overexposure to the test substance during this study is expected to be very low.

2.3.3 Risk Associated with Scripting of Field Activities

AHETF may script certain participant activities to achieve diversity in some factors that might have an impact on exposure potential for a scenario. In particular, for this closed cab airblast application study scripting may be needed to ensure that at least three loads are handled or that certain amounts of active ingredient are handled. However, workers will not be asked to use equipment they do not have recent experience with (i.e., within the past year).

In order to ensure all MUs involve handling at least three loads, AHETF may ask some workers to use a smaller tank size or a higher spray volume than they would normally select. This might lead to a slightly longer work period for those workers which may increase the risks of acute toxicity to the surrogate chemical and of heat-related illness. This type of scripting is only likely for MUs involving the lower amounts of active ingredient handled (AaiH) in the study, such as 5 to 9 or 10 to 17 pounds of AaiH (Section 7.8). If spray volume is increased, the worker's exposure would be to a more dilute spray solution. The increased work period might increase the risk of heat-related illness, but this scripting is likely to result in work periods of only about 4 hours. In summary, scripting to ensure at least three loads are handled involves MUs with relatively low chemical exposure and relatively short work days, so this type of scripting is not likely to result in increased risk.

In order to achieve diversity in AaiH at the high end, AHETF may ask some workers to use larger tank sizes or a lower spray volume per acre than they would normally select. These changes might result in longer work periods and greater chemical exposure than would otherwise occur and this may increase the risks of acute toxicity to the surrogate chemical or heat-related illness. With regard to the increased risk of heat-related illness, this will primarily depend on local environmental conditions. For these MUs, researchers must be extra vigilant in following the guidance discussed above for minimizing the risks of chemical exposure and heat-related illness. Therefore, AHETF believes the risk of chemical toxicity for this study is low relative to other approved label uses.

2.3.4 Psychological Risks

Participating in AHETF exposure monitoring studies involves activities that are unusual and might cause subjects psychological distress. These include:

- Performing an over-the-counter pregnancy test prior to participation (females only)
- Allowing a researcher to assist with removing long underwear

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Minimizing the risk of psychological harm related to pregnancy tests involves providing a private place for women to take the test and following procedures outlined in SOP AHETF-11.D to ensure the confidentiality of a positive result. Minimizing the risk of embarrassment during undressing involves providing a private dressing area and ensuring a worker of the same gender will be available to assist in the process.

2.3.4 Risk of Exposure to Detergents During Face/Neck Wipe and Hand Wash Sampling

A very dilute detergent solution (0.01% v/v Aerosol® OT in water) is used as a surfactant for face/neck wipes and hand washes for all MUs. The only variation between MUs is in the duration of exposure since longer work periods or frequent eating breaks can lead to multiple hand washes and/or face/neck wipes. This surfactant is in a very dilute solution and its use represents a very short exposure period, but the undiluted surfactant causes mild to moderate skin and eye irritation in animals. This risk is minimized by making fresh solutions shortly before monitoring, being careful to avoid accidental exposure to the eyes during face/neck wipes, and having an eye rinse station on hand in case of an accidental exposure.

A long history of using this mild detergent solution in pesticide exposure monitoring studies indicates the likelihood of skin or eye irritation is negligible.

2.3.5 Background Risk of Injury Associated with Agricultural Work

Agriculture remains one of the country's most dangerous occupations (i.e., farm occupations, see Bureau of Labor Statistics). It perennially ranks in the top ten occupations measured by fatality rate (on-the-job deaths divided by total number of workers) or injury/illness rate. The most common risks for serious injury to farmers are vehicular accidents (especially tractor rollovers, but also accidents while driving machinery on roads) and entanglement with moving parts of farm

machinery. Farm workers are also commonly exposed to a variety of chemical products that present increased risks compared to the general public. These include pesticides, fertilizers, solvents, lubricants, fuels, etc.

For this closed cab airblast application study, the risk of injury will involve the use of mechanical equipment for all MUs (the tractor as well as the airblast sprayer) and for some MUs will likely involve the use of chemicals in addition to the AHETF surrogate chemical, such as spray adjuvants or other pesticide products. These risks are discussed below.

This study will require workers to utilize two pieces of equipment: a closed cab tractor and an airblast sprayer. AHETF will have very little input on the choice of equipment that workers utilize during exposure monitoring since it is generally dictated by the crop involved and the size of the farm or operation. However, AHETF will require that all participants have experience operating the particular equipment they will utilize in the study. Workers will operate their usual tractor unless researchers determine the closed cab is not intact. If that happens, the worker can use another suitable tractor with which he has experience. Workers will use their usual sprayer unless AHETF requests a different tank size. If that happens, the worker can use a more suitable sprayer with which he has experience, but if no such sprayer is available another worker will be selected who has the necessary experience with that equipment. These practices are designed to ensure the risk of injury from equipment is not increased by asking a worker to use equipment he is not familiar with.

Growers often choose to include chemicals other than the pesticide product in their tank mixes, such as anti-foam agents, spreaders, stickers, other pesticides, or fertilizers. This is likely to be the case during this study, but it is impossible to know in advance, since some decisions are made at the last moment depending on agronomic conditions. AHETF generally is not concerned by the use of such “tank mix partners” as long as they are legal uses, don’t interfere with chemical analysis of the AHETF surrogate pesticide being applied, and do not require the worker to wear any additional PPE. Prior to allowing the use of tank mix partners AHETF researchers will ensure that none of these situations exists. Since AHETF does not ask that additional products be added, participation in the study does not result in an increase in the chemical toxicity risk associated with tank mix chemicals above what would normally be experienced by the worker. Nevertheless, a researcher will review the label precautions for all tank mix products with the worker prior to their handling the products. This discussion will be documented by the researcher and ensures the

workers are informed of the risks associated with these tank mix products.

In summary, this study will likely involve a risk of physical injury based on the nature of the agricultural work involved and possibly an increased risk of heat illness. The following practices, designed to minimize these risks and respond to injuries, will be followed during this study:

- Selecting only experienced pesticide handlers
- Requiring experience operating the equipment to be used
- Reminding workers of safe chemical handling practices
- Identifying nearby hospitalization facilities in case of emergency
- Monitoring the heat index and stopping the study if conditions warrant
- Providing transportation to medical treatment and covering the costs of treatment
- Having a medical professional on site to observe the workers and provide urgent care
- Observing study participants throughout the monitoring period
- Ensuring that all tank mix products are used according to approved label (s) and that no additional PPE is required.

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2.4 Benefits

The risks and benefits of the study described in this protocol will be reviewed with potential participants during the consenting process. There are no personal benefits to the study participants. Growers who allow the study to be conducted using their equipment, crops and facilities will be reimbursed for the pesticides used for the study. While this is beneficial to the grower, it is considered a minor benefit when compared to the costs of running their businesses. The AHETF member companies will accrue the advantage of fulfilling their regulatory data requirements and improving regulatory risk assessments, while substantially reducing the number of human subjects necessary to conduct similar studies by individual registrant companies.

Data from the AHETF exposure monitoring program has the potential to improve the ability of EPA and other regulatory agencies to accurately assess potential occupational risks associated with spraying pesticides using airblast equipment and closed cab tractors. The knowledge obtained from the monitoring program is generalizable and will be used to assess risks to new pesticides. Knowledge could also be used by EPA to impose stricter safety standards on currently used pesticides, when appropriate. Consequently, the farm community will be better protected and at the same time less likely to be

needlessly deprived of product benefits.

Since data suitable for use in a generic database do not exist for closed cab airblast application workers, society will benefit from data generated by this study from the improved risk assessments resulting from the use of the data by EPA and other regulatory agencies.

2.5 Risk/Benefit Balance

By monitoring exposure to professional agricultural handlers who follow their normal practices, but wear an additional layer of clothing (as an inner dosimeter which traps chemical that penetrates the work clothing), this study presents a greater than minimal risk to participants. The primary risk comes from their employment as an agricultural worker where accidents and chemicals contribute to injury and illness. In particular, this scenario involves the use of mechanical equipment that could cause physical injury and handling chemicals that could cause adverse health effects. However, workers will be experienced with the equipment they will be using and will follow their usual practices while handling pesticides approved for this use pattern.

Participating in this study increases the risk of heat-related illness, but this risk is mitigated by a medical management program which emphasizes prevention measures and guidelines for stopping participation when warranted based on environmental conditions.

In conclusion, the benefit to agricultural workers as a whole and to society in general, in the form of more accurate measurements of potential exposure to pesticides, must be weighed against the risks to participants. Airblast applications are common in both orchard and trellis crops across the country and a wide variety of experts indicated to AHETF that closed cabs are most common and are becoming more common. Therefore, a modern set of data for this scenario will provide a significant benefit to society. This study will contribute directly to that data set. Because AHETF has calculated MOEs which indicate that acute toxicity effects are unlikely, and because there are extensive procedures established to minimize all risks to participants, the likelihood of serious adverse effects is small. Therefore, AHETF believes the risks to study participants from this study are offset by the benefit to society.

2.6 Respect for Subjects

2.6.1 Subject Privacy

The AHETF engages many procedures designed to protect subject privacy during recruitment, consent, study conduct, and maintenance

of study records. The consent form also summarizes important confidentiality issues for subjects. These procedures, summarized below, will be followed during this study.

Initial contact with workers during recruitment will be made without the presence of their employer as described in detail in Sections 2.7 and 6.2 of this protocol. If workers are interested in participating, a private meeting with the Study Director or his/her designee will be used to obtain consent.

Pregnancy tests, required for female participants, must be conducted within 24 hours of the start of the monitoring period. These will be self-administered in a private restroom, but under the supervision of a female researcher. Positive results from pregnancy tests will not be documented or given to a woman's employers or co-workers. If a female volunteer has a positive pregnancy test result, she must withdraw from participation but can do so without stating a reason. Consent forms and all other records associated with the worker will be promptly shredded (SOP AHETF-11.D). Negative results must be confirmed by a female researcher and recorded in the study files.

Certain worker information will be collected during the course of this worker exposure monitoring study. The information collected, such as notes taken by study observers, will not be available to a participant's employer. Most information identifies subjects only by a unique worker identifier. Forms and paperwork that contain personal information (including a worker's name or address) will be kept confidential in a sealed envelope while in the field. After the study is completed, this confidential envelope will be sent to AHETF archives with the other raw data. Unrestricted access to this confidential information is allowed only to the AHETF Administrative Chair (SOP AHETF-6.B).

The information collected in this study may, under certain regulatory circumstances, be given to the U.S. Environmental Protection Agency (EPA) or to state governmental agencies and other countries. Participants in the study will be informed their names will not be disclosed, but that absolute confidentiality cannot be guaranteed because of the need to give information to these parties.

The results of this research study may be presented at meetings or in publications; however, only a unique worker identification number will identify each worker in reports or presentations.

2.6.2 Freedom to Withdraw

The absolute right for subjects to withdraw from the research is the

cornerstone of protection of human subjects. Prospective and enrolled subjects will be informed of their right to withdraw without consequence prior to and during the conduct of the research.

Any volunteer expressing a need or desire to withdraw from the research after exposure monitoring begins will be paid $80 and allowed to return to their normal work duties for their employer. If a participant withdraws while being monitored, the long underwear and air sampling pump will be removed, and the hand and face/neck samples will be collected with the worker's consent. The Study Director will decide whether these samples will be analyzed (SOP AHETF-8.K).

2.7 Informed Consent

The Study Director or designated member of the study team will obtain informed consent from all study volunteers prior to their participation in the study. The consenting process is conducted in a private meeting between the researcher and the volunteer (and possibly other individuals as described below). Depending on the circumstances, consenting may occur several days prior to the study up to the day of the study. In either case the volunteer will be given a copy of the consent form to review at least one day before the consent meeting. The volunteer may invite other persons to be present during the consent meeting. For example, the volunteer may feel more comfortable with a confidant or counselor in the consent meeting with him/her.

Study participation will be limited to English or Spanish speakers. When Spanish speakers are involved, a bilingual researcher will be utilized to translate verbal information presented by the Study Director or designee. Potential participants that have limited reading ability will have the consent form verbally explained in their preferred language (English or Spanish) with an impartial witness present. Witnesses must have no association with AHETF, its member companies, researchers, growers, or workers. Witnesses must have some familiarity with farming and will be recruited from any appropriate source such as a university, grower association, or other organization. The witness cannot serve as the interpreter or an advisor to the volunteer. The witness will sign the consent form to acknowledge that the study participant apparently understood the information presented to him/her.

During the private consent meeting the worker will be provided with a full explanation of the study, its requirements, any potential risks, and its likely benefits. Workers will be informed that the grower or their employer will be reimbursed for the product used in the conduct of the study on their farms. Workers will be advised of their right to withdraw from the study at any time and for any reason without jeopardizing their normal position with their employers. Each volunteer will be provided a copy of the supervisor's signed

Employer's Cooperation Statement (in the worker's preferred language) that states they will not suffer any consequence if they decide to participate or not and they will receive their usual pay for the day when the study is conducted. The volunteer will be informed that he/she will receive the $20 remuneration payment even if he/she decides not to participate.

The volunteer will be provided information about the risk of the particular product he/she will handle, including signs and symptoms of acute overexposure. The product and its risks will be identified in a Product Risk Statement that is an attachment to the consent form. The participant must read, understand, and sign and date the attachment. Appropriate sections of the product label and Material Safety Data Sheet will be discussed by the person conducting the consent meeting and made available for review by the volunteer. WPS requirements, especially proper use of clothing, personal protection equipment, and cleaning facilities will be discussed.

The Study Director or designated member of the study team will discuss the germane aspects of the AHETF medical management plan with the prospective participants. Information will be provided about the risk of heat stress, including signs and symptoms, and ways to prevent it.

The IRB-approved consent form will be presented in the preferred language (English or Spanish) of the volunteer. All sections of the consent form including the test substance Product Risk Statement will be discussed in detail.

During the discussions with potential participants, ample time will be provided for questions and any additional information or clarification that is requested will be provided. When the Study Director or designated member of the study team is satisfied that the volunteer understands the requirements and risks of the study, and if the worker still wants to participate, he/she will be asked to sign and date the informed consent form and the Product Risk Statement. The member of the study team conducting the interviews (and witness, if applicable) will also sign the consent form and provide a copy of the signed form (and signed attachments) to the worker. The worker will be informed of the impending date of the study and paid $20 for their participation in the private meeting.

When the pool of available worker volunteers at a site, or a particular citrus grove, exceeds the number of MUs required, a simple random selection of equivalent participants will be made. All potential participants will be informed of the possibility of not being selected for this reason. Volunteer workers who decide against participation or who are not selected will be paid $20 for meeting with the study team member and released to resume their normal activities.

In all situations, if the AHETF interviewer is not comfortable that the worker

fully understands the discussions and the contents of the consent form, the worker will be excluded from consideration to participate in the study. This will be ascertained by providing repeated opportunities to ask questions and by asking questions of the potential volunteers that would require a response that indicates understanding of key issues for all sections of the consent form. These responses will be documented and if necessary the person conducting the consent meeting will re-explain topics until the volunteer demonstrates an appropriate understanding.

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2.8 Study Procedures

During the consenting process the Study Director or designated researcher will inform each volunteer of the procedures used during the study. Volunteers will be informed if they participate in this study, they will do the following:

1. Provide their name and years of experience making closed cab airblast applications.
2. Confirm whether they have received pesticide safety training or are exempt from pesticide safety training.
3. Allow researchers to measure and record their height and weight.
4. Allow researchers to record their gender, age, and preferred language.
5. Allow the researcher to take notes on the discussions during the informed consent session(s).

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Volunteers will also be informed about the procedures to expect on the day of their participation in the study. The Study Director or designated researcher will explain the following procedures to each volunteer during the consenting process. Participants must do the following on the day of the study:

1. Arrive at the study site approximately 1 hour before starting their work.
2. Wash their long-sleeved shirt and long pants before participating in the study to remove any residues of the product we are studying.
3. Bathe or shower the evening or morning before participating in the study to remove any residues of the product we are studying.
4. Wear all personal protection equipment required by the product label (see Product Risk Statement).
5. Work about 4 to 8 hours applying a commercial pesticide according to their normal practices and spray at least 3 loads. Participants will apply the pesticide according to the product label.
6. Wear new long underwear underneath their long-sleeved shirt and long pants. Participants may wear their choice of personal undergarments under the long underwear. The long underwear will be supplied by AHETF and collected at the end of the day. Participants will be asked to dress and undress with the assistance of a researcher of the same sex. A changing area will be provided for privacy. When participants complete their work in the study, they will put on their own clothes and return to

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their normal work. Participants will be informed there is a risk of becoming overheated and suffering heat illness.

7. Have a tube attached to their shirt collar and connected to a portable air-sampling pump on a belt worn around the waist. Participants will be informed that the pump may be uncomfortable or annoying.
8. Have their face and neck wiped with gauze pads moistened with a mild detergent and water mixture. This will be done before they eat anything, any time they would normally wash their face, and at the end of the workday. Participants will be informed there is a risk of eye or skin irritation from the detergent and water.
9. Have their hands washed in a mild detergent and water mixture. This will be done before they eat anything, any time they would normally wash their hands (such as before using the toilet), and at the end of the day. Participants will be informed there is a risk of skin irritation from the detergent and water.
10. Allow researchers to watch all of their work activities and take notes on what they do.
11. Allow photographs and video recordings to be taken. Participants will not be photographed or video recorded while dressing or undressing. AHETF will own all rights to the photos and videos and may use them for any purpose.

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2.9 Post-Exposure Follow-Up

During the consenting process each volunteer will be provided the opportunity to request a summary of their personal results from the study. This will require the worker to provide a name and address (mail or e-mail). The results will include the distribution of chemical exposure among the various body areas measured so the worker can be aware of where most dermal exposure occurs. Results are typically available six to nine months after monitoring occurs. The personal information related to this follow-up will be retained in the confidential envelope described above (SOP AHETF-6.B).

Just prior to the completion of the worker's participation in the study, a researcher will remind the participant he/she should bathe or shower as soon as practical and that they have received a copy of the signed consent form with phone numbers for reporting any health changes they think might be related to participation in the study. Post-study inquiries will be forwarded to the Study Director who will deal with the situation as appropriate and notify AHETF management (SOP AHETF-11.B).

3.0 SITE OF THE FIELD PHASE OF THE STUDY

The site for the field phase of the study will be commercial citrus groves in Polk and Hillsborough counties in Florida. These counties were selected because Polk is

highest in orange production and Hillsborough is an adjacent county accessible to major transportation routes. In addition, AEHTF has already expended resources to discuss airblast applications with the handler community in Florida citrus (Bruce, et. al. 2007) and identified a suitable Local Site Coordinator. These counties are typical of citrus producing areas of Florida that utilize conventional closed cab airblast equipment to maintain the groves. The counties are also adjacent to citrus producing counties that can be contacted if suitable test conditions cannot be found in these two.

Exposure monitoring will be conducted in at least three citrus groves and require at least three citrus growers within the identified counties.

Researchers will identify eligible growers using a random method as described below.

The primary considerations for site selection will be the availability of citrus crops sprayed with airblast equipment, suitable growers that are willing to use the AHETF surrogate compounds and are willing to participate in the study, and the availability of a Local Site Coordinator with experience conducting similar studies and a familiarity with agricultural practices in the area. Full details of the site selection process and actual sites will be recorded in the study file.

4.0 ELIGIBLE GROWER POOL SELECTION

4.1 Use of Local Resources to Identify Potential Eligible Local Growers

AHETF researchers will contact local resources from each of the following categories in Polk and Hillsborough counties in Florida:

- Local Site Coordinator (LCS)
- Commercial Applicator Firms that service citrus groves
- University Agricultural Researchers / County Extension Agents
- Crop Consultants (e.g., pest control advisors or commercial applicators) that service citrus groves
- Chemical Dealers or Sales Representatives
- Citrus Grower Associations

The researchers will briefly explain the AHETF Exposure Monitoring Program to the local resources who are then asked for a list of growers in Polk and Hillsborough counties who are commercial citrus producers and might utilize airblast equipment in their operations. The list of growers from all of the resources will be compiled and duplicate names eliminated. All local resource contacts shall be documented in a detailed record that shall be maintained in the study file.

4.2 Random Selection of Eligible Growers

The compiled list of growers from local resources shall be placed in random

order for further consideration. The randomization process will be documented and maintained in the study file.

The growers shall be contacted, one at a time, following the random order, to determine whether the grower is 'eligible' to participate in this study. Researchers making the contacts will briefly explain the AHETF Exposure Monitoring Program including the need for the proper equipment, potential worker volunteers, ethical aspects of the study, and reimbursement for the products they supply for the conduct of the study on their farms. Growers are considered eligible who:

- Are willing to cooperate with AHETF, including the ethical aspects of the research,
- Are commercial citrus producers,
- Spray their crop(s) with conventional airblast equipment with closed cabs,
- Have at least one worker with experience making closed cab airblast applications,
- Are willing to allow AHETF to recruit his/her worker(s) for the study
- Have sufficient acreage so the minimum AaiH stratum can reasonably be handled by a worker in one day, and
- Are willing to use at least one of the surrogate active ingredients listed in the study protocol and agree to be reimbursed only for the products utilized in the course of the study on their farm.

Growers who meet the criteria above but indicate they use commercial applicators to make airblast applications to their crop will tentatively be considered eligible. Those growers will be asked to identify their preferred commercial applicator(s) and researchers will contact them to screen them for willingness to cooperate by providing suitable equipment and workers to spray that specific grower's crop. This step in the procedure ensures that first the crop acreage is identified and then equipment and workers associated with that acreage are identified. The actual workers involved could be the grower himself, the grower's employee, or an employee of a commercial applicator that services that grower.

Each grower identified as eligible (sometimes with an associated commercial applicator) is placed into a working pool and the following information is assembled to allow construction of an efficient MU selection design:

- Crop(s) available, with acreage that might be treated
- Specific location of crop(s) that might be treated
- Description of equipment available (e.g., number, type, and size)
- Surrogate chemical(s) that might be utilized
- Approximate timing of surrogate applications
- Number of workers available
- AaiH those workers might be able to handle in a day

Screening of the growers (in the order of the random list) continues until the pool of eligible growers (and/or commercial applicators) contains at least 10 workers who may potentially volunteer for the study, and at least 2 workers are available for each of the AaiH strata. This pool will include more growers and more workers than are ultimately needed for the study.

This process results in a random sample of eligible growers and, by association, a random pool of potential workers associated with eligible growers. All grower contact discussions and decisions made during this eligibility screening will be documented in a detailed study notebook provided by AHETF or kept in files bearing the study number.

5.0 EFFICIENT MU DESIGN

The Study Director and Local Site Coordinator will assemble the information obtained from the pool of eligible growers to construct a plan to efficiently assign all MUs in the study. Details of the potentially available MUs will be used to identify one configuration of MUs (i.e., growers, chemicals, workers, AaiH, timing) that will result in an efficient study. The efficient configuration will be comprised of a group of at least three growers that are near each other, can provide separate workers for all the five strata of AaiH, utilize some diversity in equipment, and plan to make applications within a narrow time frame. The growers and/or commercial applicators in the chosen configuration provide the pool of workers from which study participants will be recruited.

6.0 PARTICIPANT SELECTION

6.1 Site Inspection

The Study Director and/or Local Site Coordinator shall arrange to visit growers from the pool of eligible growers to confirm the suitability of their operation for the study. In accordance with SOP AHETF-11.B the individual growers will be asked to sign a non-coercion statement (Employer Cooperation Statement) affirming to their workers and AHETF that they will not coerce or unduly influence their workers to either participate or not participate in the study. Growers must also certify that alternate work will be provided on study days for workers who choose not to volunteer; and that the employee's decision to participate or not will have no impact on their employment. For grower/owners or grove operators/managers or commercial applicators that do not have a supervisor, but who are eligible handlers themselves, this form is not applicable and will not be used.

6.2 Initial Potential Participants Recruitment

AHETF will follow standard procedures (see SOP AHETF-11.B) to recruit potential participants for this closed cab airblast application study. Individual workers will be recruited during an initial site inspection or subsequent visit(s) to an eligible grower facility.

The Study Director or designated researcher will seek permission from the eligible grower to approach his/her employees to recruit volunteers for the study. Depending on the number of employees and size of the grower facility the Study Director or researcher may contact employees through the use of an informational recruitment flyer posted in a common work area. Such a flyer will briefly describe the research study and provide contact information for employees who may have an interest in participation in the study. The flyer shall have been previously reviewed and approved by an IRB.

Alternatively, or subsequent to the use of a flyer, the Study Director or researcher will arrange a meeting with the grower's employees who express an interest in participation. Such meetings will always occur without the grower or supervisors being present (SOP AHETF-11.B). The Study Director or researcher shall make a presentation describing the AHETF Exposure Monitoring Program, the goals of the research study, the procedures used in exposure monitoring, and the risks and benefits to participants. Contact information will be provided, and individuals will be encouraged to contact AHETF if they desire additional information about the study or are interested in participating in the study. All presentation materials, such as handouts or visual aids, shall be reviewed and approved by an IRB prior to use in recruiting subjects.

The Study Director or researcher shall continue conducting site inspections and potential participant recruitment as described above until an adequate number of eligible growers and potential participants have been secured for an efficient configuration of all MUs in the study. During this process, the following restrictions will be maintained:

- At least 10 workers who may potentially volunteer for the study
- At least 2 workers available for each of the AaiH strata
- No more than 2 MUs from any one grower (this effectively requires at least 3 different growers since 5 MUs are desired)
- No workers may be used more than once
- No piece of equipment (tractor plus sprayer) may be used more than once

As indicated above, the efficient configuration must include a sufficiently large selection of eligible growers and potential participants to ensure there are adequate numbers to fill all MUs in the study, even in cases where growers or participants are not available at the last minute for the time interval scheduled for the field phase of the study.

6.3 Participant Selection and Consenting

The Study Director or designated researcher will establish a pool of eligible growers and workers (potential participants) from those in the efficient configuration who shall be contacted prior to initiating the field phase of the study to confirm their availability and interest in being in the study.

The Study Director or designated researcher will arrange a place and schedule to conduct consent meetings with individual volunteers from the eligible pool. Prior to such meetings, accommodations will have been made for interpreters, witnesses, and ancillary personnel who must be present for the meeting. Consent meetings shall be conducted as described above in Section 2.7.

7.0 FIELD MATERIALS AND METHODS

7.1 Test System Identification - Workers

The test system for this study is the worker handling pesticides according to label directions. Workers may include farm owners, farm operators, farm employees, contract applicator employees, or employees of agricultural research facilities. Passive dermal dosimetry methods will be used to determine potential exposure of experienced workers handling the test substance. Inclusion/exclusion criteria have been enumerated in Section 2.1 of this protocol. The recruitment and consenting process will follow the procedures presented in Sections 2.7, 6.2, and 6.3 of this protocol. Details are provided in SOP AHETF-11.B. A total of five applicators are anticipated for this study.

7.2 Justification of the Test System and Test Substances

Experienced agricultural workers handling pesticide products using commercial product packaging and typical handling procedures will be monitored. Monitoring these workers provides the best estimate of potential dermal and inhalation exposure for handlers applying pesticides with conventional airblast equipment using closed cab equipment.

The test substances selected for this study are registered and approved for use in a wide variety of agricultural settings, including airblast application to citrus crops. The justification for their possible use in this study is that they have each been deemed suitable by the Sponsor as surrogate compounds for generating exposure data appropriate for a generic database. In addition, the analytical methods have been validated and these products have the requisite degree of stability under field, storage, and transit conditions.

7.3 Mixing/Loading Stations and Application Area

Field maps and/or sketches will be provided in the raw data showing the exact locations where mixing/loading and application occur. Relative distances between mix/load areas and application areas will be recorded. These will include area and local maps or sketches for all sites involved in the study.

7.4 Study Personnel – Field

The study team will be comprised of a sufficient number of people to conduct the following activities:

1. Monitoring the workers and environmental conditions to ensure safe working conditions
2. Assisting with the donning and collection of all dosimeters in a time-efficient manner to minimize the time from completion of the work cycle to sampling (requires a female researcher if there will be female participants)
3. Fortifying field recovery samples
4. Calibrating air sampling pumps and recording beginning and ending flow rates
5. Observing and recording all work practices, recording site details and treatment details
6. Taking a photographic record of representative study-related activities
7. Evaluating the working order and condition of application equipment
8. Monitoring by a Quality Assurance Officer of operations for compliance with the GLP regulations

7.5 Test Substances

7.5.1 Approved Test Substances

The test substances approved for use in this study are listed in Section 2.3.2 above and Table 1 below. The most appropriate test substance, based largely on the preference of the grower, will be used at each of the individual locations. A different test substance may be used at each location and by each worker within a location if appropriate.

Selection of the exact test substance is determined as the product selected by an eligible grower for his crop on the day of the study. As previously described, eligible growers are selected from an efficient configuration of MUs who plan to use or are willing to use one of the products approved by the AHETF. As the time approaches to conduct the field phase of the study, the grower will confirm the actual product he will be using on the day of the study. The researchers will insure a sufficient amount of the test substance product will be available at the

grower site. The AHETF will reimburse the grower for the product used in the study at the completion of the study on his farm.

The product name, active ingredient and nominal concentration, EPA registration number, CAS number, lot number, formulation type, package type, and package size will be recorded for each product used by monitored workers.

Table 1. Approved Test Substances for AHE55

Test Substance	Active Ingredient	Type	Activity
Sevin® brand 80WSP	Carbaryl	Powder in water soluble bags	Insecticide
Sevin® brand XLR Plus	Carbaryl	Liquid flowable	Insecticide
Sevin® brand 4F	Carbaryl	Liquid flowable	Insecticide
Fyfanon® 8 Lb Emulsion	Malathion	Emulsifiable concentrate	Insecticide
Fyfanon®	Malathion	Emulsifiable concentrate	Insecticide
Malathion 8-E	Malathion	Emulsifiable concentrate	Insecticide
Gowan Malathion 8 Flowable	Malathion	Liquid flowable	Insecticide

7.5.2 Active Ingredient Stability

The stability of the test substances under recommended storage conditions will be documented before the start of the study. Generally, AHETF will rely on data supplied by the product registrant that were submitted to support the EPA registration of the test substance. Study researchers will record the storage conditions, including temperature, during the days of use of the products at the eligible grower's facility.

7.5.3 Purity Analysis

A sample of each lot of test substance used by each worker in the study at each location will be collected and sent to a designated laboratory for GLP purity analysis (content of active ingredient in the test substance). Purity analysis will be conducted concurrently with analytical phase of the study. Documentation of such analyses will be retained in the study raw data.

7.5.4 Retention Samples

Retained samples from each lot of the test substance(s) used in the study will be sent to the AHETF archive facility.

7.6 Application Parameters

Carrier:	Water
Target application rate:	Products will be applied at a rate specified on the label for the particular crop. Rates depend on target crop and field needs. Actual application rates will be documented in study raw data.
Target application volume:	Application volume will comply with the product label. Volumes depend on target crop and field needs. Actual application volumes will be documented in study raw data.
Route of application:	Applications will be made using available common airblast application equipment.

7.7 Equipment Accuracy Verification

Mixing/Loading equipment accuracy will be verified according to field testing facility SOPs prior to use in this study. This will include equipment used to pump or meter the carrier during the mixing/loading process.

Copies of relevant facility maintenance records (if available) for all mixing/loading and application equipment used for this study will be obtained and retained with the field raw data. The Study Director or designated member of the study team will assure equipment operation is acceptable according to SOP AHETF-10.D.

Workers will only be allowed to handle equipment for which they are familiar and have used recently. This will help ensure the safety of the worker when handling equipment and ensure that the procedures followed by the worker are normal and typical of their usual job function.

7.8 Amount of Material Handled

The amount of test substance that is mixed and loaded for each applicator worker will be determined and recorded in the raw data. Each worker will handle an amount of active ingredient designed to achieve a within-cluster diversification of AaiH following the standard approach of partitioning the

practical AaiH range for the scenario into five strata. These strata are:

(1) 5 to 9 pounds ai handled
(2) 10 to 17 pounds ai handled
(3) 18 to 30 pounds ai handled
(4) 31 to 55 pounds ai handled
(5) 56 to 100 pounds ai handled

A single MU will be conducted in this study from each of the five strata.

The volume of spray mixture applied will be determined and recorded in the field raw data, along with other critical measurements including application area and duration. Upon completion of spraying each load of diluted product, the amount of spray volume remaining in the tank(s) will be determined and recorded in the raw data. Disposal of excess spray mixture will occur in accordance with applicable regulations.

7.9 Rationale for the Route of Administration

The above handling procedures represent typical agricultural practices for each particular location and test substance.

8.0 DERMAL EXPOSURE SAMPLING

Full details of procedures for dermal and inhalation exposure sampling, and sample removal, are specified in the most recent versions of SOPs AHETF-8.A, 8.B, 8.C, and 8.D. At the completion of the monitoring period, exposure samples will be taken in the following order to minimize cross contamination: inhalation samples (discussed in the next section), then hand washes, then face/neck wipes, and finally inner dosimeters as described below and in SOP AHETF-10.E.

Workers will wear the clothing and PPE required by the product label. Depending on the particular product, this may include long pants, long-sleeved shirts, waterproof gloves, chemical resistant gloves, protective eyewear, shoes, and socks. The clothing can be provided by each worker as long as the Study Director agrees they are compliant with the WPS. All items worn must be compliant with the WPS, and the clothing must have been laundered since being worn while handling pesticides, or be new. Any clothing items deemed unacceptable by the Study Director will be replaced by alternate clothing (see SOP AHETF-8.F). Upon approval by the Study Director, workers may wear a hat or cap.

Workers will wear one layer of work clothing over the inner dosimeters. The inner dosimeter will consist of 100% white cotton long underwear, pre-washed and provided by the AHETF. The inner dosimeter is designed to represent the worker's skin and will act as a collection medium that will be analyzed. It will be worn throughout the period of monitoring and removed at the end of the work period, with

the assistance of a member of the monitoring team.

Workers' hands will be washed just prior to the exposure monitoring period as described below. This assures that the worker hands are free of pesticide and provides an opportunity for researchers to ensure the worker understands how to assist with the hand washing procedure. The face and neck area will also be wiped just prior to the exposure monitoring period. All of the pre-monitoring hand wash and face/neck samples will be discarded.

At the end of the monitoring period (and after the inhalation exposure equipment is removed as described below), the worker will first remove his/her PPE (e.g. waterproof gloves) and shoes, then enter a clean, private area for collecting the remaining samples. Once inside the private area, the worker will remove his/her outer clothing and socks. The outer layer of clothing and socks will not be collected or analyzed. To reduce the potential for cross contamination, each set of outer work garments will be used only once. Dermal exposure samples will be collected in the following order: final hand wash sample, final face/neck wipe sample, and the inner dosimeter.

Hand exposure will be measured by having the worker wash their hands in a 0.01% Aerosol OT solution according to a standardized washing procedure described in the most recent version of SOP AHETF-8.B. Interim hand wash samples will be collected whenever a worker would normally wash his/her hands (e.g., before using the toilet, etc.). These interim hand wash samples will be numbered sequentially, as described in SOP AHETF-8.F. After an MU is completed (i.e., at the end of the monitoring period) one final hand wash will be collected from each worker. The post-activity hand wash sample for each MU will be the final hand wash sample for the monitoring period and receive the final sequence number for the MU. This sample will be clearly marked as the post-activity hand wash. All hand washes collected during and at the end of the work period will be treated as separate samples. All hand wash samples will be poured into pre-labeled containers and placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will be maintained in frozen storage until analysis.

Face/neck exposure will be measured by wiping the entire face and neck areas (front and back of neck) with two gauze sponges, sequentially, that have been wetted with 0.01% Aerosol OT as described in the most recent version of SOP AHETF-8.C. Interim face/neck wipe samples (consisting of two gauze sponges) will be collected prior to eating. After each MU is completed, a final face/neck wipe sample will be collected from each worker after the hand wash sample is collected and before removal of the whole body dosimeters. Face/neck wipe samples will be wrapped in aluminum foil prior to placement in pre-labeled re-sealable plastic bags. All wipes collected during the study for a worker will be combined in the same container, resulting in a single sample for analysis. If more than two samples (4 sponges) are in a sample container, the laboratory must be notified as to the number in the container. All face/neck wipe samples will be placed in pre-labeled containers and placed in temporary frozen storage as soon as possible for transport to the analytical facility.

Samples will be maintained in frozen storage until analysis.

Finally, the inner layer of clothing (inner dosimeter) will be removed with the assistance of a member of the study team and sectioned into two sections for all MUs (upper body and lower body). The sections will be individually wrapped in aluminum foil, placed in pre-labeled containers and placed into temporary frozen storage as soon as possible for transport to the analytical facility. Samples will be maintained in frozen storage until analysis.

9.0 INHALATION EXPOSURE SAMPLING

Full details of the personal air-sampling method, attachment of pumps, monitoring of workers, and pump calibration are given in the most recent versions of SOP AHETF-8.D and 10.A. Suitable low-volume personal air-sampling pumps and OVS tubes with a glass fiber filter and the appropriate sorbent for the test substance being used are required. Valid calibration equipment, specified in SOP AHETF-10.A, and Tygon® (or equivalent) tubing are also required. The pumps and calibration equipment will be uniquely labeled and this information recorded in the raw data records.

Before the work commences, the sampling pump will be attached to a belt around the waist of the worker to be monitored. Tygon® tubing (or equivalent) attached to the inlet valve of the pump will be placed over the shoulder of the worker and attached to the air-sampling tube. A clip will be used to attach the tube to the collar of the worker, thus positioning it in the breathing zone of the worker. The inlet of the air-sampling tube will be facing downward, similar to the nasal passage of a worker.

Each pump will be calibrated, as specified in SOP AHETF-10.A, to a nominal sample flow rate of approximately 2 L/min and will operate for the duration of the exposure monitoring period. Flow rates will be measured before and after each exposure monitoring period and detailed records of flow rates and sampling durations will be maintained in the raw data records.

The pumps will be turned on immediately prior to the start of the monitoring period and will operate continuously until the end of the period. Detailed time logs will be maintained to allow the length of the exposure period to be calculated.

Periodically throughout the monitoring period, the pumps will be inspected to ensure they are still running and the tubing checked to ensure that there are no kinks. Workers will be instructed to inform a study team member if the pump fails to operate or the tubing becomes kinked.

If a pump stops operating during the work cycle, it will be replaced with a pre-calibrated replacement pump or given fresh batteries as soon as possible. Only the pump or batteries will be changed, the same sampling tube and tubing will continue to be used. At the conclusion of each exposure monitoring period, after the final flow rate has been recorded, the OVS tube will be disconnected from the tubing leading to

the pump. The OVS tube will be sealed at both ends, placed in a pre-labeled container, and placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will be maintained in frozen storage until analysis (SOP AHETF-8.A).

10.0 CONTROL OF BIAS

Sampling bias will be controlled by sampling multiple workers over a period representative of a typical work day, and by sampling over the entire body of each worker. Quality control samples in the field and in the laboratory also act as methods for controlling bias.

11.0 FIELD RECOVERY EVALUATION

11.1 Fortification Procedures

Full details regarding field recovery evaluation procedures for all sampling media are given in the most recent version of SOP AHETF-8.E. The SOP instructions for "spiking using vialed spikes" and analytical standard in solvent will be followed.

Sample matrix fortifications designed to assess the stability of the active ingredient during field, storage and transit conditions in or on the sampling materials (inner dosimeters, hand wash solutions, face/neck wipes, and air sampling matrices) will be conducted on a minimum of one day of exposure monitoring at each location, or more days as appropriate for environmental conditions.

Fortification vials with solutions of active ingredient in appropriate solvent will be shipped and stored under frozen conditions until used in the field. The entire contents of the fortification vials will be applied to the sampling media. The OVS tubes will be pre-spiked with the active ingredient (generally in an organic solvent) at the analytical laboratory and kept frozen until their use in the field.

Storage conditions of the individual vials used for fortifications, and of the fortified OVS tubes, will be specified by the analytical laboratory and the actual storage details will be recorded in the study file.

After fortification, the inner dosimeters and OVS tubes will be exposed to ambient conditions (i.e., weathered) for the longest expected exposure monitoring period in a location away from possible contamination (e.g., upwind of mixing/loading and application operations). Inner dosimeter samples will be covered with a single layer of shirt material during weathering. Segments representing any body area may be used for inner dosimeter fortification samples. An air sampling system will be set up in a

manner similar to that of the workers, in which a pump will continuously draw air through the pre-fortified filter and OVS tube for the entire duration of the work period.

Hand wash and face/neck wipe samples will be fortified and immediately placed in frozen storage without exposure to ambient conditions. In addition, on each fortification day, duplicate samples of the inner dosimeters fortified in the field at the highest level, and duplicate OVS tubes fortified in the laboratory at the highest fortification level, will be processed for immediate frozen storage and used as travel spikes. These travel spikes will be analyzed only if deemed necessary by the Study Director, for example to help determine the cause of unusually low field fortification recovery results.

Finally, on each fortification day, two untreated control samples of each matrix will be processed similar to the field fortification samples (i.e., some are weathered). Packaging, storage and shipment of the field fortification samples will be the same as for the worker exposure samples.

11.2 Field Fortification Levels

Matrices will be fortified in triplicate at the following levels:

Matrix:	Fortification Levels (µg/sample):
Inner Dosimeters	5, 100, and 2,000
Face/neck Wipes	5, 100, and 2,000
Hand Wash	5, 100, and 2,000
OVS Tubes	0.05, 0.5, and 5.0

12.0 OBSERVATIONS

Observations will be recorded according to SOP AHETF-10.C throughout the monitoring period while the workers perform their tasks. Any specific occurrences that could affect exposure will be noted on the observation forms. Measurements will be made of the amount of test substance handled. A detailed time log will be maintained for all activities. A photographic record will be taken of representative study-related activities during exposure monitoring.

13.0 ENVIRONMENTAL MONITORING

Exposure monitoring will not be conducted under meteorological conditions

inappropriate for the conduct of the activity (e.g., excessive precipitation, excessive wind speed or other adverse condition). Adequate protection from the elements will be provided for handling worker exposure samples and field fortifications in case of inclement weather.

Environmental conditions, including air temperature, relative humidity, wind speed, and wind direction will be recorded by means of an on-site, portable weather station during exposure monitoring. Measuring equipment will be calibrated as per the field contractor's SOP. Additionally, observations concerning pertinent weather conditions, such as amount of cloud cover, degree of sunshine, rainfall, relative humidity, etc. for each day of monitoring will be recorded in the field raw data.

Most importantly, environmental conditions will be monitored regularly by the Study Director or designated members of the study team to evaluate the risk to workers of heat-related illness according to SOP AHETF-11.G and Section 2.3.1 of this protocol. These temperature, relative humidity, and heat index values will be recorded in the field raw data.

14.0 SAMPLE IDENTIFICATION, SHIPPING AND STORAGE

14.1 Sample Identification

The sample identification process is described in the most recent version of SOP AHETF-8.F. Samples will be identified and tracked by unique sample numbers assigned by AHETF. During the analytical phase of the study, the laboratory may assign its own sample numbers as long as the AHETF number is cross-referenced and included in the documentation of the sample.

14.2 Shipping

Samples will be shipped frozen to the analytical laboratory designated for the specific active ingredient used at each location. Full chain of custody record will be available for all samples.

14.3 Storage

All samples will be placed into frozen storage as soon as possible after collection; the analytical laboratory will store samples under frozen conditions until analysis. Freezers will be monitored and the temperatures documented.

15.0 ANALYTICAL PROCEDURES

Experimental exposure and field recovery samples will be analyzed according to the analytical methods for the active ingredient in the specified test substance used in the field. The methodology will have been validated for use in the relevant matrices prior to the initiation of the sample analyses.

15.1 Reference Substance(s)

The reference substance for this study is the analytical standard used by the analytical laboratory to prepare analytical standard solutions.

The Study Director or an authorized representative will obtain analytical standard from the registrant or suitable commercial supplier. Receipt of the standard will be documented, including label identification, date of receipt, person receiving the standard, and the amount received. Preparation of all stock and serially diluted solutions will be documented.

The stability of the analytical standard (reference substance) will be documented before the start of the study. Generally, AHETF will rely on data supplied by the product registrant that were submitted to support the EPA registration of the technical grade active ingredient. An expiration date and recommended storage conditions will be based on the stability data to ensure the analytical standard strength does not change appreciably during conduct of the study. Analytical standards are to be stored under the recommended conditions.

GLP determination of the percent ai analysis (content of ai in the reference substance) will be performed for each lot of reference substance used in the study prior to the use of that substance for sample analyses. Documentation of such analyses will be retained in the study raw data file.

15.2 Analytical Methods

The latest revisions of the following validated analytical methods will be used:

Analytical Method No. ARTF-AM-005 entitled, "Determination of Diazinon and Malathion in Inner Dosimeters."

Analytical Method No. ARTF-AM-006 entitled, "Determination of Diazinon and Malathion in Hand Wash Solutions."

Analytical Method No. ARTF-AM-009 entitled, "Determination of Diazinon and Malathion in OVS Air Sampling Tubes."

Analytical Method No. ARTF-AM-010 entitled, "Determination of Diazinon and Malathion in Facial/Neck Wipes."

ARTF-AM-011, "Determination of Carbaryl in Dermal Dosimeters" by Gary Westberg, Revision 4, September 2003

ARTF -AM-012, "Determination of Carbaryl in Hand Wash Solutions" by Gary Westberg, Revision 2, June 1998

ARTF-AM-013, "Determination of Carbaryl in OVS Air Sampling Tubes" by

Gary Westberg, February 1997

ARTF-AM-014, "Determination of Carbaryl in Cotton Facial/Neck Wipes" by Gary Westberg, Revision 2, April 1998

Equivalent instrumentation, apparatus, and reagents may be substituted for those specified in the method. All substitutions must be clearly documented in the raw data.

15.3 Analytical Design

All analytical procedures, techniques and matrices will be provided by the AHETF. Procedures and techniques will be followed as rigidly as possible. No changes are permitted without the prior approval of the AHETF Analytical Monitor and the Study Director.

All data will be measured against a standard curve (five-point minimum) that brackets the levels of the matrix spikes. If necessary, a solvent blank for the standard solutions will be injected prior to the standard solutions for each run.

Analytical data sets for the study will be considered acceptable if the following criteria are met. If these criteria cannot be met, the analytical monitor must be contacted immediately.

1) The limit of determination, r^2, or the regression coefficient, r, must be reported for all curves to demonstrate sufficient linearity of detector response in the range of residues quantified. All r^2 values must be 0.90 or greater or all r values must be 0.94 or greater.

2) Back calculations of the standard to the calculated curve which is based on the standards run in a set of samples will be performed for all analytical sets. The back calculations of the standards to the curve will be around +/-15% for all standards but the lowest concentration standard may back calculate to around +/-20%. No standard will be discarded from a set unless there is a good reason for its being discarded and not without consultation with the analytical monitor.

A minimum of two laboratory spikes must be included in each analytical set. For large analytical sets, include approximately one spike for every ten field samples. The spiking concentrations will bracket the expected levels in the field samples. The LOQ is defined in each analytical method.

For all samples wrapped in aluminum foil, the inner surface of the foil wrapping will be rinsed with at least 50 mL of extraction solvent, which will be added to the total extract volume. The final volume of solvent used must be documented.

The filter, plus front and rear sorbent sections of the OVS tubes, (along with the retainer ring and sorbent section separators) will be analyzed together as one unit.

15.4 Analytical Statistical Methods

Chromatographic quantification (either GC or HPLC depending on the method) will be achieved using a standard curve obtained from peak heights or areas of injections of several concentrations of standards. The standard curve will be a least squares fit unless otherwise approved by the AHETF Analytical Subcommittee. Means and standard deviations (arithmetic and/or geometric), and coefficients of variation may be calculated on the limited data set generated in this study.

16.0 STUDY RECORDS

16.1 Field Records

Raw data will be obtained to cover all aspects of the study, including but not limited to the following:

1. Test and reference substance lot numbers, receipt and storage location(s) use records
2. Crop description and growth stage, if applicable
3. Mixing/loading equipment details, if applicable
4. Application equipment details, if applicable
5. If available, application equipment maintenance records (retained in the study file)
6. Environmental conditions for the entire monitoring period, including data used for making determinations of potential heat stress indices
7. Approvals from the Institutional Review Board covering the protocol and the Informed Consent document, and all amendments to either document
8. All correspondence with the Institutional Review Board
9. Personal details of workers, including consent forms and documentation of consent process (which will be maintained under confidential conditions as per SOP AHETF-6.D)
10. Trial location maps, including description, dimensions, and exact locations of plots and mixing/loading stations
11. Pounds active ingredient handled, monitoring time, acres treated, and volume of liquid applied
12. Dermal exposure sampling information
13. Inhalation exposure sampling information, including pump identification, calibration, flow rates and times of sampling
14. Field recovery procedure information for all sampling media

15. Test and reference substance, and sample storage temperature records
16. Observations on work practices, including photographs
17. Sample information (including inventory and chain of custody)

Field raw data will be recorded directly into the study notebook provided by AHETF. All data generated during this study will be kept in files bearing the study number. All forms and paperwork that contain personal information (including a worker's name and address) will be kept confidential in a sealed envelope while in the field. After the study is completed, this confidential envelope will be sent to AHETF archives with the other raw data (SOP AHETF-6.B).

16.2 Analytical Records

All study-specific original documents and data generated in the course of this study, including but not limited to the following, will be maintained and turned over to the AHETF when requested, or at the completion of the study.

1. Analytical worksheets, chromatograms, methods, residue calculation sheets and other pertinent analytical data
2. Laboratory notebooks or bench sheets used to record details of the analyses
3. Chromatograms and/or machine-generated analysis reports and data
4. Spreadsheets and other calculated data
5. Chain of custody records

In addition to the above study-specific raw data, the following records must also be kept, and true copies submitted with the raw data:

a. Storage conditions for reference substances and samples
b. Reference substance use log
c. Balance and instrument log book pages
d. Communications logs or records

Following completion of the field or analytical portion of the study, copies of the relevant records will be indexed and sent to the Study Director for preparation of the final report. All original raw data will be transferred directly to the AHETF-designated GLP study archive at Quality Associates, Inc., 8161 Maple Lawn Boulevard, Suite 200, Fulton, MD 20759.

17.0 DATA HANDLING

17.1 Communication of Results

Results will be communicated from Principal Field and Analytical Investigators to the Study Director and the designated AHETF Study Monitor(s) on a regular and timely schedule. Volunteer subjects will have an

opportunity to fill out a form to request their personal study results when they are available. Individual results requested by subjects will be communicated in accordance with SOP AHETF-11.B.

AHETF has an adverse effects reporting procedure in place and will submit reports to EPA, IIRB, and appropriate state authorities if potential adverse effects to workers are found (see SOP AHETF-1.F and AHETF-11.F). The Study Director has the primary responsibility for identifying potential adverse effects during study conduct and as exposure results are obtained.

17.2 Statistical Methods

Detailed statistical evaluations of exposure data from this study and any existing data will be conducted by AHETF for each use scenario in its generic database.

18.0 QUALITY ASSURANCE

AHETF intends that all regulatory studies are conducted in accordance with the FIFRA GLP Standards (40 CFR part 160). Field and analytical aspects of this study will be monitored by the relevant quality assurance unit(s) (QAU) while this study is in progress to ensure compliance with the FIFRA GLP regulation and adherence to this protocol and relevant SOPs. The QAU(s) will submit copies of its/their inspection reports to the Study Director and AHETF Sponsor Representative (40 CFR part 160.35 [4]). The final report will be audited by the QAU specified in Section 1.15 to ensure that the contents of the report accurately describe the conduct and findings of the study.

The final report will contain a Quality Assurance Statement from the QAU of each contributing laboratory conducting QA audits, and from the QAU specified in Section 1.15.

19.0 WORKER SAMPLE RETENTION

All sample extracts, extracted sample matrices, unanalyzed fortification matrices, and analytical standards will be retained until the Study Director and Analytical Monitor determine they are no longer useful. These materials are the property of the AHETF and will be stored or disposed of in a safe and lawful manner by the appropriate authorized personnel with the approval of AHETF and with QA verification at the performing facility.

20.0 PHASE REPORTS

Separate final reports will be prepared for the field and analytical phases of the study.

20.1 Field Report

Upon completion of the field phase at each individual location, the field investigators will submit reports for individual locations to the AHETF and the Study Director in a format specified by the AHETF. Each field report will describe the procedures followed at that location and must contain, but is not limited to, the following:

1. Identification of the locations of the study, and the general environmental conditions during the exposure monitoring periods
2. A field laboratory QAU statement giving dates of inspections and dates that findings were reported to the Study Director and AHETF Management
3. A summary of the worker recruitment and consent process
4. A description of the workers and handling activities
5. A summary of worker observations identifying any specific occurrences that may contribute to unusual worker exposure
6. A detailed summary of the amount of test substance handled by each worker
7. A detailed summary of the length of time each worker was monitored
8. A complete description of the field recovery procedure with a summary of specific handling and weathering of all field samples
9. A complete description of collection, handling, storage, and shipping of field samples

20.2 Analytical Report

At the completion of the analytical phase, each analytical laboratory that analyzed samples for this study will submit a report to the AHETF and the Study Director in a format specified by the AHETF. Each analytical report will describe the procedures followed for analysis of sample matrices and must contain, but is not limited to, the following:

1. Results of analyses
2. An analytical laboratory QAU statement giving dates of inspections and dates that findings were reported to the Study Director and AHETF Management
3. A detailed description of the methods
4. Example calculations
5. A summary of the concurrent lab recovery data
6. Representative chromatograms of control, treated, fortified samples and calibration standards
7. A typical standard curve

21.0 FINAL STUDY SUMMARY REPORT

A final summary report will be prepared according to a standardized format provided by AHETF. The report will contain a description of the conduct of the studies that comprise this scenario as well as a statistical analysis of the exposure data for the scenario. The original signed copy of the summary report will be archived at the AHETF GLP study archive.

22.0 PROTOCOL CHANGES

22.1 Amendments

Amendments to this protocol during the course of the study are permissible and subject to review and approval by the Study Director, the Sponsor representative and the IRB prior to implementation. Protocol amendments shall to be documented in accordance with SOP AHETF-2.C and reported in the Field Report, Analytical Report and Summary Reports.

22.2 Deviations

GLP deviations are to be documented on the "Statement of GLP Compliance" in the summary report. A description of any changes to the protocol must appear in the Field Report, Analytical Report and Summary Reports. Any deviations to the protocol, lab SOPs or GLPs, or situations that may affect the integrity of the study must be communicated to the Study Director in a timely manner. Any deviations affecting the safety or rights of the subjects must also be reported to the IRB. Protocol deviations are to be documented in accordance with SOP AHETF-2.C.

23.0 REFERENCES

Bruce, E., L. Smith and V. Standart. 2007. Report of workplace meetings with citrus and pecan growers and employees. With attached: AHETF exposure studies: input from the local workplace community. Georgia and Florida, July 2007. Prepared for the Agricultural Handlers Exposure Task Force, 8 August 2007.

LS Consulting

From: LS Consulting [lsconsulting@oh.rr.com]
Sent: Friday, February 29, 2008 10:16 PM
To: Robert Roogow (rroogow@iirb.com)
Subject: AHETF SOPs Cited in AHE55 Protocol
Importance: High
Attachments: AHETF-11G0 - ID & Control of Heat Stress JAN08 v2 QA.pdf; AHETF-1B1_-_Personnel_Responsibilities JAN08 QA.pdf; AHETF-1F0_-_Potential_Referable_Findings.pdf; AHETF-2C2-ProtocolDesign.pdf; AHETF-6B1 - Access to Archived Data.pdf; AHETF-6D0_-_Access_to_Confidential_Worker_Info.pdf; AHETF-8A3 - Inner Dosimeter-draft 021208.pdf; AHETF-8B4-Hand Wash Samples-draft 021208.pdf; AHETF-8C4 - Face Neck Wipes.pdf; AHETF-8D2 - Air Samples-draft 021208.pdf; AHETF-8E4 - Matrix Fortification JAN08 QA.pdf; AHETF-8F4 -Sample Identification JAN08 QA.pdf; AHETF-8K0 - Sample Quality JAN08 QA.pdf; AHETF-10A0 - Rotameter Calibration.pdf; AHETF-10C3-WorkerStudyObservations.pdf; AHETF-10D0 - Application Equip Operation Verification.pdf; AHETF-10E2-WorkerSampleCollectionSequence.pdf; AHETF-11B0 - Recruitment of Study Volunteers & IC JAN08 QA.pdf; AHETF-11C0_-_Worker_Health_Status2.pdf; AHETF-11D0 - Pregnancy Testing JAN08 QA.pdf; AHETF-11F0 - Adverse Events Reporting.pdf

Robert,

The attached SOPs are cited in the AHE55 Protocol. All have been revised to some extent recently and are in the process of being signed by task force representatives. I will have them signed and delivered to you via email on Monday, March 3. Please do not hesitate to call me if you need more information or have questions. Thanks for following this submission so diligently.

Larry

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, OH 44060
440/255-1954

Personnel Responsibilities

Chapter 1: Administration
AHETF-I.B.I.

Effective Date : 03/03/08

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

Last Revision Date: February 1, 2003 Previous Version Number: 1.B.0

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines the roles and responsibilities of personnel participating in studies conducted for the Agricultural Handlers Exposure Task Force (AHETF). This may include contracted personnel who directly oversee the conduct of a study, or phase of a study.

1.2 This SOP was revised to modify section 5.0 to clarify the responsibilities the assigned Study Director may delegate, section 6.0 to define Principal Field Investigator and Principal Analytical Investigator, and to add section 7.0 to describe the required ethics training for AHETF personnel.

2.0 RESPONSIBILITIES

2.1 The Task Force member companies and contracted companies will provide the appropriate personnel to manage, conduct, and monitor all regulated studies and other projects.

2.2 The AHETF is both the study Sponsor and testing facility. Independent companies that are members of the Task Force are sponsor representatives. They will assure compliance with the following requirements. Please refer to SOP AHETF-1.A.

3.0 TESTING FACILITY (AHETF) MANAGEMENT

3.1 The testing facility management for the AHETF consists of member company representatives serving on various committees and subcommittees, with various levels of responsibility and in various capacities.

3.2 There will be chosen representatives who will be the primary management contacts for the AHETF. These positions will be the Technical Committee Chair, the Technical Committee Vice-Chair, the Task Force Manager, and the Subcommittee Chairs.

3.3 As required by the EPA GLPs, § 160.31, the testing facility management shall:

a. designate the Study Director.

b. Replace the Study Director promptly, when necessary during the conduct of the study.

c. Assure that there is an independent QAU.

d. Assure that the test, control, and reference substance(s) or mixture(s) have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable.

e. Assure that personnel, resources, facilities, equipment, materials, and methodologies are available as scheduled.

f. Assure personnel clearly understand the functions they are to perform via the study protocol, SOPs, and memoranda.

g. Assure that corrective actions are taken, as necessary, for all GLP regulation deviations reported by the QAU, and documented.

4.0 AHETF TASK FORCE MANAGER

4.1 One individual will be assigned by AHETF management as the Task Force Manager, who will authorize study protocols, approve SOPs, oversee the contracting of third-party companies for studies and other projects, and provide overall study coordination until study completion and archiving. The Task Force Manager is a representative of AHETF management.

4.2 This person may be consulted regarding study conduct by the participants listed above, and may serve as an arbiter to settle issues involving AHETF studies.

4.3 The Task Force Manager, as well as the Study Director, has the authority to terminate an AHETF study that no longer has interest to the AHETF, or has been compromised (scientifically or through regulatory misconduct) by the contractor(s).

5.0 STUDY DIRECTOR

5.1 Good Laboratory Practice Standards require that a single person assume responsibility for the conduct of a study. Responsibilities, as defined in the GLPs, §160.33, apply to the scope of the AHETF Study Director's involvement in assigned studies. The Study Director shall assure that:

a. The protocol, including any change, is approved - in writing by the Study Director and sponsor's representative - and followed.

b. All experimental data are recorded and verified.

c. Unforeseen circumstances that may affect the integrity of the study are noted as they occur, and corrective action is taken and documented.

d. Test systems are as specified in the protocol.

e. All applicable Good Laboratory Practice Standards are followed.

f. All raw data, documentation, protocols, specimens and final reports are transferred to the archives during or at the close of the study.

g. Specific responsibilities are assigned to AHETF personnel, contracted Principal Investigators, or other designees, as necessary; for example, if the Study Director is unable to be at a specific study site during an investigation. These may include recruiting volunteers, conducting informed consent meetings, and intervening a worker's activities if the worker is in danger. Specific responsibilities of the Study Director that are undertaken by other on-site investigators will be documented in the raw data with the consent of the Study Director.

h. The progress of the field and analytical portions of AHETF studies, including the preparation of each final report, are monitored and the AHETF Management is informed of progress $^{and}/_{or}$ problems.

5.2 The AHETF Study Director will be contracted to oversee the field and analytical phases of each AHETF study. Please refer to SOP AHETF-1.C.

6.0 PRINCIPAL INVESTIGATORS

6.1 For each field and laboratory study, contractor facility management may assign a person to fulfill the role of principal investigator (PFI: Principal Field Investigator; PAI: Principal Analytical Investigator), as necessary. The PFI's and PAI's responsibility involves direct communication with the AHETF Study Director. The PFI/PAI may have direct and immediate responsibility over portions of an AHETF study in the absence of the Study Director or designated AHETF member.

6.2 In situations where several contractors are participating on an AHETF study, each contractor will designate its own PFI/PAI who will coordinate their activities with the Study Director.

7.0 ETHICS TRAINING FOR RESEARCHERS

7.1 Researchers that participate in the study and interact with study participants must undergo ethics training.

7.2 The training shall include successful completion of the course from the National Institutes of Health (NIH; Human Participant Protections Education for Research Teams) and/or the Basic Collaborative IRB Training Initiative Course (CITI; The Protection of Human Research Subjects). There are links to both of these on-line training courses at www.wirb.com (start with link at bottom of home page called Training Requirements).

7.3 Copies of the certificates of completion for the ethics courses will be included in the raw data and in the respective personnel files (maintained by the AHETF and all contract facilities.)

7.4 Study Directors shall have first aid training that includes recognition of signs and symptoms of heat-related illness (see SOP AHETF-11.G). A copy of the certificate of completion of this training will be included in the Study Director's personnel file, maintained by the AHETF.

Adverse Events Reporting for Institutional Review Boards

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-II.F.O.

Effective Date : March 3, 2008

APPROVAL David Johnson	DATE 3/3/08
APPROVAL	DATE 3/3/08
Last Revision Date: N/A	Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 This SOP outlines the steps to be taken to address an unanticipated adverse event resulting from participation in an Agricultural Handlers Exposure Task Force (AHETF) worker exposure study.

2.0 PROCEDURES

2.1 The investigator (the Study Director) must familiarize himself with the references cited in this document.

2.2 Investigators are required to report adverse events that meet both of the following criteria (definition is from the Western Institutional Review Board):

a. Event is **UNANTICIPATED** (An unanticipated event is any adverse experience where the nature, severity or frequency is not identified in the investigator brochure or described in the protocol. Events which are already cited in the investigator brochure or protocol are not unanticipated and do not have to be reported to WIRB),

AND

b. Event is **POSSIBLY RELATED** to the study design, procedures, or drug/device. If the adverse event is clearly not related to the study drug, device, procedures, or washout process, it would not represent a risk to other subjects in the research and, therefore, does not have to be reported to WIRB.

2.3 If these criteria are not met then the event does not have to be reported to the IRB.

2.4 The Study Director (SD) must submit the written report of any suspected adverse event that occurs during a study, even if the event is brought to his attention by another researcher. The report should fully describe the event and any pertinent information leading up to it and following it (e.g., observers and/or medical professional comments prior to the occurrence). The report should include all relevant information of any similar events that occurred previously in other AHETF-conducted studies.

2.5 The SD must submit the written report to the IRB within 10 business days of the occurrence of the potential adverse event.

2.6 The report should include all relevant information, including any similar events that occurred previously in other AHETF-conducted studies.

3.0 REFERENCES

3.1 Office for Human Research Protections (OHRP), Dept of Health and Human Services: Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events. January 15, 2007 (guidance on regulations at 45 CFR part 46).

3.2 U.S. Dept of Health and Human Services (DHHS): Guidance for Clinical Investigators, Sponsors, and IRBs – Adverse Event Reporting – Improving Human Subject Protection). April 2007.

3.3 Western Institutional Review Board (WIRB): A guide for Researchers. Version 1.5, October 2006. www.wirb.com. Download on May 3, 2007.

Chapter 11: **Pregnancy Testing**
HUMAN SUBJECT MANAGEMENT
AHETF-II.D.O.

Effective Date : 03/03/08

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

Last Revision Date: N/A Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 This SOP outlines the steps to be taken to assess the reproductive status of a female worker who is being considered for participation in an Agricultural Handlers Exposure Task Force (AHETF) worker exposure study. AHETF policy does not permit pregnant workers to participate in its worker exposure studies. Federal Regulations (40 CFR Part 26, §26.203) prohibit a pregnant or nursing female from participating in these studies.

1.2 These procedures are also intended to protect the worker's privacy with respect to her employer and co-workers concerning the outcome of the pregnancy test.

2.0 PROCEDURES

2.1 Each female worker will be told during the recruitment and consent processes that any woman who is pregnant or nursing is ineligible to participate in an AHETF worker exposure study. The worker will be informed that no additional remuneration will be provided for taking the pregnancy test (*i.e.*, $80, or the amount specified in the protocol), for the inconvenience of participating in the exposure monitoring will not be provided to a woman who has a positive pregnancy test result and who therefore cannot participate in the study).

2.2 Within 24 hours prior to study participation, any woman who is being

considered for participation will be asked to take a urine pregnancy test (over-the-counter variety).

a. The pregnancy test kit will be provided by AHETF.

b. The pregnancy test will be supervised by a female researcher who will explain how to take the test.

c. The researcher will escort the female worker to the bathroom and wait outside while the worker self-administers the test.

2.3 The outcome of the test will initially be known only to the worker.

2.4 After the test, the worker will be asked to state her desire to continue or withdraw from participation in the study.

a. If the worker chooses to withdraw from the study

i. She will be allowed to do so without stating a reason.

ii. The test results will not be revealed to the employer or co-workers.

iii. The test results will not be documented. Consent forms and all other records associated with the worker will be promptly shredded.

b. If the worker states the desire to participate

i. A female researcher trained in the interpretation of pregnancy tests will confirm that the pregnancy test is negative.

ii. The negative pregnancy test results will be recorded in the study raw data.

2.5 With the confirmation of a negative test result, the worker will be permitted to continue in the study consent process.

Chapter 11: **Worker Health Status**
HUMAN SUBJECT MANAGEMENT
AHETF-II.C.O.

Effective Date : March 3, 2008

APPROVAL David Johnson DATE 3/3/08

APPROVAL DATE 3/3/08

Last Revision Date: N/A Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 The following SOP describes the procedure used during the informed consent process to determine the general health status of potential participants and whether they have any medical condition(s) which could impact their ability to participate in an Agricultural Handlers Exposure Task Force (AHETF) worker exposure study.

2.0 INTRODUCTION

2.1 The AHETF requires workers to be in good health and able to perform the work activity for which they will be monitored. The AHETF respects the medical privacy of the worker. As a result, the AHETF will make no effort to obtain worker medical records and will rely on self-reported health status.

3.0 PROCEDURE

3.1 The worker will be asked during the informed consent process if they consider their general health status to be good. Only workers who answer "yes" will be allowed to participate in the study.

3.2 The worker will be asked during the informed consent process if he/she has any medical condition(s) that could impact his/or ability to participate in the study. If needed, the Study Director will discuss with the worker what this question means. Only workers who answer “no” will be allowed to participate in the study.

Disqualification of a worker due to health concerns will not be documented in the raw data and all other data pertaining to this individual will be promptly discarded. However, they will be counted as having been screened for participation, as per IRB guidelines.

Recruiting, Informing and Seeking Consent from Study Volunteers

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-II.B.O.

Effective Date : March 3, 2008

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

Last Revision Date: N/A Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines general procedures for recruiting, informing, and seeking informed consent from workers in field studies being conducted by the Agricultural Handlers Exposure Task Force (AHETF). A more detailed study-specific recruitment plan will be developed for each field study and will be included the study-specific protocol.

2.0 ETHICS TRAINING FOR RESEARCHERS

2.1 The Study Directors (SD), Principal Field Investigators (PFI), Task Force Field Study Monitors, Local Site Coordinators (LSC), worker observers, and others working on behalf of the Task Force who interact with study participants, will have completed one or more ethics training courses. Certificates of completion for the course(s) will be available prior to their participation in the field phase of the study on behalf of the AHETF. Details on the courses are defined in SOP AHETF-1.B.

3.0 PROTOCOL APPROVAL

3.1 Workers will not be recruited for participation in any field study until after the following items have been completed:

a. IRB approval has been obtained for the study protocol, consent forms and documentation required by 40 CFR 26

b. Approval of the proposed study by the Director of the California Department of Pesticide Regulation when a study is to be conducted in California

c. Review of the proposed study by EPA and the Human Studies Review Board, and

d. IRB approval of any changes in the protocol or any supporting document required as a result of the reviews by EPA, the HSRB, and/or CDPR

4.0 RECRUITMENT OF WORKERS

4.1 Recruitment of workers typically occurs in two phases. The first phase occurs during the planning stages of the study and involves communications between the SD and prospective cooperators or LSCs. These communications or visits are to determine the suitability of potential sites for the study and to identify potential pools of workers for monitoring. However, no contacts with prospective workers will be made during this time unless the protocol has gained final approval by the appropriate agencies as described above. During the first phase, written assurance will be obtained from the employer that the workers will not suffer any consequence if they decide either to participate or not to participate in the study and that there will be no coercion of the workers (see Attachment 11-B-1).

4.2 When all appropriate approvals for the protocol have been obtained the SD may initiate the second phase of recruitment in which contacts are made with prospective workers. The process is as follows:

a. Growers will have been identified who are willing to cooperate with AHETF in the monitoring study and the SD will have determined the grower site(s) to be acceptable. The grower or other responsible personnel will have given permission for the SD to contact their employees to determine employee interest in study participation

b. The SD then initiates contact with the employees typically by distributing an IRB-approved flyer which generally describes what participation in the study entails and providing a contact number for the SD. The SD organizes a meeting with only the interested workers present. This may be done one-on-one or with a group of interested workers.

4.3 The meeting with interested workers will consist of the following:

a. Growers, LSC or other personnel to which employees might report will not attend.

b. The SD will explain the nature of the study and the general content of the protocol and Consent Form (according to a script approved by the IRB).

c. The SD may also show an IRB-approved video presentation or pictures of how the dosimetry and air samplers are worn and how face/neck wipe and hand-rinse sampling is performed.

d. Eligibility criteria will be reviewed and all questions will be answered.

e. Informed Consent Forms will be available for review by potential workers.

f. Potential workers also will be shown the written assurance obtained from the employer that they will not suffer any consequence if they decide not to participate in the study and that there will be no coercion of, or undue influence on, the workers.

g. At the conclusion of the meeting interested workers may either contact the SD at a later time to express their intent to participate or may go through the individual private consent process at that time (described below in Section 7).

4.4 Attachment 11-B-2 provides a flow diagram of the recruiting and consent processes.

5.0 INCLUSION AND EXCLUSION CRITERIA

5.1 Potential participants may be farm owners, farm operators, farm employees, contract applicator employees, or commercial applicators, etc. Employees of agricultural research facilities may be used if they meet the inclusion/exclusion criteria for the study.

5.2 Inclusion criteria include people who:

a. Are freely willing to participate.

b. Are trained in the task that will be monitored - workers must have received basic pesticide handling training in accordance with the Worker Protection Standard (WPS) or equivalent Canadian regulations, or must be exempt from such regulations. Each participant must confirm that they have received the required training or that they are exempt from the requirement.

c. Have recent (*i.e*., within the last year) experience performing the task that will be monitored in the study, and in operating the equipment to be used in the study.

d. Are at least 18 years old (age must be verified with a government-issued photo identification).

e. Consider themselves to be in good general health with no medical conditions that could impact their ability to participate in the study (see SOP AHETF-11.C for more details).

f. Agree to perform pesticide handling tasks in conformance with label and WPS requirements (e.g., monitored workers must agree to wear all PPE required by the label).

g. Are English or Spanish speakers (*see below for further discussion of this topic*).

5.3 Exclusion criteria include people who:

a. Are ill or physically unfit to perform the work tasks (see SOP AHETF-11.C for more details).

b. Are cognitively impaired as deemed by the SD.

c. Are pregnant or nursing (pregnancy status will be determined no more than 24 hours prior to participation in the study - see SOP AHETF-11.D for more details; nursing status is self-reported).

d. Are minors, *i.e.*, under 18 years of age.

e. Can't produce a government-issued photo identification to prove their age.

f. Normally elect to wear more protective clothing or PPE than is required by the study protocol and/or product label.

g. Act as the local site coordinator; or are employees of: the SD, pesticide manufacturers or contractors of the AHETF (Exception: employees of local site coordinator may participate if they meet the inclusion criteria).

h. Are not fluent in English or Spanish

6.0 LANGUAGE REQUIREMENTS

6.1 Study participation will be limited to English or Spanish speakers. All workers can select the Consent Form in the language of their choice for reading during the consent process (if they are readers) and will sign their preferred version of the form. For workers whose preferred reading language is Spanish, AHETF obtains an IRB-approved translation of the Consent Form.

6.2 While AHETF does not intentionally recruit workers with limited literacy, pesticide handlers occasionally do fall into this category and are therefore included in the target population. Special precautions are used with such workers (described below). Reading ability will be self-reported by the worker.

6.3 When the need for a witness arises*, i.e.* if a worker has limited reading ability, only an impartial witness will be used. An impartial witness will have no association with researchers in this study nor will they be a part of the management of the grower where the research is being conducted. In addition, an impartial witness must have a general understanding of agriculture. The witness will also sign the Consent Form.

6.4 Since the SDs contracted by the AHETF are typically monolingual (they are only English speakers) there is a need for an interpreter to communicate with workers who only speak Spanish. The interpreter might be an employee at the study site (e.g., employee of a grower or a commercial applicator), a person of the worker's choosing, or might be someone located during discussions with the local agricultural community on a study-specific basis. If an interpreter is used, the SD will ensure the interpreter knows enough about the research design and the content of the Consent Form to provide an accurate translation. If necessary, this will involve tutorial discussions from the SD. To test the understanding by the interpreter, the SD will ask him/her to explain some portions of the Spanish Consent Form, in English. Interpreters will translate the Study Director's (English) discussion into Spanish during the consent process. They will also be utilized during the study should any issues arise which can't be resolved directly with the worker. Interpreters are not considered part of the research team and will not sign the Consent Form.

6.5 An interpreter who assists in consent form communication between the study director and the worker will not be permitted to serve as an impartial witness for that worker.

6.6 The following procedures will be followed with each individual wanting to participate in an AHETF study. The SD will go through the entire consent process with the worker (see Section 7.0 below). The following paragraphs describe how workers with varying reading and language skills will be guided through the consent process. Attachment 11-B-3 provides a summary of the procedures described below.

a. Workers who are fluent in English and have the ability to read English will be provided a copy of the Consent Form in English, will be allowed to read the Consent Form in its entirety and ask questions of the SD or research staff pertaining to their participation in the study. A copy of the signed Consent Form will be provided to the worker.

b. Workers who speak English, but cannot read English will have the Consent Form read to them and they will be allowed to ask any questions of the SD or research staff pertaining to their participation in the study. An impartial witness will verify that the worker has apparently understood the materials read to and discussed with them. The witness may assess the worker's understanding by their answers to the questions asked of the worker by the SD (see Section 7 below). A copy of the signed Consent Form will be provided to the worker.

c. Workers who are fluent in Spanish and have the ability to read Spanish will be provided a copy of the Consent Form in Spanish, will be allowed to read the Consent Form in its entirety and ask questions of the SD or research staff pertaining to their participation in the study. Interpreters for Spanish speakers will be provided. A copy of the signed Consent Form will be provided to the worker.

d. Workers who speak Spanish, but cannot read Spanish will have the Consent Form read to them and they will be allowed to ask any questions to the SD or research staff pertaining to their participation in the study. Interpreters for Spanish speakers will be provided. An impartial witness will verify that the worker has apparently understood the materials read to and discussed with them. The witness may assess the worker's understanding by their answers to the questions asked of the worker by the SD (and relayed by the interpreter; see Section 7 below). A copy of the signed Consent Form will be provided to the worker.

7.0 INFORMED CONSENT PROCESS

7.1 Although Consent Forms are unique to individual studies, each Consent Form will contain the elements required by 40 CFR 26.1116.

7.2 The SD will be responsible for obtaining informed consent from all study workers prior to their participation in the study.

7.3 Informed consent discussions will be conducted by the SD in private with each worker and others that the worker may want to have present.

Interpreters and witnesses may also be present as described above in Section 6.0.

7.4 The SD will inform the worker that he/she will receive $20, or the amount specified in the protocol, even if he/she decides not to participate following the discussion.

7.5 During the private meeting the SD will provide each worker with a full explanation of the study, its requirements, any potential risks, its benefits, alternatives to participation, etc. Workers will be advised of their right to withdraw from the study at any time and for any reason without jeopardizing their normal position with their employers or their daily wages. Workers will receive an additional $80, or the amount specified in the protocol, if they decide to participate (don the dosimeters) but withdraw before the end of the monitoring period. Each worker will be provided a copy of the supervisor's signed form (described above) that states they will not suffer any consequence if they decide not to participate.

7.6 The SD will provide information about the risk of the surrogate chemical in the study, including signs and symptoms of acute overexposure. This information will be presented as an attachment to the Consent Form and must be signed by the worker (and impartial witness, if present). The product label and Material Safety Data Sheet also will be explained. WPS requirements, especially proper use of clothing, personal protection equipment, etc., will be discussed. Refer to SOP AHETF-11.E for details.

7.7 The SD will discuss the medical management plan with the prospective participants. Information will be provided about the risk of heat stress, including signs and symptoms, and ways to prevent it. Details on heat stress and its presentation are outlined in SOP AHETF-11.G, while details on emergency medical procedures are outlined in SOP AHETF-11.H.

7.8 During the discussions between potential participants and the SD, ample time will be provided for questions and the SD will provide any additional information or clarification that is requested.

7.9 The IRB-approved Consent Form will be presented in the preferred language (English or Spanish) of the worker. All sections of the Consent Form will be explained in detail. When the SD is satisfied that the worker understands the requirements and risks of the study, and if the worker still

wants to participate, he/she will be asked to sign and date the Consent Form and the SD will provide a copy of the signed form to the worker.

7.10 An additional document, "Product-Specific Risk Statements", will be attached to the Consent Form. If the study is conducted in California, the "Experimental Subject's Bill of Rights" will also be attached. These documents will be reviewed, signed and dated by the worker, and copies will be provided.

7.11 In all situations, the SD will not sign the Consent Form unless he/she believes the candidate fully understands the information presented. This will be ascertained by providing repeated opportunities to ask questions and by asking questions of the potential workers that would require a response that indicates understanding of key issues. The following are examples of some possible questions and possible answers:

a. Q: When can you withdraw from the study?
A: Whenever I want.

b. Q: What has your supervisor said about your volunteering?
A: I'm free to make that decision on my own & it won't affect my employment.

c. Q: What will you wear so we can measure the amount of chemical in the air that you breathe?
A: An air pump on my belt.

d. Q: What type of personal protective equipment must you wear for this study?
A: Gloves (the answer will depend on the specific product being used in the study – gloves are an example answer for a product requiring gloves)

e. Q: Can you name two risks of participating in the study?
A: Physical risk, chemical risk, overheating, etc.

7.12 The SD will not sign the Consent Form unless he/she believes they have done everything possible to ensure that the process has been free of any element of coercion or undue influence, and that the worker understands the material in the Consent Form.

7.13 If more workers volunteer to participate than required for a particular site or location, the SD will randomly select the required number of workers from the available pool (*e.g.*, by lot or from choosing from a randomized list).

8.0 FOLLOW-UP PROCEDURES

8.1 Each study participant will be provided an opportunity to request a copy of the exposure data resulting from their activities in the study. A summary of their personal study data will be mailed to the address provided by the participant(s) desiring it (the SD or designee will complete the form in Attachment 11-B-4). This form (and all forms that contain the worker's name and address) will be maintained in a confidential file with the study records as outlined in SOPs AHETF-6.B and -6.D.

8.2 When the monitoring period is completed, or at the time a participant withdraws from the study, the SD will remind the worker that he/she has received a copy of the signed Consent Form that has phone numbers for reporting any health changes the worker thinks may be related to his/her participation in the study. Worker inquiries of this nature will be forwarded to AHETF management to be resolved on a case-by-case basis.

ATTACHMENT 11-B-1

Employer Cooperation Statement

Employer / Supervisor: _____

Study Director: _____

Date of Discussion: _____

Site of Discussion: _____

Employer / Supervisor Cooperation Statement:

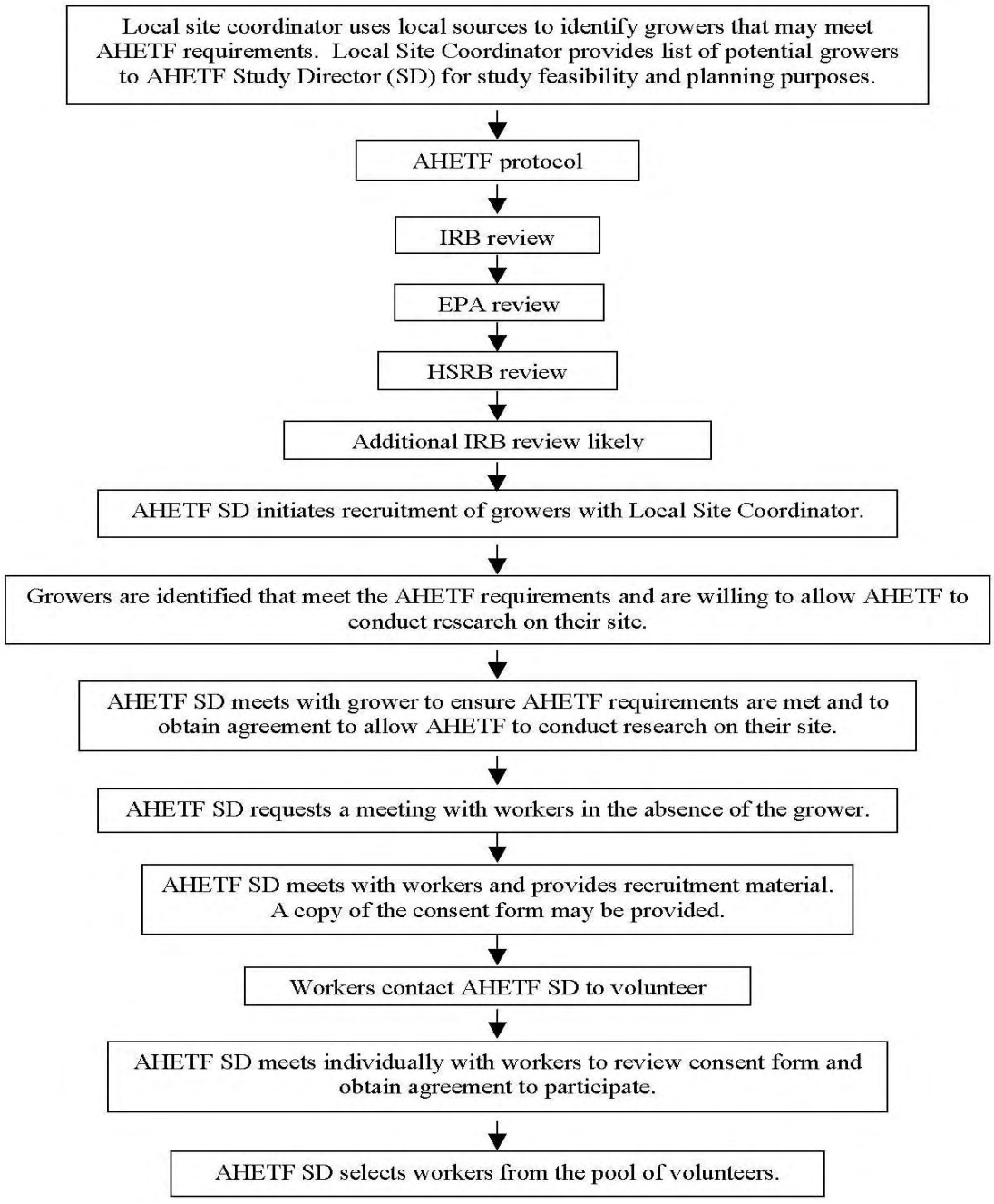
I certify that I'm authorized to make the following statements:

- After discussing the nature of the study with the Study Director, I will allow AHETF to recruit any of my employees with applicable training and experience (as determined by the Study Director) in the tasks involved in the study.
- While I acknowledge that there may be benefits to me:
    - I will neither encourage nor discourage my employees to participate in the study.
    - An employee's decision to participate, not to participate, or to withdraw from participation in the study will have no impact on his/her employment status or pay.
    - Employees who decide not to participate, who withdraw from participation, or who complete participation in less than a typical work shift will be offered alternative work at their usual pay to complete their usual work shift.
    - Employees will receive their normal pay for days they participate in the study.

Signature: _____ Date: _____

Title and Affiliation: _____

ATTACHMENT 11-B-2



ATTACHMENT 11-B-3

Language Procedures

	Worker Speaks English (and maybe Spanish, too)	Worker Speaks Spanish (but not English)
Worker Can Read This Language	SD Discussions in English Consent Form in English No Translator needed No Witness needed	SD Discussions in English Translated into Spanish Consent Form in Spanish Translator needed No Witness needed
Worker Cannot Read This Language	SD Discussion in English SD reads English Consent Form to worker No Translator needed Witness needed (English)	SD Discussion in English Translated into Spanish Translator reads Spanish Consent Form to worker Translator needed Witness needed (bilingual)

ATTACHMENT 11-B-4

REQUEST FOR PERSONAL STUDY RESULTS - AHETF Study (AHExx)

This worker wishes to receive a copy of his/her personal study results.

Name: _____

Address: _____

City: _____

State: _____

Zip Code: _____

Study Worker ID: _____

Description of Data Sent:_____

_____

_____

Sent By: _____

Date Sent: _____

Worker Sample Collection Sequence

Chapter 10: FIELD OPERATIONS
AHETF-10.E.2.

Effective Date : March 3, 2008

APPROVAL David Johnson	DATE 3/3/08
APPROVAL	DATE 3/3/08
Last Revision Date: January 1, 2006	Previous Version Number: 10.E.1

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the sequence for the research personnel to follow when collecting worker samples from the field phase of the Agricultural Handlers Exposure Task Force (AHETF) exposure studies.

1.2 This SOP was revised to change the term "replicate" to monitoring unit or worker.

2.0 COLLECTION SEQUENCE

2.1 Upon completion of the monitoring period, the worker shall return to the appropriate staging area. Research personnel collecting dosimetry samples must change their disposable gloves (latex, vinyl, etc...) between each sample collected described as follows.

2.2 The research personnel will check the air pump flow rate using equipment and techniques described in SOPs 8.D and 10.A. The air sample will be collected according to SOP 8.D, and the air pump and lines removed from the worker.

2.3 The worker will then remove their own personal protective equipment (PPE), which may include chemical-resistant (CR) gloves, a respirator, glasses, hat or CR headgear. This headgear may contain head patch samples. If inner head patches were utilized during the study, the researcher will remove the inner head patch according to SOP 8.H.

2.4 If head patches were utilized in the study, the outer head patch will be collected by research personnel, according to SOP 8.H., after the worker removes their headgear.

2.5 The worker will then remove any body PPE (e.g., apron, coveralls, or gloves) and their shoes, then the worker may enter the clean, private area where they will remove their outer work clothes and socks.

2.6 If no sock dosimeters were used on the study, skip to section 2.7 and collect a hand wash sample. Otherwise, upon removal of outer garments (shirt, then pants, then outer socks) by the worker, the researcher will remove the sock dosimeters, according to SOP 8.I.

2.7 Immediately after the worker has removed his outer clothing and if the socks dosimeters (if used) have been collected, the researcher will collect hand wash samples, according to SOP 8.B.

2.8 After collection of hand washes, the researcher will collect face/neck wipe samples, according to SOP 8.C.

2.9 After collection of the face/neck wipes, the researcher will remove the inner dosimeter from the worker and process it, according to SOP 8.A.

2.10 At this point, all worker samples will have been collected and the worker shall dress in his/her street clothes and may be dismissed.

2.11 Any deviations to this procedure must be documented in the raw data and the Study Director informed of the changes and reasons. This sequence only applies to the post-monitoring period sample collection procedure. Interim samples that are collected will be done according to the specific matrix sample SOPs and identified according to SOP 8.F.

Application Equipment Operation Verification

Chapter 10: FIELD OPERATIONS
AHETF-IO.D.O.

Effective Date : October 15, 2003

APPROVAL _____ DATE 09-27-03

APPROVAL _____ DATE 09-26-03

Last Revision Date: N/A Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides the steps for the Study Director, or designee, to follow when assessing the operability of application equipment (groundboom, aerial, airblast, handheld, *etc.*) prior to being used in Agricultural Handlers Exposure Task Force (AHETF) worker exposure studies.

1.2 This SOP will cover various commercial application equipment that may be used on AHETF worker exposure studies. Since the AHETF will measure handler exposure (applicator) under expected working conditions using standard industry practices, no modifications or maintenance will be performed by the AHETF to the equipment. In order to maintain an acceptable level of scientific integrity, the AHETF will perform several steps to assess the operational capabilities of the application equipment.

2.0 EQUIPMENT RECORDS REVIEW

2.1 The Study Director will obtain copies of pertinent maintenance and calibration records provided by the equipment owner. These copies will be maintained by the AHETF in the appropriate study file.

2.2 The Study Director, or designee, will review the equipment records prior to the application. The records should indicate reasonable maintenance has been conducted by the equipment owner/operator, and that the output of the equipment has been checked within the six months prior to the AHETF study.

3.0 VISUAL EQUIPMENT INSPECTION

3.1 The Study Director, or designee, will perform a general visual inspection of the application equipment. Visible signs of damage shall be noted. The overall condition of the equipment will be documented.

3.2 The Study Director shall point out any deficiencies or questionable parts of the equipment to the owner/operator. If deemed necessary, the owner/operator shall perform the needed repairs prior to the AHETF application.

3.3 All observations and corrective actions (if applicable) will be documented in the study file.

4.0 VERIFICATION OF GENERAL OPERATION

4.1 The output of the application equipment will be visually assessed prior to the application. This entails verifying that each nozzle (or other delivery mechanism) is discharging while the equipment is running and at operating pressure. This should be done without the test substance in the tank. Individual output from any nozzle may be collected and measured at the discretion of the Study Director. All observations or measurements made will be documented in the study file.

4.2 The overall operation of the equipment shall be verified. Any significant problems that interfere with the application shall be discussed before proceeding with the application. All observations and corrective actions (if necessary) will be documented in the study file.

5.0 APPLICATION EQUIPMENT OUTPUT

5.1 If deemed necessary by the Study Director, a complete measurement of each nozzle's output shall be completed, in duplicate, prior to the AHETF application. If the output is dependent upon the equipment's speed, then timed passes will be conducted over a known distance of similar terrain to the treated areas. All results and calculations will be documented in the study file.

Worker and Study Observations

Chapter 10: FIELD OPERATIONS
AHETF-10.C.3.

Effective Date : March 3, 2008

APPROVAL David Johnson	DATE 3/3/08
APPROVAL	DATE 3/3/08
Last Revision Date: January 1, 2006	Previous Version Number: 10.C.2.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes procedures for the necessary observations to be performed during the field phase of the Agricultural Handlers Exposure Task Force (AHETF) exposure studies.

1.2 The SOP was revised to include more details on what observers should be looking for in relation to worker health status.

2.0 FIELD NOTEBOOKS

2.1 To standardize and facilitate data collection, a field notebook will be provided to the field contractors prior to the exposure-monitoring period. The notebook will provide the necessary forms for study data collection. Instructions for the use of notebook will be located at the front of notebook.

2.2 The provided notebook will contain the AHETF study number and contractor project number on each page. If additional pages are inserted into the field notebook, this information must be included on the inserted pages.

3.0 SITE DETAILS

3.1 Record site details on the appropriate forms in the field notebook.

The Principal Field Investigator (PFI) should record the following information, at a minimum:

a. Prepare a sketch map of the working area giving key details such as compass points, orientation of rows in test plot, mixing/loading area.

b. Record on the form the study number, site reference, date and initials.

c. Attach a copy of a map with the nearest town circled and give details from there.

d. If details of the location change (*e.g.,* move to a different location for application), prepare a new sketch showing the new conditions.

4.0 ENVIRONMENTAL CONSIDERATIONS

4.1 Outdoor environmental conditions, including but not limited to, wind speed, wind direction (relative to the test site and direction of application), air temperature and relative humidity will be monitored and recorded locally by means of a weather station at each trial site during worker monitoring, or by reference to data from the nearest NOAA weather station. Measuring equipment for on-site weather stations will be calibrated per the contractor's SOP.

4.2 Indoor environmental conditions, including but not limited to, air temperature and relative humidity will be monitored and recorded by means of calibrated measuring devices located within the designated test areas. Measuring equipment for indoor monitoring will be calibrated per the contractor's SOP. The ventilation system will be described in the raw data.

4.3 At all test sites, environmental conditions that could pose a potential heat-related illness threat will be diligently monitored as part of the AHETF program to minimize potential heat stress on workers. Refer to SOP AHETF-11.G.

5.0 EQUIPMENT DETAILS AND OPERATION VERIFICATION

5.1 Details of application equipment will be recorded in the field notebook. Application equipment operation will be verified, and calculations recorded, as defined in the study protocol and SOP AHETF-10.D.

6.0 WORKER OBSERVATIONS

6.1 Each dedicated worker's observer must use the appropriate form in the field notebook to record the times and descriptions of all activities including mixing, loading, and/or application activities; resting, lunch, washing hands, driving vehicles, *etc*.

6.2 Describe clothing and personal protective equipment (PPE) worn and crop/site condition. Document all clothing worn, including PPE prior to the start of observations during the work period. Note any clothing defects and bring to the attention of the Study Director, Principal Field Investigator (PFI), or AHETF personnel on-site. Record any instances of removal of protective equipment during the monitoring period.

6.3 Be sure that the air sampling pump has been turned on before the worker enters the mixing/loading areas, begins any activities for the day, or uses any application equipment. If the PFI has not turned on the air sampling pump immediately after the worker was dressed, it is the observer's responsibility to turn the pump on and record the start time in the field.

6.4 Record start and stop time for all activities. Record the productivity of each worker during the activities (*e.g.*, specifically the amount of product handled, if known). It is recommended that all study personnel synchronize their watches prior to the start of the day's activities.

6.5 Record any actions that might explain any unusually high or low exposure values for any of the body parts (*e.g.,* spills, maintenance of equipment, keeps gloves on, *etc.*).

6.6 Pay attention to the workers' hands during the exposure monitoring period, this includes time handling the test substance, donning/removing PPE, standing around waiting, or performing non-study related activities. Look for hand contact to contaminated equipment or clothing associated with contact to the head/face, other workers, personnel, *etc*.

6.7 Periodically note the workers' clothing. Look for new rips or tears, perspiration, chemical spills/stains, or anything that appears out of the ordinary. Also check and document the operation of the personal air sampling pump. Document as "Pump Running" not "Pump On".

6.8 Report any unusual or unauthorized activities observed (eating without handwash, not wearing PPE during chemical exposure, *etc*…) to the Study Director, PFI, or AHETF QAU.

6.9 Record observations pertinent to the worker assigned. For example, when observing a loader, it is not necessary to note the specifics of the application equipment. This information can be cross-referenced later.

6.10 Monitor the health status of the worker, especially under conditions of temperature and humidity which may promote a heat-related illness. Refer to SOP AHETF-11.G for specific warning signs and condition criteria. Record any reactions a worker may exhibit and any remedial actions taken.

6.11 Keep observations brief and to the point. Don't use worker names; rather use their ID for the study. Don't record long explanations of activities unless absolutely necessary to explain what is occurring. Document what activities are directly related to handling the test substance.

6.12 The observations made will be reviewed and placed in the field report at the conclusion of the study. Try to write neatly and clearly while describing the activities observed. Be as succinct as possible. Typically 3-5 pages of notes should be collected during an average work period.

6.13 Observe the worker for the entire time period of the exposure monitoring , from when the worker is dressed at the start of the day until he/she enters the staging area for sample collection; this includes during lunch breaks, performing other daily activities, and during interim sample collections. This does not include observing the worker during restroom breaks. If the worker cannot be seen during application, this should be noted, and is to be expected at times. If the observer needs to take a break, get another researcher to monitor the worker during the observer's absence.

6.14 Do record the names of non-study compounds observed being handled during the monitoring period. Use generic terms like anti-foam agent, surfactant, insecticide, *etc*. in observation notes and document chemical or trade names, if known, in the specific loading/application procedures.

6.15 A pre-study explanation of required observations may be conducted before the conduct of the study commences. The AHETF QAU and/or Study Director will be responsible for providing additional training on this SOP. The AHETF Study Director will determine if research personnel would benefit from such training on a per study basis.

Rotameter Calibration

Chapter 10: FIELD OPERATIONS
AHETF-IO.A.O.

Effective Date : October 15, 2003

APPROVAL _____ DATE 09-27-03

APPROVAL _____ DATE 09-26-03

Last Revision Date: N/A Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides the steps to properly calibrate a rotameter used for measurement of the air flow rate through an OVS air sampling tube used to collect air monitoring samples during Agricultural Handlers Exposure Task Force (AHETF) worker exposure studies.

2.0 EQUIPMENT REQUIRED

2.1 The following equipment is needed to calibrate the rotameters:

a. Personal low-volume air-sampler pump(s) (*e.g.*, SKC, or equivalent)

b. Tygon® tubing or equivalent

c. Appropriate calibration device or primary air flow meter (*e.g.,*BIOS DryCal®, Kurz Mass flow meter, Buck Calibrator, bubble meter and stopwatch, or equivalent)

d. Field rotameter with an appropriate measurement range

3.0 CALIBRATION PROCEDURE

3.1 Place air-sampler pumps on chargers before each use. If the pump is fully charged proceed to 3.2.

3.2 Verify calibration of a rotameter once a year or if rotameter operation becomes suspect.

3.3 Start by calibrating five individual air-sampler pumps to five individual flow rates using a primary air flow meter (*e.g.* BIOS DryCal®, calibrated according to the SOP for the appropriate flowmeter). Select five flow rates that span the scale of the rotameter being calibrated.

3.4 Evaluate the rotameter calibration by attaching, one at a time, the five air flow calibrated air-sampler pumps from 3.3 to the rotameter. Hold the rotameter perpendicular to the ground and after the rotameter has been allowed to stabilize, a reading from the middle of the ball can be taken and recorded.

3.5 If any reading deviates more than ±5%, the rotameter will be discarded and replaced with a new rotameter.

Sample Quality

Chapter 8: MATRIX SAMPLES
AHETF-8.K.O.

Effective Date : 03/03/08

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

Last Revision Date: N/A Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 Unexpected situations can occur during exposure monitoring studies that can have an effect on sample quality. These situations may occur at various stages of the study (*i.e.*, sample collection, packaging, shipping, storage and analysis). This Standard Operating Procedure (SOP) provides examples of unexpected situations in which samples should be invalidated. This list is not meant to be all-inclusive; however it does provide some examples, especially during the field phase of the study, for when samples may be deemed to be compromised.

1.2 Whenever sample matrices are not collected, analyzed, and/or reported, a full explanation will be provided in the raw data as well as in the appropriate phase report (*i.e.*, Field or Analytical), and/or the Summary Report.

2.0 SITUATIONS DURING EXPOSURE MONITORING IN WHICH SAMPLES ARE INVALIDATED

2.1 In some cases, determining whether a sample has been compromised, and is therefore invalid, is clear. It is the decision of the Study Director to determine that a sample has clearly been compromised and should not be collected for processing (*i.e.*, labeled and stored for possible subsequent analysis). However, if the situation is not so unequivocal, then the samples should be collected and the decision will be made at a

later time whether to analyze them. This decision will be made by AHETF management in conjunction with the Study Director and other appropriate field personnel.

2.2 Examples of circumstances in which samples should be invalidated are listed below:

a) If the worker's activities are not in compliance with the label requirements and/or WPS

b) If the worker is drenched by rain during monitoring

c) If a sample is known to have been contaminated by an event that was not part of the worker's activities (example: face/neck wipe is dropped on the ground in the staging area)

d) If a complete set of dermal dosimeter samples (*i.e.*, whole body dosimeter, face/neck wipes, and hand washes) is not collected (*e.g.*, a worker must leave due to an emergency or a worker forgets and washes his/her hands prior to collection of the last hand wash sample)

e) If a sample cannot be positively identified due to mislabeling

f) If a sample is improperly stored under conditions not consistent with quality assurance samples

2.3 If the portable air sampling pump stops working and the investigator is unable to determine how long the pump was stopped, the inhalation sample will be considered invalid. However, the loss of an inhalation monitoring sample does not preclude acceptability of the dermal monitoring samples.

3.0 SITUATIONS AFTER THE FIELD PHASE IN WHICH SAMPLES ARE INVALIDATED

3.1 It is possible that during transit, storage, or analysis that samples may become compromised. The most likely situation is that individual samples could be compromised during analysis. Decisions regarding sample integrity after the field phase of the study will be made by AHETF management in conjunction with the Study Director and other appropriate analytical personnel.

3.2 Examples of circumstances in which samples should be invalidated are listed below:

a) If a sample is known to have been contaminated (*e.g.*, a matrix sample is inadvertently spiked with standard solutions)

b) If a complete set of dermal dosimeter samples (*i.e.*, whole body dosimeter, face/neck wipes, and hand washes) is not available

c) If a sample cannot be positively identified due to mislabeling

d) If a sample is improperly stored under conditions not consistent with quality assurance samples

Sample Identification

Chapter 8: MATRIX SAMPLES
AHETF-8.F.4.

Effective Date : 03/03/08

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

Last Revision Date: April 30, 2008 Previous Version Number: 8.F.3.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the procedures to uniquely identify field samples collected during Agricultural Handlers Exposure Task Force (AHETF) worker exposure studies.

1.2 This SOP was revised to change the term "replicate" to Monitoring Unit (MU) [refers to the monitoring period or worker.]

2.0 NUMBERING PROCEDURE

2.1 All samples (exposure and fortification) will be identified by the protocol (AHETF study) number and a unique identification number that describes the type of sample. Individual MU numbers or codes may not be reused should a specific worker's monitoring period be started and then cancelled, even if no samples were collected for analysis. Additional MU number(s) will be assigned, as necessary.

2.2 The sample identification number will be formatted as an alphanumeric string, separated by hyphens (-) between each code:

SN-XX-NN-YY-ZZ

2.3 The identities of the codes are listed on the following page.

2.4 The following is a list of the coded pairs to be used in the sample identification format SN-XX-NN-YY-ZZ:

SN: The last two digits of the AHETF five character study number.

XX: A code for the type of sample:

WS - Worker Sample
FF - Field Fortification Sample

NN: For exposure samples - The two-digit MU identification number. This can be a sequential number for each MU or an alpha-numeric code to distinguish between applicator and mixer/loader workers, as follows:

Ax - Worker Sample – Applicator only with sequential sample no.
Mx - Worker Sample – Mixer/loader only with sequential sample no.

For exposure field fortification samples - A two digit number to denote the study day of fortification (*e.g.* day 01, 02, 03) based on the actual day of the study the samples are fortified on.

YY: A code for the type of the samples

ID - Inner Dosimeter
AR - Air Sampling Media
HW - Hand Washes
FW - Face/Neck Wipe

ZZ: Unique 2 Character Codes For All Samples

Fortifications (FF samples only)	
Tx*	travel spike
Lx*	low spike
Mx*	mid spike
Hx*	high spike
Cx*	control sample

Dosimeters (WS ID samples only)	
LB	lower body
UB	upper body
LA	lower arms
UA	upper arms
FT	front torso
RT	rear torso
UL	upper legs
LL	lower legs
SX	socks
OH	head patch, outer
IH	head patch, inner

A sequential number will be noted for each control and fortified sample to note worker samples.

Air – Handwash - Face/Neck Wipe Samples (WS samples only)
Sequential number to denote multiple samples (if more than one sample is collected) from the same MU during a monitoring period, -01 is the first sample collected, -02 is the second, *etc.* If only one air sample, hand wash, or face/neck wipe sample is collected, then –01 will be the only sample number used. If more than one must be collected during the monitoring period, use a sequential number for each, with the highest number used for the final sample collected that day.

2.5 The following is a list of example sample ID numbers:

01-WS-02-ID-LL:	Study AHE01 – worker sample - MU 2 - inner dosimeter - lower legs
41-WS-A5-ID-BL:	Study AHE41 – worker sample - applicator MU 5 - inner dosimeter - lower body
05-WS-M5-HW-01:	Study AHE05 – worker sample – mixer/loader MU 5 - first (or only) hand wash collected.
55-WS-05-HW-02:	Study AHE55 – worker sample - MU 5 – second hand wash collected
55-WS-03-AR-01:	Study AHE55 – worker sample - MU 3 - air sample (first or only sample)
55-WS-03-AR-01:	Study AHE55 – worker sample - MU 3 - air sample (first or only sample)
55-WS-09-FW-01:	Study AHE55 – worker sample - MU 9 - face/neck wipe (first or only sample)
77-FF-01-IH-L1:	Study AHE77 – Field Fort. - first study day - inner head patch - first low level
11-FF-01-ID-L2:	Study AHE11 - Field fort. – first study day - inner dosimeter - second low level
22-FF-03-FW-H1	Study AHE22 - Field fort. – third study day - face/neck wipe - first high level [this may be the *second* day of fortifications for AHE22]

Fortification of Matrix Samples

Chapter 8: MATRIX SAMPLES
AHETF-8.E.4

Effective Date : 03/03/08

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

Last Revision Date: April 30, 2006 Previous Version Number: 8.E.3

1.0 PURPOSE AND SCOPE

1.1 This SOP describes the methods by which agricultural worker exposure monitoring matrices, (*i.e.*, inner dosimeters, hand washes, face/neck wipes, inner socks, outer head patches, inner head patches, and OVS tubes) are to be spiked. This SOP applies to the use of all worker exposure matrices when used for producing field fortification recovery data for the Agricultural Handlers Exposure Task Force (AHETF).

1.2 This SOP was revised to provide additional explanation about the purpose of weathering and how fortification samples are handled to simulate exposure conditions. This information is contained in the new Section 2.0.

2.0 BACKGROUND

2.1 Field fortification samples are exposure matrix samples that are fortified (or spiked), generally in the field, with known amounts of active ingredient and subsequently analyzed to determine the amount of active ingredient recovered. Field fortification samples are subjected to the same environmental, handling, shipping and storage conditions as worker samples. Because these conditions are similar, and because field fortification samples are analyzed along with worker samples, recovery values calculated from analysis of fortification samples are applicable to worker exposure samples. Field fortification recoveries are therefore used to adjust residue levels found in worker samples for residue losses that might have occurred during collection, handling, shipping and storage.

2.2 It is important that field fortification samples simulate worker samples as much as possible. For example, some worker matrices collect residue throughout the entire monitoring period and are therefore subject to environmental conditions for several hours. To simulate this in field fortification samples, certain matrices are "weathered" in the field concurrently with worker samples. That is, they are fortified (generally before any worker monitoring starts) and exposed to the environment until worker monitoring has been completed on that day. Samples that are weathered include: inner dosimeters, socks, head patches (inner or outer) and OVS tubes. On the other hand, face/neck wipes and hand wash samples are collected at discrete times during the day and are not subject to environmental conditions during sample collection. Therefore, these sample types (both worker samples and field fortified samples) are not weathered, but are instead placed into storage immediately after collection.

2.3 The field fortification process simulates two other conditions that worker samples experience. First, inner cloth dosimeters (whole body dosimeters, WBD), socks, and head patches are covered with a material similar to what covers the worker samples: a layer of cloth to simulate outer clothing covers inner dosimeter and sock samples, and headgear material (e.g., chemical-resistant hat) covers inner head patches. Second, OVS tubes have air drawn through them at the same rate that air is drawn through the worker air tubes.

2.4 AHETF also prepares and collects non-fortified (control) samples to determine if background residues of active ingredient are present. For the same reasons as described above, control samples of inner dosimeter, inner and outer patch, sock and OVS tube are weathered, while control samples of hand wash and face/neck wipe are not weathered.

2.5 In addition, fortified inner dosimeters (and if appropriate, socks and head patches) and OVS tubes are prepared as "travel spikes" and are not weathered. These samples provide a source of determining whether or not degradation occurs in transit. Travel spikes are not analyzed unless there are unexplained low residue recoveries of the corresponding field fortification samples. In this situation, recovery results from travel spikes might provide insight into where in the preparation, collection, transit and storage process, losses may have occurred**.**

3.0 EQUIPMENT/REAGENTS REQUIRED

3.1 The following examples of equipment and solutions are required for each day that field fortifications are to be conducted:

a. Exposure monitoring matrix samples based upon protocol specified monitoring matrices (inner dosimeter material cut according to SOP AHETF-8.A. [upper and lower sections for two section monitoring or upper/lower arms & legs and front/rear torso for six section monitoring], moistened face/neck wipes, OVS tubes, and hand wash solutions, and if required, 50 cm^2 and 100 cm^2 head patches [made of inner dosimeter material], and socks).

b. Appropriate containers for fortified matrix samples (*e.g.*, bags, bottles, jars, *etc.*)

c. Appropriate pipettes (*e.g.* 1.0 mL, non-graduated Pasteur pipettes, *etc.*)

d. Appropriate syringe (*e.g.*, 100 µL)

e. Distilled or deionized water

f. Anionic detergent solution (0.01% v/v Aerosol® OT 75). Refer to the SOP AHETF-8.B for solution preparation.

g. Paper towels

h. Disposable gloves

i. Aluminum Foil

j. Rinsing solvent (to be the same as the solvent used to make spiking solutions)

4.0 SPIKING MATERIALS

4.1 Spiking materials may be in the following forms:

a. Active ingredient (ai) in an organic solvent

b. Formulated product in water

c. Formulated product pre-weighed into a container in which a specific amount of water is to be added in the field prior to being spiked onto (into) a matrix material.

d. Pre-spiked OVS tubes.

5.0 SPIKING TECHNIQUES

5.1 There are two (2) basic procedures that may be used for the fortification of worker dermal exposure matrices for the AHETF. They are by pipette and by vial.

5.2 When applying a spiking material to the various matrices, it is important to ensure that the solution/suspension gets well mixed prior to spiking and/or distributed as evenly as possible.

5.3 The spiking material needs to be distributed mechanically, typically with a pipette or vial, over the largest amount of matrix area as possible.

5.4 **Spiking ai in solvent**: A volume, typically 1 mL, of spiking solution will be drawn up into the pipette and then applied appropriately to the matrix of choice.

5.5 **Spiking formulated product in water**: A well-mixed aliquot, typically 1 mL, will be taken from a well-shaken bottle of the formulation suspended in water. The shaking may be done by hand, on a stirring plate, or using a mechanical shaker. Once the suspension looks evenly distributed, an aliquot is taken and applied appropriately to the matrix of choice.

5.6 Spiking using entire solution vials: Vials containing a known aliquot of a known concentration of spiking material will be sent to the field along with instructions on how to apply the spike to a matrix. The person doing the spiking will take a given spiking vial, unscrew the cap, and apply the contents to the matrix. The contents may be poured directly from the vial or removed via a Pasteur pipette (or equivalent). Use of a pipette may be desired for smaller matrices where more exact placement of material is necessary. The vial and pipette will sometimes be rinsed several times

with the solvent (e.g. deionized or distilled water, acetone, acetonitrile, etc.) that was used to prepare the solution and applied to the matrix or as directed by the analytical laboratory (see below). The vial shall be retained with the fortified sample. The cap should be discarded and should not be rinsed. Vials should be marked with a label that may be tied to the vial with string or is a self adhesive label, which may be removed easily from the vial and will not interfere with analysis of fortified matrices.

6.0 SPIKING PROCEDURES

6.1 Inner Dosimeters

a. The dosimeters must be placed on a piece of aluminum foil prior to spiking. After spiking and weathering (if applicable), the sample will be wrapped in the same piece of foil it was placed on for spiking and weathering then inserted into the sample container.

b. The spiking material will be added to inner dosimeters; ensure the fortification is added to a dosimeter that has been folded to provide at least 6 layers of cloth. This insures that all the material is absorbed by the cloth.

c. When spiking with solution vials, the person doing the spiking will unscrew the cap and apply the contents to the matrix. The vial will be rinsed several times as directed by the analytical laboratory with the solvent that was used to prepare the solution or suspension. This may be done several times, however; too much solvent will cause the spike to run through the fabric, so judgment is needed. The empty spiking vial will be placed on its aluminum foil with the matrix prior to folding the foil.

d. When pipetting the solution onto the dosimeter, the tip of the pipette may be used to help distribute the spike (typically 1 mL) in lines evenly over the surface of the dosimeter. At no time can there be a bead of spiking material left on the surface. (The spiking liquid may tend to bead up on the surface. Gently pushing the pipette tip over the bead will help to get the liquid into the matrix.)

e. For dosimeters exposed to ambient conditions, the inner dosimeters will be folded over after fortification and covered with a single layer of shirt material during exposure. Effort should be made to ensure that the spiking solution has been completely absorbed by the material prior to covering.

6.2 Hand Washes

a. When spiking from a solution or suspension in the field, the appropriate amount of spiking solution (typically 1 mL) will be added to the hand wash.

b. When spiking with vials, the cap to the solution vial will be unscrewed from the vial and discarded without rinsing. The contents will be added to a 500 mL Aerosol OT (AOT) sample and the vial then dropped into the sample. The sample will then be swirled or the jar inverted to ensure proper mixing of the spiking material with the sample matrix.

6.3 OVS tubes

a. The tubes will be spiked at the laboratory with the proper amount of analytical standard. The tubes will always be spiked with an ai solution using a syringe. The spike will be applied by inserting the needle through the glass fiber filter and approximately one quarter of the way into the front sorbent bed.

b. Depress the syringe plunger slowly to avoid the ai solution from "bleeding out" of the sorbent and adhering to the glass tube. Each tube will be spiked with a minimum of 5μL up to, but not exceeding, 100 μL of solution. The actual amount of spiking solution to use will be determined by the analytical laboratory and documented in the raw data.

c. Tubes fortified in the laboratory will be sent frozen in plastic bags to the field. The bags will be to be taken out of the freezer and allowed to come to ambient temperature before they are used in the field. Just before they are to be put on the personal air sampling pumps, they should be taken out of the

bag and allowed to finish equilibrating with the environment. They then will be placed onto the pumps and air pulled through them for the approximate length of time the worker replicates are in the field.

6.4 Face/Neck Wipes

a. Pre-wet two face/neck wipes as described for field samples in SOP AHETF-8.C.

b. When spiking with solution vials, the two gauze pads will first be placed into the sample jar or on clean foil. The contents of the vial will then be transferred onto the gauze pads. The vial will be placed with the sample without being rinsed. The cap will be discarded without rinsing. The sample will be wrapped in foil and placed in a plastic bag, or the jar will be capped and sealed after fortification, as appropriate. In the laboratory, the vial will be rinsed as part of the extraction procedure.

c. When pipetting the solution onto the wipe, the tip of the pipette may be used to help distribute the spike (typically 1 mL) in lines evenly over the surface of the wipe, if necessary.

6.5 Socks

a. The socks must be placed on a piece of aluminum foil prior to spiking. After spiking and weathering, the sample will be wrapped in the same piece of foil it was placed on for spiking and weathering then inserted into the sample container.

b. For spiking and weathering, ensure the sock sample consists of 2 socks (1 pair). The actual spiking material will be placed on the one sock that is closest to the foil. This sock will then be covered by the second sock and both socks will be folded. This procedure simulates a sock covered by a worker's pants and shoes.

c. When spiking with prepared solutions in vials, the person doing the spiking will unscrew the cap and apply the contents to the matrix. The cap will be discarded without rinsing. The vial will be rinsed several times with the solvent that was used to prepare the solution, as directed by the analytical laboratory.

Multiple rinses may be done; however, too much solvent will cause the spike to run through the fabric, so judgment is needed. Place the empty spiking vial in its aluminum foil with the matrix.

d. When pipetting the solution onto the dosimeter, the tip of the pipette may be used to help distribute the spike (typically 1 mL) in lines evenly over the surface of the dosimeter. At no time can there be a bead of spiking material left on the surface. (The spiking liquid may tend to bead up on the surface. Gently pushing the pipette tip over the bead will help to get the liquid into the matrix.)

6.6 Outer Head Patches

a. For field fortification samples, only, an outer head patch will consist of 6 layers of inner dosimeter material, each layer cut to a 50 cm^2 area wrapped in aluminum foil. The foil should be placed underneath the pile of patches and used to wrap the weathered spiked patch sample once the weathering period is completed.

b. The field fortification suspensions will be applied to the topmost layer of patches. The additional layers will be used to ensure that no spiking material leaches out onto the foil that underlies the pile of patches.

c. Outer head patches **will not be** covered during the weathering period.

6.7 Inner Head Patches

a. For field fortification samples, only, an inner head patch will consist of 4 layers of inner dosimeter material, each layer cut to a 100 cm^2 area, wrapped in aluminum foil. The foil should be placed underneath the pile of patches and used to wrap the weathered spiked inner dosimeter patch sample once the weathering period is completed.

b. The field fortification suspension will be applied to the topmost layer of material. The additional layers will be used to ensure that no spiking material leaches out onto the foil that underlies

the pile of patches.

c. Inner head patches will be covered with chemical resistant headgear similar to the type worn by the workers during the application period, or other suitable material to simulate the headgear, as approved by the Study Director.

7.0 FORTIFICATION SAMPLE IDENTIFICATION AND HANDLING

7.1 Refer to SOP AHETF-8.F. for the procedures to uniquely identify fortification samples.

7.2 Fortification samples that are exposed under the open sky should have the necessary materials to protect the samples in the event of rain.

7.3 Fortification samples are packaged, stored and transported in the same manner as the test samples for a particular matrix. The fortification samples should not be placed into the same shipping/storage container with control samples or with field samples.

Collection of Air Samples Using OVS Tubes

Chapter 8: MATRIX SAMPLES
AHETF-8.D.2.

Effective Date : March 3, 2008

APPROVAL David Johnson	DATE 3/3/08
APPROVAL	DATE 3/3/08
Last Revision Date: March 10, 2003	Previous Version Number: 8.D.1.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides a description of procedures for collecting air samples using OSHA Versatile Sampler (OVS) tubes during the Agricultural Handlers Exposure Task Force (AHETF) exposure studies.

1.2 The OVS tube will be positioned in the breathing zone of the worker. The air will be sampled at a flow rate applicable to the characteristics of the OVS tube. A plastic tube holder will be used to position and protect the OVS tubes on the worker.

1.3 This SOP was revised to change the terms "replicate" and "monitoring period" were replaced with either "worker" or "monitoring unit."

2.0 MATERIALS REQUIRED

2.1 The following materials are required for collecting air samples from each worker:

a. OVS Tubes, 13 mm glass tubes [*e.g.*; mfr. SKC, Inc. with 270 mg & 140 mg absorbent beds separated by polyurethane plug, and glass fiber filter at the inlet], or equivalent

b. Plastic OVS tube holder

c. Tygon® or equivalent tubing and clips for securing tubing to the

worker (a minimum of two required)

d. Low volume personal air-sampler pump (battery operated)

e. Air flow meter (*e.g.*, Kurz Mass Flow Meter, rotameter, bubble flowmeter, or equivalent)

f. Sealable bags (*e.g.*, Ziploc® freezer bags)

g. Disposable gloves (*i.e.*, latex)

h. Cooler with dry ice, or freezer

3.0 AIR-SAMPLER PUMP PREPARATION

3.1 Place air-sampler pumps on chargers before each use. If the pump is fully charged proceed to 3.2.

3.2 Adjust air-sampler pump flow rate before use in each monitoring unit. Air sample pump flow rate adjustment will take place on the day prior to or the same day the pumps are to be used.

3.3 Adjust air pumps to the targeted airflow rate with the appropriate OVS tube/ sampling train attached.

3.4 Follow appropriate contractor SOPs for the individual calibration methods for contractor equipment. SOPs used will be documented in the AHETF raw data.

3.5 Adjust the airflow rate to appropriate target rate as defined in the study protocol [*e.g.,* 2 liters per min (L/min)] and document the flow rate and pump number in the raw data.

3.6 Turn off the air-sampler pump and set aside. Repeat steps 3.3 and 3.5 until all needed sampling pumps (including backups) have been adjusted.

4.0 SAMPLING PREPARATION

4.1 Remove the outlet cap from the OVS tube and connect the outlet of the tube (the smaller 6 mm end) to the end of the air tubing that is connected to an adjusted personal air-sampler pump. Be sure the glass fiber filter is attached to the inlet (the larger 13 mm end) and is left open.

4.2 Position a belt snugly around the worker's waist, or use that worker's belt (if appropriate) to support the sampling pump. Attach the pump to the belt using the clip on the pump. Position the pump wherever it feels most comfortable to the worker.

4.3 Place the OVS tube over the shoulder of the worker (to the front of the torso) in the approximate position for sampling (in the breathing zone of worker).

4.4 Use a binder clip to attach the tubing, approximately at its midpoint, to the worker's clothing so that it will not interfere with the normal work operations nor catch on anything. The tubing may be run inside the worker's clothes. If tubing is run inside, ensure that clean, decontaminated tubing is used. **Do not reuse contaminated tubing!**

4.5 Remove the inlet cap and start the pump. Check the flow rate with a calibrated rotameter (Please refer to the AHETF-10.A or appropriate contract testing facility SOP). Adjust the air-sampler pump flow rate if the measured flow rate deviates greater than ±5% from the target flow rate.

4.6 Document the pump number, start time and the flow rate measured with the rotameter in the raw data.

4.7 Place the OVS tube in the plastic holder and clip the holder to the workers' collar (in the breathing zone). If the holder does not have an integral clip, use a binder clip, wire or plastic tie to attach to the worker's collar or lapel. Be sure the tubing is not crushed or restricted when attached. The inlet must face downward, in a vertical orientation.

4.8 Observe the worker for a few minutes upon starting to work to ensure the sampling apparatus is functioning properly, and is not interfering with the worker. Periodically monitor the pump during the monitoring unit to ensure it is functioning properly.

4.9 Pumps will run continuously throughout the duration of the monitoring unit, including lunch and other breaks.

4.10 Should a pump malfunction during the monitoring unit, it will be replaced immediately with a new, prior adjusted pump (section 3). Remove the OVS tube from the old pump and attach it to the new, adjusted pump, and repeat steps 4.6 through 4.9. These activities will be documented in the appropriate study file(s) and include (at a minimum) the time the malfunction was discovered, the time reading on the pump (if available), the time the new pump was started and the new measured flow rate.

4.11 At the end of the monitoring unit, remove the OVS tube from the plastic protective holder, measure the terminal flow rate with the rotameter, turn off the pump, record the stop time and flow rate, and remove the pump, tubing and OVS tube from the worker.

5.0 SAMPLING PROCEDURE

5.1 Upon completion of the monitoring unit, remove the OVS tube from holder, cap both ends and place into frozen storage (*i.e.*, on dry ice or in a freezer).

5.2 Clean disposable gloves will be worn by sampling personnel to minimize any contamination of the OVS tube. Gloves will be changed after handling each tube.

6.0 SAMPLING INTERVALS

6.1 OVS tubes will be collected at the end of the monitoring unit, unless otherwise instructed by the protocol.

7.0 FIELD STORAGE

7.1 Place samples collected during the study in the field in a cooler with dry ice or portable freezer until processed and placed into “permanent” frozen storage for shipping at the end of the monitoring day (or as soon as practical). If dry ice is not available, the Study Director must be notified before sample collection and other suitable storage conditions must be noted in the raw data.

Dermal Face/Neck Wipe Samples

Chapter 8: MATRIX SAMPLES
AHETF-8.C.4.

Effective Date : March 3, 2008

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

Last Revision Date: April 30, 2006 Previous Version Number: 8.C.3.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes procedures for collecting pesticide residues from workers' face/neck during the Agricultural Handlers Exposure Task Force (AHETF) worker exposure studies.

1.2 This SOP was revised to change the term "replicate" to monitoring unit or worker.

2.0 EQUIPMENT REQUIRED

2.1 The following materials are required for collecting dermal face/neck samples:

a. 100% cotton gauze (8 layers, 4" x 4"/10cm x 10cm sponges)

b. Anionic detergent solution (Aerosol® OT - sodium dioctyl sulfosuccinate).

c. Syringe or pipette

d. Disposable gloves (*i.e.*, latex)

e. Aluminum foil

f. Resealable bags or glass jars with Teflon-lined lids

g. Cooler with dry ice or a freezer

3.0 SAMPLING PROCEDURE

3.1 The field personnel collecting samples will wear clean, disposable gloves while collecting these dermal samples. (Note: some packaging may contain two sponges; check to make sure each sponge is 8 layers)

3.2 Dispense approximately 4 mL of the detergent solution (0.01% Aerosol® OT) on the gauze sponge with the syringe or pipette (or other appropriate means of moistening the sponge).

3.3 Thoroughly wipe the worker's face/neck (front & back) with the moistened sponge.

3.4 Repeat steps 3.2 and 3.3 again, for a total of two dermal wipes per sample. Wrap both sponges in aluminum foil (only if using a sealable bag) and place in the prelabelled bag otherwise place both wipes in a prelabelled jar, close the top, and place in frozen storage.

4.0 SAMPLING INTERVALS

4.1 Prior to the monitoring unit start, one dermal face/neck wipe sample will be collected from each worker and the wipes discarded.

4.2 One dermal face/neck wipe sample will be collected prior to eating.

4.3 After the monitoring unit is completed, one dermal face/neck wipe sample will be collected from each worker after the hand wash sample is collected per SOP 8.B. and before removal of whole body dosimeters. The wipes will be combined with the samples collected prior to eating, if applicable. If more than two samples (4 wipes) are in a sample bag or jar; the laboratory must be notified as to the total number in the container.

5.0 FIELD STORAGE

5.1 Place samples collected during the study in the field in a cooler with dry ice or portable freezer until processed and placed into frozen storage for shipping at the end of the monitoring day (or as soon as practical). If dry ice is not available, the Study Director must be notified before sample collection and other suitable storage conditions must be noted in the raw data.

Hand Wash Samples

Chapter 8: MATRIX SAMPLES
AHETF-8.B.4.

Effective Date : March 3, 2008

APPROVAL David Johnson	DATE 3/3/08
APPROVAL	DATE 3/3/08
Last Revision Date: January 1, 2006	Previous Version Number: 8.B.3.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides a description of procedures for collecting pesticide residues from worker's bare hands during the Agricultural Handlers Exposure Task Force (AHETF) exposure studies.

1.2 This SOP was revised to clarify that the workers will have their hands washed prior to participating in an AHETF study, as stated in sections 4.1 and 5.1. Also the terms "replicate" and "monitoring period" were replaced with either "worker" or "monitoring unit."

2.0 EQUIPMENT REQUIRED

2.1 The following materials are required for collecting dermal hand wash samples:

a. Metal or glass bowl **(Do not use plastic bowls for performing handwashes)**

b. Aerosol® OT Solution, 10% w/w. This is a concentrated solution of the anionic surfactant dioctyl sodium sulfosuccinate (also known as AOT) which will be diluted in water and used to wash hands (500 mL for each handwash).

c. Distilled or deionized water (in 1 gallon jugs, or other appropriate container)

d. Graduated cylinder or appropriate measuring device

e. Glass jars with Teflon® lined lids, or equivalent

f. Reclosable plastic bags (1 gallon size; optional for storage)

g. Disposable gloves (*i.e.*, latex)

h. Pipette(s) (*e.g.,* 2, 5, 10 mL, *etc.*)

i. Cleaning solutions (*i.e.,* alcohol (methanol, isopropanol), alcohol/water mixture, acetone, *etc.*)

j. Paper towels

k. Cooler with dry ice or freezer

3.0 HAND WASH SOLUTION PREPARATION

3.1 The desired solution concentration is 0.01% v/v Aerosol® OT (AOT) in water (500 mL for each handwash). Sufficient quantities should be made for the projected number of handwashes to be collected on a daily basis or within the allowable shelf life time period.

3.2 Pipette an appropriate amount of 10% w/w AOT solution into the water and dilute 1,000-fold to make a bulk 0.01% v/v AOT solution. For example, 3.8 mL of 10% AOT in one gallon of water or 4 mL of 10% OT in 4.0 liters of water. Document the brand of water (if store bought) and where it was purchased. If the water is **not** store bought, document the source. The AOT solution may be made up in plastic water jugs prior to use, for handwashes or field fortifications. Add the appropriate amount of AOT concentrate directly to the water in the jug or bottle, or other suitable container(s).

3.3 Store the bulk AOT solution in glass jars, plastic bags, water jugs, or suitable container(s). The shelf life of the 0.01% Aerosol® OT solution at room temperature is 48 hours. Reclosable plastic bags may also be used for short-term storage of AOT solution aliquots to facilitate collecting handwash samples in the field.

4.0 WASHING PROCEDURE

4.1 Prior to participating in an AHETF exposure monitoring study, each worker will have their hands washed by a researcher according to the procedure outlined in this SOP. This will serve to clean the hands as well as provide some practice for the hand wash procedure that will be used in the study. The researcher will describe and assist with at least one washing procedure. The rinsate will be discarded.

4.2 At the end of the monitoring unit, upon removal of the worker's personal protective equipment (PPE) and shoes/socks, the worker will be taken to a designated clean "privacy area" for removal of exposed outer clothing. For interim handwashes during the monitoring period, follow steps 4.5 through 4.9.

4.3 Disposable paper, plastic mat, or aluminum foil will be placed on the chairs and floor of the changing area to reduce cross-contamination. The materials will be changed after the processing of each worker.

4.4 Handwash samples must be collected **after** the outer clothing and PPE have been removed, or after sock dosimeters have been collected, as described in SOP 8.I, if applicable. Hand washes must be completed **before** the face/neck samples are collected.

4.5 Don clean disposable gloves, and carefully push up the whole body (inner) dosimeter cuffs from the worker's wrists. Have the worker place both hands over a bowl, and pour approximately 400 mL of 0.01% Aerosol® OT solution over the worker's hands for approximately 30 seconds. The worker will scrub their hands while the wash solution is slowly poured over the worker's hands.

4.6 The worker shall then immerse their hands in the 400mL of the wash solution in the collection bowl and lightly scrub their hands in the solution for a minimum of 30 seconds.

4.7 The worker should lift their hands out of the wash solution, and while holding their hands over the bowl, the remaining approximate 100 mL of Aerosol® OT is poured over the worker's hands to rinse. Allow the hands to drain for approximately five seconds.

4.8 Carefully pour the entire 500 mL of rinsate into a pre-labeled jar seal and place in cool storage. (A total of 500 mL must be collected for each handwash sample.)

4.9 Clean the bowl with solvent between workers. Rinse once with clean water, followed by two rinses with solvent, followed by a final rinse with water. Allow the bowl to air dry or wipe dry with a paper towel before reusing.

5.0 SAMPLING INTERVALS

5.1 Workers' hands will be washed with the diluted AOT solution with the assistance of a researcher, and prior to the monitoring unit. This hand wash sample will be discarded.

5.2 Handwash samples should be collected whenever the workers would normally wash their hands; (*i.e.*, before eating, before using the bathroom, *etc.*) unless specified differently in the study protocol. For interim handwashes, carefully unbutton the cuffs of the worker's outer shirt and push up the sleeves before washing hands.

5.3 After the monitoring unit is completed, one final wash will be collected from each worker.

6.0 FIELD STORAGE

6.1 Place samples collected during the study in the field in a cooler with dry ice or portable freezer until processed and placed into frozen storage for shipping at the end of the monitoring day (or as soon as practical). If dry ice or portable freezer is not available, the Study Director must be notified before sample collection and other suitable storage conditions must be noted in the raw data.

Whole Body Sampling – Inner Dosimeters

Chapter 8: MATRIX SAMPLES
AHETF-8.A.3.

Effective Date : March 3, 2008

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

Last Revision Date: April 30, 2006 Previous Version Number: 8.A.2.

1.0 PURPOSE AND SCOPE

1.1. This Standard Operating Procedure (SOP) provides a description of procedures for collecting pesticide residues from whole body dosimeters worn by workers during the Agricultural Handlers Exposure Task Force (AHETF) exposure studies.

1.2. The inner dosimeter will be used as a collection medium and will be analyzed. The inner dosimeter will be worn over the worker's own undergarments and directly underneath the specified work clothing and personal protective equipment (PPE), if appropriate.

1.3. This SOP was revised to clarify the privacy allowed the volunteer workers in Sections 3.1 and 4.3. The terms "replicate" and "monitoring period" were replaced with either "worker" or "monitoring unit."

2.0 MATERIALS REQUIRED

2.1. The following materials are required for using and collecting whole body dosimeter samples from each worker/monitoring unit:

a. 100% cotton, white, long underwear (inner) — with long sleeves, round neckline and no elastic (pre-washed - see SOP AHETF-8.J.).

b. Disposable gloves (*i.e.,* latex)

c. Scissors

d. Cleaning solutions (*i.e.,* methanol, isopropanol, alcohol/water mixture, acetone, *etc.*)

e. Sealable bags or other suitable bags

f. Aluminum foil wrap

g. Disposable paper or plastic mat

h. Hangers, if appropriate

i. Cooler with dry ice, or freezer

3.0 USE OF WHOLE BODY DOSIMETER

3.1. The worker(s) will be given a new inner dosimeter prior to initiation of each monitoring unit. The workers will be allowed to change in a clean "privacy area". Once the worker is inside the privacy area, a researcher of the same sex as the worker will remain with the worker to instruct and assist the worker on how to put on the dosimeter. Disposable gloves should be worn by the worker and the research personnel to minimize contamination.

3.2. Care should be taken to provide clothing of adequate fit. The inner dosimeter arm and pant cuffs should not extend beyond the work clothing cuffs (wrists and ankles).

3.3. Cut the large excess off the pant legs and pull up the inner dosimeter arms so that the inner dosimeter will not come out from underneath the outer dosimeter during the performance of the activity.

4.0 COLLECTION PROCEDURE

4.1. Upon completion of the sock sample collection, as described in SOP 8.I (if sock sample collection is required by the study), the inner dosimeters will be collected. The inner dosimeters must be collected after all other samples have been collected from the worker.

4.2. Disposable paper, plastic mat, or aluminum foil will be placed on the

chairs and floor of the changing area to reduce cross-contamination. The materials will be changed after the processing of each worker.

4.3. After completion of the monitoring unit and collection of other samples, the worker will return to the privacy area. Once the worker is inside the privacy area a researcher, of the same sex as the worker, will accompany the worker in the privacy area to assist with removing the dosimeter, to minimize cross contamination between the worker's clothing and the inner dosimeter, and to minimize loss of residues.

4.4. The research personnel collecting samples will always wear disposable gloves when handling any work clothing, dosimeters, and PPE. Gloves will be changed between handling PPE, work clothing, and inner dosimeter collection. Remove garments in a manner to avoid cross-contamination.

4.5. Ensure that the scissors have been decontaminated with solvent prior to use. Scissors must be cleaned between each worker's dosimeter.

4.6. Remove and discard any buttons from clothing.

4.7. As described in the study protocol, the inner dosimeters will be sampled in one of two methods. If the upper/lower method is used, follow Section 4.8; if the six section method is used, then follow Section 4.9.

4.8. Cut the dosimeter into two (2) sections:

a. Lower Body (all sections below waist*)
b. Upper Body (all sections above waist*)

* Cut just below the second button from the bottom to separate the torso from the lower section.

Proceed to section 4.10 of this SOP.

4.9. Cut the inner dosimeter into six (6) sections:

a. Right & left upper arms (shoulder to elbow)
b. Right & left lower arms (elbow to cuff)
c. Front torso (above the waist*)
d. Rear torso (above the waist*)
e. Right & left upper legs (waist to knee)
f. Right and left lower legs (knee to cuff)

* Cut just below the second button from the bottom to separate the torso from the lower section. Cut along the seams to separate the front torso from the rear torso. Refer to Attachment A.

4.10. Inner dosimeters may be hung on hangers during the sampling as long as the dosimeters do not contact the floor or other dosimeters.

4.11. Place each sample section on a piece of aluminum foil (sufficient size to completely wrap the dosimeter). Do not allow samples to contact any surface before placement onto the foil. Ensure that the edges of the foil wrap are folded together to prevent loss of test material. Place a label on the aluminum foil that identifies the sample and place the sample into a labeled, sealable bag. Seal all bags.

4.12. There shall be either two (2) or six (6) inner dosimeter samples per worker, depending upon the protocol specified sampling method.

5.0 SAMPLING INTERVALS

5.1. Inner whole body dosimeters will be collected at the end of each monitoring unit, unless otherwise instructed by the protocol.

6.0 FIELD STORAGE

6.1. Place samples collected during the study in the field in a cooler with dry ice or portable freezer until processed and placed into frozen storage for shipping at the end of the monitoring day (or as soon as practical). If dry ice is not available, the Study Director must be notified before sample collection and other suitable storage conditions must be noted in the raw data.

Attachment A

Diagram of Inner Dosimeter

Access to Confidential Worker Information

Chapter 6: ARCHIVES
AHETF-6.D.O.

Effective Date : March 3, 2008

APPROVAL David Johnson	DATE 3/3/08
APPROVAL	DATE 3/3/08
Last Revision Date: None	Previous Version Number: None

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the Agricultural Handlers Exposure Task Force (AHETF) policy to obtain access to AHETF confidential worker information for review after being placed in the designated permanent archive facility.

2.0 CONFIDENTIAL WORKER INFORMATION

2.1 Certain worker information will be collected during the course of any AHETF worker exposure study. Forms and paperwork that contain personal information (such as worker's name and address) must be kept confidential.

2.2 The Study Director will place any forms containing such information in a sealed envelope, marked as "CONFIDENTIAL WORKER INFORMATION – DO NOT RELEASE – CONTACT AHETF ADMINISTRATIVE CHAIR" along with the AHETF Study No. and will be placed in the study file with the remaining raw data.

2.3 The confidential information shall be permanently archived with the study raw data as required by Good Laboratory Practices (GLP) regulations (40 CFR Part 160)

3.0 ACCESS RESTRICTIONS

3.1 Only personnel authorized by the AHETF Administrative Committee Chair may have access to the data. Any person(s) requesting access to confidential worker information must submit the request and the reasons for the request in writing to the AHETF Administrative Committee Chair for authorization.

3.2 The designated AHETF Archivist, or alternate, is instructed to remove the Confidential Worker Information envelope from the archived data file when presenting the raw data for review to any AHETF member, company representative, or regulatory agency; unless otherwise directed by the AHETF Administrative Committee chair.

3.3 Access can only be authorized when specifically requested by EPA or when required for legal reasons.

3.4 Only the Archivist, or alternate, should have direct physical access to the data. A written record of access shall be maintained by the designated archive facility for all AHETF studies.

3.5 No confidential worker information may be removed and distributed from the AHETF archives without the written approval of the AHETF Administrative Committee Chair. Only verified copies shall be provided for off-site data review, unless otherwise stated.

3.6 Other than restrictions provided in this SOP, these data are subject to the same storage and handling requirements as set forth in SOPs AHETF-6.A and AHETF-6.B.

Access to Archived Data

Chapter 6: ARCHIVES
AHETF-6.B.I.

Effective Date : March 3, 2008

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

Last Revision Date: February 1, 2003 Previous Version Number: 6.B.0

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the Agricultural Handlers Exposure Task Force (AHETF) policy for member companies to obtain access to AHETF study data and final reports for review after being placed in the designated permanent archive facility.

1.2 This SOP was revised to add section 5.0 Confidential Worker Information.

2.0 ACCESS RESTRICTIONS

2.1 Only personnel authorized by AHETF management may have access to review the data. Any person(s) requesting access to AHETF study data must contact the proper AHETF management personnel or Task Force Manager for authorization. All requests must be made in writing.

2.2 Only the Archivist, or alternate, should have direct physical access to the data. A written record of access should be maintained by the designated archive facility for all AHETF studies.

2.3 A list of personnel with clearance to access archived materials should be maintained by the designated archivist, if available.

2.4 No original data may be removed and distributed from the AHETF archives without the written approval of the AHETF. Only verified copies shall be provided for off-site data review, unless otherwise stated.

2.5 As all AHETF data are strictly confidential, no additional or unauthorized copies of any AHETF data may be made, except as authorized in writing by the AHETF.

2.6 Photocopies of the raw data may be retained by the AHETF Quality Assurance Unit, as needed, and will be destroyed at the direction of the AHETF.

3.0 DATA ACCESS PROCEDURES

3.1 The applicable standard operating procedures of the archiving facility shall apply to all access, maintenance, and record keeping of the archived materials.

4.0 POST-ARCHIVING DATA TRANSFER

4.1 Should it become necessary, AHETF study data, or portions thereof, may be transferred to another designated facility or location for retention at the discretion of the AHETF management. The AHETF will notify the archive facility personnel which data will be transferred.

4.2 Data transfer procedures, as described in SOP AHETF-9.G, will apply to all transfers.

5.0 CONFIDENTIAL WORKER INFORMATION

5.1 Certain worker information will be collected during the course of any AHETF that will contain confidential worker information. This information will be kept separate from the raw data generated during the AHETF study. Refer to SOP AHETF-6D for specific handling and access requirements to confidential worker information.

Protocol Design and Preparation

Chapter 2: PROTOCOLS
AHETF-2.C.2.

Effective Date : March 3, 2008

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

Last Revision Date: January 1, 2006 Previous Version Number: 2.C.1.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the content requirements, standard format, responsible personnel, review, and distribution of Agricultural Handlers Exposure Task Force (AHETF) study protocols, which are the written instructions to perform specific experiments investigating exposure to pesticides.

1.2 This SOP is for internal administrative use by the AHETF. It is not to be distributed to contractors, unless specific authorization is provided by the AHETF management.

1.3 This SOP was revised to incorporate additional protocol elements regarding the use of human subjects in exposure research.

2.0 DEFINITIONS

2.1 The EPA GLPs define a study as "any experiment at one or more sites, in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its effects, metabolism, product performance, environmental and chemical fate, persistence and residue, or other characteristics in humans, other living organisms, or media." (40 CFR Part 160, August 17, 1989, § 160.3).

2.2 A protocol is a written study plan that indicates the objectives and all methods for the conduct of a study.

3.0 PROTOCOL REQUIREMENTS

3.1 AHETF protocols must contain (but not be limited to) the following information for GLP compliance and ethics requirements for human testing. Certain GLP and ethics requirements that are not applicable to most studies conducted by/for the AHETF have been taken into account and either modified or omitted, based upon the importance and impact of those requirements.

a. Descriptive title and objective of the study.

b. Identification of the test substance and control or reference substances by name, chemical abstract service (CAS) number or code number.

c. Name and address of sponsor (AHETF).

d. Name and address of contracted testing laboratories (including field contractors).

e. Proposed experimental start and termination dates.

f. Justification for selection of test system.

g. Procedure for test system identification.

h. Description of the experimental design including the methods for the control of bias.

I. Each level of the test, control, or reference substance to be administered, expressed in appropriate units.

j. The method and frequency of administration of the test, control or reference substance, (*e.g.,* backpack/ knapsack sprayer, granular application, *etc.)*, and the reason for its choice.

k. The type and frequency of tests, analyses, and measurements to be made.

l. The records to be maintained.

m. Dated signatures of the Study Director and AHETF Sponsor Representative (Task Force Manager, and/or Technical Committee Chair).

o. Proposed statistical methods.

p. Ethics requirements for human testing as required by 40 CFR, part 26, including but not limited to: recruitment procedures, health and safety issues, remuneration, and inclusion/exclusion criteria.

3.2 The Study Director or designee is responsible for preparing protocols for studies under his/her direction according to a standard format to be provided by the AHETF.

3.3 All AHETF study protocols will be signed and dated by the Study Director, and Technical Committee Chair or Task Force Manager to initiate the study and indicate Sponsor approval of the protocol. Approval signatures must be obtained from the Study Director before any data collection for that study. The protocol should be acknowledged, either electronically or in writing, by the AHETF Field Monitor and AHETF Analytical Monitor, as appropriate. Monitors do not need to sign the protocol, amendments, or deviations.

4.0 REVIEW PROCESS

4.1 Draft protocols will be forwarded to the appropriate AHETF representatives (as noted in section 6.0 and at the Study Director's discretion) and to the AHETF contracted Quality Assurance Unit for review before finalization.

4.2 The Study Director will be notified of errors found or requested changes noted during the review process. Appropriate corrections or changes will be returned to the Study Director. The revised copy will be approved (*i.e.*, signed and dated) and distributed to the designated personnel.

4.3 The Study Director will submit the final draft protocol, as well as any amendments issued, to a pre-selected Institutional Review Board (IRB) for review prior to finalization and distribution.

5.0 PROTOCOL FORMAT

5.1 Details of the protocol must address all of the applicable items in section 3.1. of this SOP. Requests for copies of AHETF protocols may be directed to the Study Director or the AHETF Task Force Manager. Changes to the protocols will be issued according to section 8.0.

5.2 A standard design, developed by the Task Force, will be followed when preparing study protocols.

5.3 All protocol files must be written in specified word processing program, to be provided to the Task Force upon request. The software that has been selected is the Microsoft® Word® for Windows® (version XP or previous) document processing program. Macintosh® formatted data are not acceptable.

5.4 All signed pages will be optically scanned separately and stored in PDF® format. These signed pages need to be inserted into the final phase report file.

5.5 Electronic submissions to the EPA must be in Adobe® Acrobat® PDF format version 5.0. Later versions of Acrobat® may be used; however, the output must be in the 5.0 format.

6.0 DISTRIBUTION OF STUDY PROTOCOLS

6.1 The original AHETF study protocol, and any amendments, will be submitted to the sponsor-contracted QAU for review. Before study completion, the original protocol, amendments and deviations, if applicable, will be forwarded to the AHETF Archives. The following is the distribution list for protocols and amendments, as appropriate:

a. Study Director (maintain original)

b. AHETF Study Monitor, (field or analytical, as appropriate)

c. AHETF Task Force Manager

d. AHETF Technical Committee Chair

e. AHETF contracted Quality Assurance Unit (copy during study)

f. AHETF Subcommittee Chairs (as applicable)

g. Principal Investigator(s)

h. AHETF Study Archive File (original to archives upon completion)

i. Other appropriate government or regulatory agencies as required.

7.0 Protocol Amendments

7.1 A change of Study Director or any planned change or revision to an AHETF protocol is issued as a protocol amendment. The reason for the change(s) or revision(s) and the effective date(s) of each revision is documented in the amendment.

7.2 The contract principal investigator or facility management will notify the AHETF Study Director of any procedures or items in an AHETF protocol that may need to be revised, added, or deleted. The Study Director will prepare and distribute the amendment(s).

7.3 The Study Director will prepare the amendment(s), and will allow the AHETF Study Monitor(s), Task Force Manager and sponsor-contracted QAU to review it before finalization, if possible. Amendments will be sent to the reviewing IRB as well (see section 4.3.)

7.4 All protocol amendments will be approved by the AHETF Study Director and Task Force Manager, by a dated signature. The appropriate AHETF Study Monitor will acknowledge the amendment as described in section 3.3. Distributions of the original amendment and copies will be followed as outlined in section 6.1 of this SOP.

7.5 Protocol amendments are sequentially numbered according to the date of issue. The first amendment issued for a study is AHETF Protocol Amendment No. 1. The second protocol amendment issued is AHETF Protocol Amendment No. 2, and so on.

8.0 PROTOCOL DEVIATIONS

8.1 Whenever a deviation from the protocol occurs, the Study Director must be notified of the deviation. The AHETF Study Director is responsible for the documentation of any protocol deviation noted for their study.

8.2 The Study Director is required to document the nature of the deviation, date(s) of occurrence, reason for the deviation, effect on the study, and any corrective actions (if any) on an appropriate form or in the raw data. The deviation must be written in a timely manner and acknowledged with the dated signature of the Study Director.

8.3 The Study Director shall notify the appropriate AHETF Study Monitor and QAU of all deviations as soon as practicable.

8.4 All protocol deviations will be approved by the AHETF Study Director and Task Force Manager, by a dated signature. The appropriate AHETF Study Monitor will acknowledge any deviation as described in 3.3. Distributions of the original deviations and copies will be followed as outlined in section 6.1 of this SOP.

Potential Referable Findings

Chapter 1: Administration
AHETF-I.F.O.

Effective Date : March 3, 2008

APPROVAL David Johnson	DATE 3/3/08
APPROVAL	DATE 3/3/08
Last Revision Date: N/a	Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines the policy for reporting to EPA potential adverse findings related to an AHETF study as required by FIFRA Section 6(a)(2).

2.0 DEFINITIONS

2.1 Study Director – The consultant who is appointed by the AHETF as the Study Director of a field exposure study as defined in the GLP regulations. The Study Director is responsible for the conduct of the study, reviewing the data as they become available and writing the final report.

2.2 Field Monitor – The AHETF member representative who is assigned to assist the Study Director and provide oversight to a specific field exposure study.

2.3 Adverse Effects Screening Subcommittee – The Subcommittee that will be the first point of contact when a potential adverse effect is identified. This Subcommittee will decide if the potential adverse effect should be referred to the Potential Referable Findings Review Subcommittee.

2.4 Potential Referable Findings Review Subcommittee – The Subcommittee that will decide if a potential adverse effect should be reported to EPA and, if so, will direct the preparation of the submission. The Subcommittee consists of:

a. Members of the Adverse Effects Screening Subcommittee
b. Administrative Committee chair
c. Technical Committee chair
d. Field Studies Subcommittee chair
e. Registrant representative of the relevant test material (in the case of multiple registrants of a test material or a product-specific task force, a representative from each)
f. Task Force counsel

2.5 New findings – This is any potentially adverse data that are generated by AHETF and are not presently covered in PHED or in previously submitted studies.

3.0 BACKGROUND INFORMATION

3.1 EPA rules under FIFRA Section 6(a)(2) concerning the reporting of potential adverse findings was revised on September 19, 1997 as referenced in 62 FR 49370; 63 Fed. Reg. 33580 (June 19, 1998). These rules describe EPA's interpretation of the requirements for pesticide registrants to submit information to EPA concerning adverse effects to the environment, wildlife and human health from their products. The rule applies to registrants, including any employee, agent or other person acting for the registrant.

3.2 There is no requirement for AHETF to submit a 6(a)(2) report since the Task Force is not a registrant. However, the AHETF may make a 6(a)(2) submission on behalf of all Task Force members when the finding involves AHETF studies and results.

3.3 If AHETF discovers a potential adverse finding during the course of field testing or data analysis that falls within the definition of FIFRA 6(a)(2), or an analogous State law, AHETF will report the finding in accordance with EPA and State requirements, as applicable. For exposure monitoring studies, if the results show a higher level of risk or exposure than would be expected from prior reports, data, etc., then a potential adverse finding may exist.

3.4 There are three reporting times (15 days, 30 days, and 3 months). The more common is 30 days after an incident occurs in the field, 30 days after the final report is signed, or 30 days after the results are known which applies when there is a potential serious finding.

3.5 It may be necessary, depending on circumstances, either for the registrant of the test material or a representative from multiple registrants to report a potential referable finding directly, rather than AHETF reporting on their behalf.

3.6 Any AHETF member has the right to submit their own 6(a)(2) letter if they wish, without regard to whether it agrees with the determination of AHETF.

3.7 Regarding the use of surrogate compounds, the AHETF, on the advice of the Potential Referable Finding Review Committee is at liberty, without liability, to report findings under FIFRA 6(a)(2). Prior to reporting, the AHETF shall raise issues and discuss them with registrant(s) of the surrogate compound.

4.0 PROCEDURES FOR IDENTIFYING AND REPORTING POTENTIAL REFERABLE FINDINGS

4.1 Purchase of Existing Data

a. If data have been previously submitted to EPA (and state agencies where applicable), they are not considered “new” and are not Referable Findings.

b. If a Potential Referable Finding issue is identified during data review, the technical subcommittee should bring it to the attention of the registrant(s) of the study test material for resolution.

c. It will be the responsibility of the registrant(s) to report Potential Referable Findings.

4.2 Incidents that Occur During the Conduct of a Study (active ingredient-specific findings)

a. It will be the responsibility of the Study Director, Field Monitor, field contractor, and any other individuals involved with the field exposure study to identify and promptly report any potential adverse effects during the conduct of the study to the Adverse Effects Screening Subcommittee and the registrant(s) of the surrogate active ingredient.

4.3 Data Generated Under Sponsorship of the AHETF that Affects the Surrogate Compound (active ingredient-specific findings)

a. It is the responsibility of the Study Director, or any other Task Force personnel who are reviewing the study data, to keep the registrant(s) of the surrogate compound informed of the results.

b. If there is a potential adverse effect that might affect the registration of the surrogate compound only, it will be the responsibility of the registrant(s) to file a Potential Referable Finding report with the EPA and applicable states.

4.4 Data Generated Under Sponsorship of the AHETF that Could Potentially Affect All Member Products (non-active ingredient-specific finding)

a. Data that could potentially affect all member products would include circumstances where the exposure data exceed what would be derived from a specific scenario in the Pesticide Handlers Exposure Database (PHED), other previously submitted data, or that are defined as “new findings”.

b. It is the responsibility of the Study Director, or any other Task Force personnel who are reviewing the study data, to identify and report any potential adverse effects to the Adverse Effects Screening Subcommittee.

c. The Adverse Effects Screening Subcommittee will be the first point of contact to evaluate whether a potential adverse effect may be referable. If so, then the matter will be referred to the Potential Referable Finding Review Subcommittee.

d. The Potential Referable Finding Review Subcommittee will determine whether a potential adverse effect will be reported to the EPA and any applicable states and, if so, will direct the preparation of the Potential Referable Findings submission.

e. The AHETF Administrative and Technical Committee representatives will be informed in writing of the Potential Referable Finding and the recommendation of the Potential Referable Finding Review Subcommittee. The Task Force representatives will have an opportunity to ask questions and express their opinions during a subsequent conference call or meeting.

Identification and Control of Heat Stress

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-II.G.O.

Effective Date : 03/03/08

APPROVAL David Johnson	DATE 3/3/08
APPROVAL	DATE 3/3/08
Last Revision Date: N/A	Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 The purpose of this Standard Operating Procedure (SOP) is to provide information on the recognition of conditions that contribute to heat-related illness that may occur during the conduct of an Agricultural Handlers Exposure Task Force (AHETF) worker exposure study, measures to be taken to minimize the risk of heat-related illness to workers during their participation in an AHETF worker exposure study, measures to be taken if a worker is affected by heat-related illness, how AHETF researchers monitor environmental conditions during the conduct of worker exposure monitoring, and stopping rules related to heat-related illness

2.0 INTRODUCTION

2.1 There is potential for heat stress to agricultural workers under certain conditions of temperature and humidity. Since workers wear an extra layer of clothing during AHETF exposure studies in addition to any required PPE, the risk of heat-related illness may be increased. This document presents a summary of situations that increase the risk of heat-related illness, procedures for preventing heat-related illness, early signs and symptoms of heat-related illness, and what to do if heat-related illness becomes apparent or suspected. AHETF Study Directors will use this information to brief field investigators and field monitors prior to each exposure study conducted by the Task Force.

2.2 The Study Director will identify any employer response plans that address

heat-related illness. As an adjunct to existing plans, the Study Director will discuss the AHETF procedures with the on-site employer and workers. The Study Director shall gain agreement to utilize the AHETF procedures during the conduct of the study. This will be documented and included in the raw data.

3.0 RISK FACTORS

3.1 Heat stress is the build-up in the body of heat generated by the muscles during work and from the environment. Heat exhaustion and heat stroke result when the body is subjected to more heat than it can accommodate. The following factors can increase the risk of a worker experiencing heat-related illnesses:

a. **Weather**: increased temperature, increased humidity, direct sunlight, and low winds all contribute to heat stress. Keep in mind the effects of high temperatures and high humidity are more than additive.

b. **Workload**: the body generates more heat during heavy work than during light or moderate work, so activities involving lifting and/or walking contribute more to heat stress than sedentary tasks.

c. **Clothing and PPE**: the evaporation of perspiration on the skin helps cool a person so the more clothes a person wears, the slower the perspiration evaporates and the longer it takes to cool down. In addition, coated and non-woven synthetic garments (e.g., rainsuits) effectively block evaporation of perspiration and contribute to heat stress.

d. **Worker conditioning**: younger workers, well-rested workers, and physically fit workers are less likely to suffer heat illness than other workers. In addition, workers who are not acclimated to working in the heat are at much greater risk of heat illness. Most importantly, workers must remain adequately hydrated, which means liquids such as water or sports drinks should be consumed before and regularly during work.

4.0 PREVENTION PROCEDURES

4.1 The Study Director shall make arrangements to provide a medical professional (emergency medical technician [EMT], paramedic, physician's assistant [PA], licensed practical nurse [LPN], or registered nurse [RN] on-site during the conduct of an AHETF study while workers are being monitored. The medical professional shall conduct periodic observations of workers during the study and will advise the Study Director regarding possible signs of heat-related illness.

4.2 During all AHETF studies, the Study Director, on-site medical professional, and the field investigators share responsibility for awareness and prevention of heat illness. The following procedures will be followed:

a. Post a copy of the poster titled "Controlling Heat Stress Made Simple" at each field site (for example, in the staging or dressing area) so workers and field investigators will remain aware of the issue and can refer to the information on the poster (which is similar to this document). Both the English and Spanish versions will be posted (see Reference 13.3).

b. Initiate worker exposure monitoring during the cool part of the day whenever practical

c. Ensure plenty of water and sports drinks are available for the workers.

d. Assure that shady areas are available during breaks.

e. Immediately before monitoring begins, remind the workers of the risk of heat stress, suggest they drink some liquid before they start work, and let them know how/where they can get liquid during the monitoring period.

f. Urge workers to drink liquid during the monitoring period and remind them that thirst does not give a good indication of how much liquid a person needs to drink. NOTE: Hand washes will not be taken during water breaks unless specifically required by the label or requested by the worker.

g. Observe workers during the monitoring period and be aware of the signs and symptoms listed in Attachment 11-G-1.

h. Require workers to take rest breaks when any signs or symptoms outlined below are present (see Attachment 11-G-1).

5.0 SIGNS/SYMPTOMS AND FIRST AID MEASURES

5.1 Researchers should be familiar with the signs, symptoms, and treatment of heat-related illnesses outlined in Attachment 11-G-1: Heat Illness Symptoms and Treatment Chart.

6.0 FIELD PERSONNEL RESPONSIBILITIES

6.1 During all AHETF studies, the Study Director, field investigators, and the on-site contracted medical professional share the responsibility for awareness of heat illness. The on-site medical professional is described in SOP AHETF 11.H (Emergency Procedures for Human Subjects).

6.2 The Study Director will have received training, such as by the American Red Cross or other recognized training organization, in the recognition of symptoms associated with heat-related illness and in what measures should be taken to relieve symptoms of heat-related illness. Documentation of training will be kept in their personnel file.

6.3 The Study Director or AHETF representative will provide instruction to the field investigators, including study observers and field monitors, regarding the recognition of signs and symptoms of possible heat-related illnesses and actions necessary if heat-related illness occurs. The basis for this instruction is outlined in Sections 3.0, 4.0 and 5.0 of this SOP.

6.4 During the consent process, the Study Director will provide the worker with information on early signs and symptoms of heat-related illnesses.

6.5 Just prior to monitoring, the Study Director will discuss heat-related illness with the participants and the need to immediately report to the individual observer or other researcher any illness or injury.

6.6 The Study Director will ensure that a copy of the poster entitled "Controlling Heat Stress Made Simple" is posted at each field study site (such as in the staging or dressing area). It will be visibly placed so workers and field investigators will remain aware of the issue and can easily refer to the information on the poster. Both English and Spanish versions will be posted.

7.0 RESPONSIBILITIES FOR CONTROL AND TREATMENT OF HEAT-RELATED ILLNESS

7.1 The Study Director is responsible for taking actions to minimize the risks of heat stress during field monitoring. These include:

a. monitoring environmental conditions (heat index based on ambient temperature and relative humidity) which may influence the risk of heat-related illness

b. when necessary, initiating specific steps intended to prevent or minimize the occurrence of various heat-related illnesses

c. when necessary, relieving symptoms of heat- related illnesses

d. determining, in consultation with the on-site medical professional, if medical treatment is required.

7.2 Prior to monitoring, the Study Director will identify and locate the closest medical facility. See SOP "AHETF 11-H – Emergency Procedures for Human Subjects" for additional information.

7.3 The Study Director will inform all study observers at the start of the study of the current Heat Index (Apparent Temperature) Category. The observer will be informed if or when the Heat Index Category subsequently changes.

7.4 The study observers will look for signs of heat illness and record their findings on their Observation Form. Recordings will be made periodically or when they are informed that a Heat Index Category has changed.

7.5 If a study observer believes a worker is showing signs of heat-related illness, he/she reports to the Study Director immediately. The affected

worker will be taken to a shady or cool location and checked by the Study Director and on-site contracted medical professional. A decision will then be made as to whether the worker will continue to participate in the study.

7.6 The Study Director, in consultation with the on-site contracted medical professional, will decide if and when to stop a worker's participation in the study. As per GLPs, the final authority to terminate a worker's participation in the study rests with the Study Director.

7.7 In response to indications that conditions are conducive to high temperatures and high relative humidity, the Study Director may elect not to initiate the study or to terminate the study operations on a particular day.

8.0 HEAT INDEX CATEGORIES

8.1 The National Weather Service (NWS) Heat Index Chart will serve as the basis for determination of the Heat Index Categories. The Heat Index Chart (calculated from a combination of ambient temperature and humidity; see next section for determination of the heat index) is divided into color-coded categories, each denoting a range of heat index (HI) temperatures at which heat-related illnesses can possibly or are likely to occur. See Attachment 11-G-2 for a copy of the Heat Index Chart.

8.2 The following table summarizes the HI Categories.

National Weather Service Heat Index (Apparent Temperature)		
CATEGORY	HEAT INDEX TEMPERATURE RANGE, °F	POSSIBLE ILLNESS
Not applicable	Less than 80	None anticipated
Caution	80-89	Fatigue **possible** with prolonged exposure and/or physical activity
Extreme Caution	90-104	Sunstroke, heat cramps or heat exhaustion **possible** with prolonged exposure and/or physical activity

Danger	105-129	Sunstroke, heat cramps or heat exhaustion **likely**, and heatstroke **possible** with prolonged exposure and/or physical activity
Extreme Danger	130 or higher	Heat/Sunstroke **highly likely** with continued exposure

9.0 DETERMINATION OF HEAT INDEX

9.1 The heat index determination requires readings of local ambient temperature and relative humidity. Appropriate meteorological instrumentation will be used to determine the HI, such as a portable monitoring device, a sling psychrometer or on-site weather station. Measurements will be recorded and included in the raw data.

9.2 Temperature and relative humidity readings will be applied to the Heat Index Chart to determine the HI. Match the measured readings to those on the Heat Index Chart. The Heat Index will be the temperature shown at the intersection of the measured temperature and humidity readings. If measured temperature and/or relative humidity readings are not shown on the Heat Index Chart, round the measured reading up until it corresponds to the next highest value shown on the chart.

9.3 The resulting HI will be increased by 10° F [6° C] **if the worker is working in direct sun**. This includes work performed in greenhouses taking direct sunlight. If working in shaded areas such as enclosed cabs, tractors with canopies, or shade houses, or during evening or prevailing cloudy conditions, then the heat index reading needs no adjustment. (Ref. 13.1)

9.4 It is not necessary to monitor the heat index if the ambient temperature is below 70° F [21° C]. However, certain combinations of ambient temperatures between 70-79° F [21 - 26° C] and relative humidity readings are equivalent to HI values found in the CAUTION Category if adjusted for working in direct sun. Therefore, once the ambient temperature reaches 70° F [21° C], begin monitoring the Heat Index at least every hour. (Ref. 13.2)

10.0 CRITERIA FOR FIELD MONITORING INITIATION

10.1 Worker exposure monitoring will be initiated as scheduled unless extremely hot conditions are present. Specifically, worker exposure monitoring will not begin if the HI is ≥ 120° F [49° C], or ≥ 110° F [43° C] when working in direct sun (DANGER Category). The Study Director, at his discretion, may choose not to initiate monitoring, regardless of the HI.

10.2 The field investigators will exercise the requisite vigilance to heat stress conditions, Sections 10.4 through 10.8. The degree of vigilance adjusts to changing environmental conditions (heat index based on temperature and humidity) that may affect worker risk to heat stress. In addition, the on-site medical professional will periodically observe workers for potential heat-related illness.

10.3 The symptoms of heat-related illness and measures to relieve symptoms as described in the following sections are based on EPA's "A Guide to Heat Stress in Agriculture", *Table 1 - Heat Illnesses and First Aid Measures*. They are not meant to be all-inclusive, but serve as general guidance for purposes of this SOP. The Study Director will be trained in the recognition of signs and symptoms of heat-related illness, and in determining measures needed to relieve symptoms, and he will exercise appropriate diligence under the specific conditions of a heat-related event. Additionally, the Study Director should consult with the on-site medical professional with regard to suspected cases of heat-related illness.

10.4 If the HI is < 80° F [27° C], or < 70° F [21° C] when working in direct sun, no specific vigilance is necessary. Observe for early signs of **possible** heat illness, such as fatigue.

10.5 If the HI falls between 80° - 89° F [27 - 32° C], or between 70° - 79° F [21 - 26° C] when working in direct sun (CAUTION Category), increase vigilance by specifically observing for **possible** signs of early heat illness, which can include fatigue, dizziness, irritability or decreased concentration, especially if the worker has been working for a while. Inquire periodically about how they feel. If symptoms arise, rest the worker in the shade for approximately 30 minutes until cool and give water or sports drink.

a. NOTE: If the worker develops heat rash, rest the worker, give water or sports drink. If the rash persists or bothers the worker, then STOP THE WORKER EXPOSURE MONITORING.

10.6 If the HI falls between 90° - 104° F [32 - 40° C], or between 80° - 94° F [27 - 34° C] when working in direct sun (EXTREME CAUTION Category), increase vigilance even further by observing for **possible** signs of: heat cramps, such as muscle spasms, heavy sweating, thirst; heat exhaustion, such as fatigue, headache, dizziness, fainting, heavy sweating increased pulse; heat stroke, such as headache, dizziness, irrationality, coma, rapid breathing. These conditions are possible if the worker has been working for a while. Inquire periodically about how they feel.

a. With signs of heat cramps, give access to plenty of water or a sports drink and assure that they are drinking. Have the worker rest in the shade until cool. STOP THE WORKER EXPOSURE MONITORING. Advise the worker to be aware of symptoms of heat exhaustion and heat stroke. Remind the worker of the AHETF policy to provide medical coverage and to seek medical help immediately if symptoms develop.

b. If the SD believes that a worker may be suffering heat exhaustion or heat stroke, immediately STOP THE WORKER EXPOSURE MONITORING. The SD should also consult with the on-site medical professional. However, if the worker's condition is considered to be serious and to require additional emergency care, a member of the study team will call 911 (or other local emergency number) and allow emergency medical personnel to respond and treat the study participant as appropriate. Take measures to relieve symptoms until professional medical care arrives.

   i. Heat exhaustion: treatment includes providing rest in shade, giving plenty of drinking water or sports drink, splashing cold water on worker.

   ii. Heat stroke: treatment includes moving to shaded area, removing outer clothing and shoes; wrapping in wet sheet or towel and fan to cool worker.

10.7 If the HI falls between 105° - 119° F [41 - 48° C], or between 95° - 109° F [35 - 43° C] when working in direct sun (DANGER Category), increase vigilance even further by paying particular attention to **likely** signs of heat cramps and heat exhaustion or **possible** signs of heat stroke with prolonged exposure.

a. If signs of heat cramps occur, treat as recommended in Section 10.6.a. above.

b. If the SD believes that a worker may be suffering from heat exhaustion or heat stroke, immediately STOP THE WORKER EXPOSURE MONITORING. The SD should also consult with the on-site medical professional. However, if the worker's condition is considered to be serious and to require additional emergency care, a member of the study team will call 911 (or other local emergency number) and allow emergency medical personnel to respond and treat the study participant as appropriate. Take measures to relieve the symptoms until professional medical care arrives. See Section 10.6.b. above.

10.8 If the HI reaches 120° F [49° C], or 110° F [43° C] when working in direct sun, STOP THE WORKER EXPOSURE MONITORING.

a. Stopping monitoring when the HI reaches 120° F should provide adequate protection to the worker. Based on the National Weather Service Heat Index Chart, (Attachment 11-G-2), this value is roughly in the mid-range of the DANGER category, and therefore does not interface with the HI values in the EXTREME DANGER category where heatstroke is highly likely with continuous exposure. It is reasonable to assume that using 120° F as the stop point will prevent the HI from ever reaching the EXTREME DANGER Category, including anytime during the period between readings.

b. Note: This stop rule does not apply if a worker is working in air conditioned equipment. However, the HI will continue to be monitored to evaluate circumstances should the worker need to go outside the cab (such as for equipment repair). If the worker must be outside the cab for a prolonged period of time (more than 30 minutes), he/she will be sent to an environment that does not exceed the HI of 120° F until conditions are such that work can be resumed. If work cannot be resumed, the worker monitoring will be terminated.

11.0 EXPENSES

11.1 Expenses associated with the reasonable and appropriate treatment for heat-related illness as a result of participating in this study will be paid for by AHETF unless such expenses are covered by the worker's own insurance or insurance provided by the employer.

12.0 INCIDENT REPORTING

12.1 Any incident of heat-related illness will be reported by the Study Director or member of the research team to the Sponsor (AHETF) and the Institutional Review Board. See SOP AHETF 11.F for additional details on reporting such events to the IRB.

13.0 REFERENCES

13.1 The National Weather Service suggests a heat index adjustment of an additional 10-15°F [6 - 8° C] for sunny conditions. The AHETF rationale for the adjustment of the heat index for sunny conditions is contained in Attachment 11-G-3.

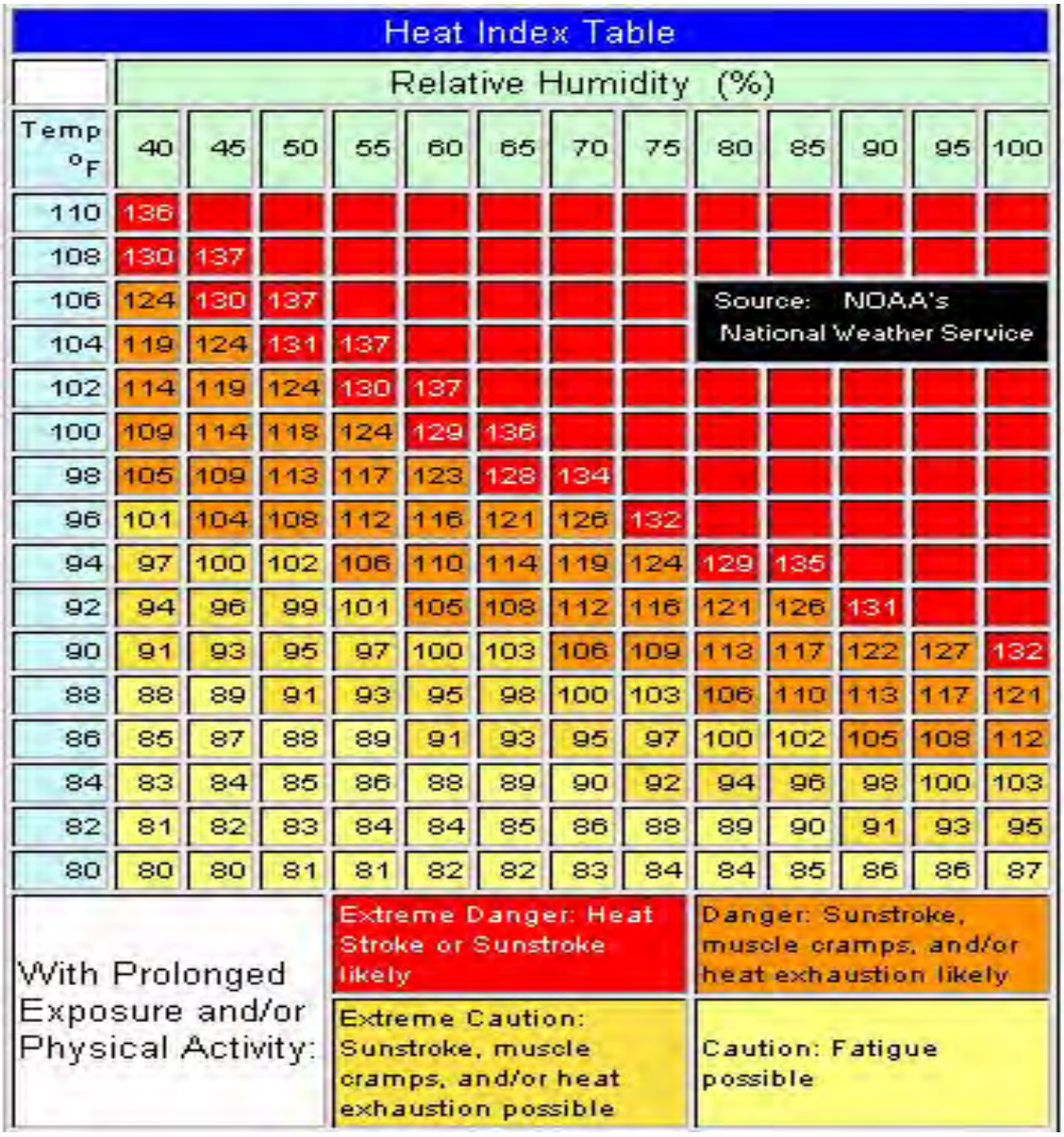
13.2 A Guide to Heat Stress in Agriculture. May, 1993. Document EPA-750-b-92-001 prepared by the United States Environmental Protection Agency and the Occupational Safety and Health Administration. *A Basic Program to Control Heat Stress – Step 4*, recommends hourly measurements of temperature and humidity.

13.3 Controlling Heat Stress Made Simple. September, 1995. GPO Document Number 055-000-00474-9 prepared by the United States Environmental Protection Agency and the Occupational Safety and Health Administration.

ATTACHMENT 11-G-1: HEAT ILLNESS SYMPTOMS AND TREATMENT CHART

Illness	Signs and Symptoms	Treatment
Early Heat Illness	Mild dizziness, fatigue, or irritability; Decreased concentration; Impaired judgment	Loosen or remove clothing, Rest the worker in the shade until cool, and give water to drink
Heat Rash	Tiny, blister-like red spots on skin; prickly sensations (generally caused by plugged sweat glands)	Rest the worker in the shade until cool, give water to drink; if the rash persists and bothers the worker, stop the monitoring.
Heat Cramps	Painful spasms of leg, arm, or abdominal muscles; Heavy sweating and thirst	Loosen clothing, give water or sport beverages, and rest the worker in the shade until cool. Stop monitoring the worker.
Heat Exhaustion	Fatigue, headache, dizziness, muscle weakness, loss of coordination, fainting, collapse. Profuse sweating; pale, moist cool skin; excessive thirst; dry mouth; dark yellow urine. Fast pulse, if conscious. May also have heat cramps, nausea, urge to defecate, rapid breathing, chills, tingling of the hands or feet, confusion, giddiness, slurred speech, irritability.	Remove to cooler, shaded area ASAP and **stop monitoring**. Rest worker lying down. Give water, as much as the worker will drink. Loosen or remove clothing. Splash cold water on body. Massage legs and arms to increase circulation. If worker has collapsed, get evaluation by physician or nurse specified in the study protocol and Consent Form.
Heat Stroke	Often occurs suddenly and is a life-threatening medical emergency. Headache, dizziness, confusion, irrational behavior, coma. Sweating may slow down or stop. Fast pulse, if conscious. Rapid breathing. May also have convulsions, nausea, incoherent speech, very aggressive behavior.	**Immediately call emergency medical services.** Move to cooler, shaded area immediately and **stop monitoring**. Remove outer clothing/shoes. Wrap in wet sheet or towel and fan to cool worker. **Get immediate evaluation** from physician or nurse specified in the study protocol and Consent Form.

Attachment 11-G-2: Heat Index Chart



Heat Index Table

Temp °F	Relative Humidity (%) 40	45	50	55	60	65	70	75	80	85	90	95	100
110	136												
108	130	137											
106	124	130	137										
104	119	124	131	137									
102	114	119	124	130	137								
100	109	114	118	124	129	136							
98	105	109	113	117	123	128	134						
96	101	104	108	112	116	121	126	132					
94	97	100	102	106	110	114	119	124	129	135			
92	94	96	99	101	105	108	112	116	121	126	131		
90	91	93	95	97	100	103	106	109	113	117	122	127	132
88	88	89	91	93	95	98	100	103	106	110	113	117	121
86	85	87	88	89	91	93	95	97	100	102	105	108	112
84	83	84	85	86	88	89	90	92	94	96	98	100	103
82	81	82	83	84	84	85	86	88	89	90	91	93	95
80	80	80	81	81	82	82	83	84	84	85	86	86	87

Source: NOAA's National Weather Service

With Prolonged Exposure and/or Physical Activity:		
	Extreme Danger: Heat Stroke or Sunstroke likely	Danger: Sunstroke, muscle cramps, and/or heat exhaustion likely
	Extreme Caution: Sunstroke, muscle cramps, and/or heat exhaustion possible	Caution: Fatigue possible

Attachment 11-G-3: AHETF Rationale for the Heat Index Adjustment for Sunny Conditions

The Heat Index Chart developed by the National Weather Service (NWS) was primarily intended for public use (Ref: "Heat Stress Guidance" from the NWS). Portions of the public include susceptible groups such as children, elderly and infirmed. Underlying assumptions in the development of the heat index values included wearing long trousers and short sleeves, light wind, and shady conditions. To account for full sun conditions, the NWS recommends a heat index adjustment of an additional 10-15° F (6-8° C). That is, if people are in full sun an additional 10-15° F is added to the current Heat Index (HI) value which is calculated based on the current temperature and humidity.

In this SOP, heat index values were adjusted by 10° F (6° C) for full sun conditions. This adjustment is reasonable under the conditions of AHETF worker monitoring studies for the following reasons:

- Workers who participate in these studies perform this work as part of their normal job, including having familiarity with working in hot environments
- Workers who participate in these studies are adults in good health
- Workers who participate in these studies are acclimatized
- No impervious clothing will be worn.
- Mixing/loading and/or applying activities are generally moderate workloads (Reference EPA "A Guide to Heat Stress in Agriculture", *Table 5- Approximate Workload Levels*)
- Heat indices are monitored hourly with appropriate control measures in place
- Study investigators constantly observe workers for signs of heat-related illness and take control measures accordingly
- A medical professional is on-site during the monitoring period to observe for signs of heat-related illness and provide treatment if necessary, including calling for medical emergency assistance

AHETF study participants wear an inner dosimeter under their work clothing, thus increasing their risk of heat-related illness. However, it is believed that this increased risk if offset by the conditions listed above and the implementation of a heat stress management plan as described in this SOP. Furthermore, conditions of worker scenarios being monitored by AHETF should be put in perspective with other occupations involving hot working environments. For example, road construction activities often involve heavy workload levels, radiant heat from hot pavement, etc. It

may be reasonable under those conditions to increase the solar load adjustment by more than 10° F. However, for agricultural mixing/loading and application activities included in the AHETF monitoring program, a 10° F adjustment is considered to be adequately protective.

LS Consulting

From: LS Consulting [lsconsulting@oh.rr.com]
Sent: Monday, March 03, 2008 8:41 PM
To: Robert Roogow (rroogow@iirb.com)
Subject: AHE55 Protocol Query

Robert,

Were you able to complete your review of the protocol and documents? Just wondering about the prospects for review.

Larry

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, OH 44060
440/255-1954

LS Consulting

From: Robert Roogow [rroogow@iirb.com]
Sent: Tuesday, March 04, 2008 12:33 PM
To: lsconsulting@oh.rr.com
Subject: RE: AHE55 Protocol Query

Larry,

From what I saw, everything looked good and it went to the board for review. As soon as I get any information, I will let you know how it went.

Robert

Robert Roogow, MS, CIM
Director of Operations
Independent Investigational Review Board, Inc.
Ph: 954-327-0778
Fax: 954-327-5778
rroogow@iirb.com

From: LS Consulting [mailto:lsconsulting@oh.rr.com]
Sent: Monday, March 03, 2008 8:41 PM
To: Robert Roogow
Subject: AHE55 Protocol Query

Robert,

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Larry

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Volume VIII, Part B:

Transmittal IIRB Review Approvals 3-4-08

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INVESTIGATIONAL
REVIEW BOARD INC.
Your Advocate for Clinical Research Participants

DATE: March 04, 2008

TO: Larry D. Smith, PhD
Principal Investigator

FROM: Kim Lerner, Chairman or
Anita McSharry, Vice-Chairman
Independent Investigational Review Board, Inc.

SUBJECT: Approval Clinical Research Protocol dated: 2/27/2008
- Informed Consent Form (Ver. 3/4/2008)
- Fyfanon® 8 lb. Emulsion Product Risk Statement (Ver. 3/4/2008)
- Fyfanon® Product Risk Statement (Ver. 3/4/2008)
- Gowan Malathion 8 Product Risk Statement (Ver. 3/4/2008)
- Malathion 8-E Product Risk Statement (Ver. 3/4/2008)
- Sevin® Brand 4F Product Risk Statement (Ver. 3/4/2008)
- Sevin® Brand 80WSP Product Risk Statement (Ver. 3/4/2008)
- Sevin® Brand XLR Product Risk Statement (Ver. 3/4/2008)
- Sevin® Brand 4F Carbaryl Insecticide Product Label and MSDS
- Sevin® Brand 80WSP Carbaryl Insecticide Product Label and MSDS
- Sevin® Brand XLR PLUS Carbaryl Insecticide Product Label and MSDS
- Fyfanon® 8LB. Emulsion Product Label and MSDS
- Fyfanon® The Premium Grade Malathion Product Label and MSDS
- Gowan Malathion 8 Product Label and MSDS
- Malathion 8-E Insecticide Product Label and MSDS
- Advertisement
- Site Questionnaire
- Agricultural Handlers Exposure Task Force SOPs

PROTOCOL: (AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

The Independent Investigational Review Board, Inc. is an institutional review Committee structured in compliance with the regulations of the Food and Drug Administration contained in the Code of Federal Regulations (2ICFR 50 and 56 and 45CFR 46) and is in compliance with the International Conference of Harmonization (ICH) Good Clinical Practice (GCP) guidelines for IRB/IECs.

phone 954-327-0778 • fax 954-327-5778 • 6738 West Sunrise Blvd., Suite 102 • Plantation, FL 33313 • info@iirb.com (email) • www.iirb.com

At the meeting held on March 04, 2008, the Committee reviewed and unanimously approved the Research Protocol, the Investigators, Informed Consent Form, Fyfanon® 8 lb. Emulsion Product Risk Statement, Fyfanon® Product Risk Statement, Gowan Malathion 8 Product Risk Statement, Malathion 8-E Product Risk Statement, Sevin® Brand 4F Product Risk Statement, Sevin® Brand 80WSP Product Risk Statement, Sevin® Brand XLR Product Risk Statement, Sevin® Brand 4F Carbaryl Insecticide Product Label and MSDS, Sevin® Brand 80WSP Carbaryl Insecticide Product Label and MSDS, Sevin® Brand XLR PLUS Carbaryl Insecticide Product Label and MSDS, Fyfanon® 8LB. Emulsion Product Label and MSDS, Fyfanon® Product Label and MSDS, Gowan Malathion 8 Product Label and MSDS and Malathion 8-E Insecticide Product Label and MSDS for the above noted research study. The Site Questionnaire and Agricultural Handlers Exposure Task Force SOPs were reviewed and unanimously accepted.

The Informed Consent Form, Fyfanon® 8 lb. Emulsion Product Risk Statement, Fyfanon® Product Risk Statement, Gowan Malathion 8 Product Risk Statement, Malathion 8-E Product Risk Statement, Sevin® Brand 4F Product Risk Statement, Sevin® Brand 80WSP Product Risk Statement and Sevin® Brand XLR Product Risk Statement are unanimously approved. The approved Informed Consent Form is identified as Version 3/4/2008 and stamped, "Approved 3/4/2008". The Informed Consent Form contains all regulatory required consent elements. The Product Risks Statements are identified as Version 3/4/2008 and stamped, "Approved 3/4/2008".

The following advertisement was reviewed and unanimously approved and stamped "Approved 3/4/2008":
- Print Ad version "Research Study Volunteers" as submitted

For print advertisement, the relative size of the font referencing payment or potential benefits cannot be any more prominent than other information contained within the advertisement.

The study has been approved for a 12 month period. Prior to the end of approval on 3/3/2009, you are required to provide the Independent Investigational Review Board with a written progress report and completed Informed Consent Form for this research and obtain approval for continuing the research. Changes to the protocol or use of non-approved recruitment materials cannot be initiated without IIRB review and approval.

In the event of any serious adverse events, significant deviations from the protocol or problems in the research, written notice to the Independent Investigational Review Board is required. Please provide this reporting to the above-noted address so that appropriate follow-up will be initiated.

Thank you for your cooperation.

KL/AMS/yc:rr

Tuesday, March 04, 2008
MINUTES

ATTENDANCE:

PRESENT	ALSO PRESENT
David Wells, MD	Marcos Rejtman, DO
Anita McSharry, RN	
Shari Somerstein, RPh	BOARD/STAFF LIASON
Edward Wiederhorn	Katy Kysela
George Garbarino	
Rabbi Akiva Mann	
Kim Lerner	

I. CALL TO ORDER

The meeting was called to order at 10:00 AM, by Chairman, Kim Lerner. The meeting was held at 6738 West Sunrise Blvd., Suite 102, Plantation, FL 33313. Quorum was determined to be present and all attendees affirmed that no significant financial or non-financial conflicts of interest existed with review of any of the items listed on the agenda

II. APPROVAL OF THE 2/26/2008 MINUTES

The minutes of the meeting held 2/26/2008 were reviewed and unanimously approved as reviewed.

III. REVIEW PROTOCOLS

a. STUDY INITIAL APPROVALS

D (Protocol AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

Principal Investigator: Larry D. Smith, PhD

- Approval Clinical Research Protocol dated: 2/27/2008
- Informed Consent Form (Ver. 3/4/2008)
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- Fyfanon® 8LB. Emulsion Product Label and MSDS
- Fyfanon® Product Label and MSDS
- Gowan Malathion 8 Product Label and MSDS
- Malathion 8-E Insecticide Product Label and MSDS
- Advertisements

- Site Questionnaire
- Agricultural Handlers Exposure Task Force SOPs'

Motion was made, seconded and the Committee unanimously approved the Research Protocol, the Investigator(s), Informed Consent Form, Fyfanon® 8 lb. Emulsion Product Risk Statement, Fyfanon® Product Risk Statement, Gowan Malathion 8 Product Risk Statement, Malathion 8-E Product Risk Statement, Sevin® Brand 4F Product Risk Statement, Sevin® Brand 80WSP Product Risk Statement, Sevin® Brand XLR Product Risk Statement, Sevin® Brand 4F Carbaryl Insecticide Product Label and MSDS, Sevin® Brand 80WSP Carbaryl Insecticide Product Label and MSDS, Sevin® Brand XLR PLUS Carbaryl Insecticide Product Label and MSDS, Fyfanon® 8LB. Emulsion Product Label and MSDS, Fyfanon® Product Label and MSDS, Gowan Malathion 8 Product Label and MSDS, and Malathion 8-E Insecticide Product Label and MSDS for the above noted research study. The Site Questionnaire and Agricultural Handlers Exposure Task Force SOPs' were reviewed and unanimously accepted.

The Informed Consent Form and Product Risk Statements are unanimously approved as revised. The Committee recommended that changes be made to the Informed Consent Form and Product Risk Statements. The approved Informed Consent Form is identified as Version 3/4/2008 and stamped, "Approved 3/4/2008". The Informed Consent Form contains all regulatory required consent elements. The Product Risks Statements are identified as Version 3/4/2008 and stamped, "Approved 3/4/2008".

The following advertisements were reviewed, unanimously approved, and stamped "Approved 3/4/2008":
- Print Ad version "Research Study Volunteers" as submitted

For print advertisement(s), the relative size of the font referencing payment or potential benefits cannot be any more prominent than other information contained within the advertisement(s).

The Committee evaluated that the risks to the subjects were minimized and that a reasonable risk/benefit ratio is established. Based on the duration of the study and the risks to the subjects, the approval is granted for a 12 month period, with a progress report required prior to continued approval. Identified questions and concerns were discussed, addressed and documented in the file. See Approval letter for Investigator's responsibilities and file for supporting documents.

RESEARCH INFORMATION AND INFORMED CONSENT FORM

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:

Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

INTRODUCTION and PURPOSE

You are invited to participate in a research study because you are at least 18 years old and have experience making closed cab airblast applications. For you to participate in this study, you must understand and sign this consent form and a Product Risk Statement that describes the risks from the pesticide. If we have used words or presented information you do not clearly understand, please ask me to explain. You may take home an unsigned copy of this consent form to think about or discuss with family or friends or researchers before making your decision. If you agree to be in this study, you will be given a signed and dated copy of this consent form and the Product Risk Statement.

The Agricultural Handlers Exposure Task Force (AHETF) was formed by a group of pesticide companies. The purpose of this study is to measure how much pesticide you might get on your skin and breathe in while you spray using closed cab airblast equipment. This will be done by measuring pesticide residues in the samples we collect from you. About 5 people will be monitored in this study. The results of the study will be used to estimate exposure and risks to workers spraying pesticides with closed cab airblast equipment.

APPROVED BY
Independent IRB
Signature 3/4/08 Date

Initials: _____
Date: _____

ELIGIBILITY

1. Experience making closed cab airblast applications in the last year.
2. Provide proof you are at least 18 years old (government-issued photo ID).
3. Confirm you do not work for a pesticide company or a contractor of AHETF.
4. General health status is "good enough to do the work". Tell us whether you have any medical conditions that affect your ability to participate in the study.
5. Pregnant or nursing women cannot participate in the study. If you are female, you must take an over-the-counter urine pregnancy test before the study. This test will be supervised by a female researcher. You do not have to tell anyone if you have a positive test. Results of a negative test must be confirmed by the female researcher or you cannot participate.
6. Confirm that you do not normally wear personal protective equipment in excess of the label requirements for closed cab airblast applications. Confirm that you will follow label directions.
7. Have a private meeting with a researcher to go over this consent form. The purpose is to make sure you understand what you are agreeing to and to have your questions answered. You may have a friend, family member or advisor with you during the meeting. If you are an employee, this person may not be from the operation's management.
8. You must understand English or Spanish.
9. You must understand and sign this consent form and Product Risk Statement.

STUDY DURATION

The duration of your participation in this study is approximately 4-8 hours of one of your normal workdays.

PROCEDURES

If you participate in this study, you will do the following:

1. Provide your name and years of experience making closed cab airblast applications.
2. Confirm whether you have received pesticide safety training or are exempt from pesticide safety training.
3. Allow researchers to measure and record your height and weight.
4. Allow researchers to record your gender, age, and preferred language.
5. Allow study staff to take notes on the discussions during the informed consent session(s).

If you read only Spanish, a Spanish version of the documents will be provided, along with a translator during our meeting. If you have trouble reading these documents in your language of choice (English or Spanish), it will be read to you.

APPROVED BY
Independent IRB

Signature 3/4/08 Date

Initials: _____
Date: _____

PROCEDURES ON THE DAY OF THE STUDY

1. Wash your long-sleeved shirt and long pants before participating in the study to remove any residues of the product we are studying.
2. Bathe or shower the evening or morning before participating in the study to remove any residues of the product we are studying.
3. Wear all personal protection equipment required by the product label (see Product Risk Statement).
4. Work about 4 to 8 hours applying a commercial pesticide according to your normal practices and spray at least 3 loads.
5. Wear new long underwear underneath your long-sleeved shirt and long pants. Wear your choice of personal undergarments under the long underwear. The long underwear will be supplied by AHETF and collected at the end of the day. You will be asked to dress and undress with the assistance of a researcher of the same sex. A changing area will be provided for privacy. When you complete your participation, you will put on your own clothes and return to your normal work.
6. Have a tube attached to your shirt collar and connected to a portable air-sampling pump on a belt worn around your waist. The pump is small and light about the size of a portable radio.
7. Have your face and neck wiped with gauze pads moistened with a mild detergent and water mixture. This will be done before you eat anything, any time you would normally wash your face, and at the end of the day.
8. Have your hands washed in a mild detergent and water mixture. This will be done before you eat anything, any time you would normally wash your hands (such as when you use the toilet), and at the end of the day.
9. Allow researchers to watch all of your work activities and take notes on what you do.
10. Allow photographs and video recordings to be taken. You will not be photographed or video recorded while dressing or undressing. AHETF will own all rights to the photos and videos and may use them for any purpose. **If you do not want to be photographed or recorded you should not participate in this study.**

PRODUCTS HANDLED

You will be asked to handle a pesticide product that is registered by the US Environmental Protection Agency (EPA) and approved for spraying citrus with airblast equipment. A variety of pesticide active ingredients might be used and farm management will select the product. However, you will know what product you will handle before you are asked to sign this consent form.

In addition to the pesticide you will spray, farm management may require tank-mixes with other registered or approved products according to label directions. You will be told before your participation which materials will be in the tank mix. We will have no

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Independent IRB
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Initials: _____
Date: _____

knowledge of any risks to you other than those provided to you on the tank-mix product labels.

RISKS AND DISCOMFORTS

In this study you will have the usual risks of handling the spray equipment. You will only use equipment you have experience operating.

You will be asked to sign a separate document, called the Product Risk Statement, that identifies the product you will spray, indicates how much of that product you might handle, and specifies the risks of handling that product. It also describes what personal protection equipment you must wear.

You will review the product label with the research staff to identify the airblast use directions and precautions. From the label, and Product Risk Statement, you will learn of any possible side-effects (such as skin irritation) and the signs and symptoms of overexposure. If you feel any of the signs or symptoms during or after the workday, or do not feel well for any reason, notify a researcher immediately. A copy of the product Material Safety Data Sheet (MSDS), is available for your review and discussion any time you desire.

Because you will wear long underwear underneath your normal work clothing, you have a risk of becoming sick from being too hot. This is known as heat stress or heat illness and can be serious or life threatening. Early signs and symptoms include feeling overheated, tired, dizzy, irritable, and having decreased concentration. If you feel any of these signs or symptoms during or after the workday notify a researcher immediately. If you don't feel well for any reason, notify a researcher immediately. You will be observed by a researcher watching for these symptoms. AHETF will stop your work if the weather gets too hot.

As a precaution, AHETF will have a paramedic, physician's assistant, nurse, or emergency medical technician on site during the study. If needed, this professional will also observe you for signs of illness and will provide medical attention.

You may have other risks or discomforts, including:

- Eye or skin irritation from the detergent and water mixture
- Discomfort from wearing a portable air sampling pump around your waist
- Being embarrassed during dressing and undressing
- Being concerned about taking an over-the-counter pregnancy test
- Working longer than normal because of the time it takes for sample collection

There may be other risks that are unknown at this time. You will be told in a timely manner both verbally and in writing of any new information that might change your decision to be in the study.

APPROVED BY
Independent IRB

Signature 3/4/08 Date

Initials: _____
Date: _____

INJURY TO PARTICIPANT
If you are injured or get sick during or after the workday, medical treatment will be available at your workplace and at a nearby health care facility. If necessary, AHETF will arrange transportation for you to receive medical attention. You may refuse medical treatment unless you get sick from too much pesticide exposure or from getting too hot, or if we believe you are too sick to make a rational decision about receiving medical treatment. AHETF will cover the cost of reasonable and appropriate medical attention that is not covered by your own insurance or insurance provided through your employer. Treatment records will not become part of the research records for this study. However, AHETF will make note of the event and this will be reported in the study report. For further information about this, you may call the AHETF Manager (David Johnson) at 660-349-4601.

You will not give up any of your legal rights by signing this form.

CONFIDENTIALITY
Your name will appear on the consent form, the Product Risk Statement, and an optional form for you to request your personal study results. All other study information will identify you only by a unique code. Records with your name will be stored in a secure, limited access archive.

Information about your participation in this study will not be given to your employer.

A study report will be written by AHETF and will be available to member companies. It will be sent to the US Environmental Protection Agency (EPA). It may also be sent to state government agencies and to governments of other countries. Your name will not be included in any study report.

We cannot promise you absolute confidentiality because of the need to give information to some organizations or to parties in legal actions, as required by law. All study information, including records which identify you, may be looked at or copied by the sponsor and any consultants working with the sponsor, by EPA or other government agencies, and by the Independent Investigational Review Board, Inc. (IIRB). IIRB is a group of people who review and monitor research to make sure the people who participate in it are protected.

You may ask the Study Director for a copy of your personal results from this study. You will need to provide your name and a mail or e-mail address.

COSTS
There will be no costs to you for participation in this study.

APPROVED BY
Independent IRB
Signature 3/4/08 Date

Initials: _____
Date: _____

BENEFITS
You will not directly benefit from your participation in the study. The farm owner may benefit from the product used in the study since AHETF will reimburse the owner for that product. Information from this study will be used to improve the quality of pesticide safety assessments for workers using closed cab airblast equipment.

PAYMENT FOR PARTICIPATION
You will be paid $20 if you meet privately with a researcher to review this informed consent. You will receive the money whether you decide to participate or not. You will receive the money in cash right after the meeting.

You will be paid an additional $80 for the day you participate in sampling. You will be paid $80 for completing the sampling day and allowing us to collect your samples. If you decide to withdraw during the sampling, you will still be paid the $80. If we remove you from the study, you will still receive the $80. Payment will be in cash at the end of the sampling day.

You will also receive your normal pay from your employer.

If more people volunteer than we need, some participants may be selected randomly (for example, by lottery). You may or may not be selected. If not selected, you will not receive the $80.

VOLUNTARY PARTICIPATION / WITHDRAWAL
Your employer has agreed to let us do the research and has confirmed he/she does not encourage or discourage you to participate in this study. Your decision to be in this study is voluntary and entirely up to you. If you decide to participate, you may change your mind later and drop out of the study at any time and for any reason. A decision not to participate, or to withdraw from the study after it begins, will have no effect on your job or pay or include any penalty or any loss of benefits to which you may be entitled.

If you withdraw, the long underwear and air sampling pump will be removed, and the hand and face/neck samples may be collected with your consent.

Your participation in this study may be stopped at any time by the researchers or the sponsor. The long underwear and air sampling pump will be removed, and the hand and face/neck samples may be collected with your consent.

If you withdraw or are removed from the study, or if the study does not last an entire workday, you will be released to resume your usual activities.

APPROVED BY
Independent IRB
Signature
3/4/08
Date

Initials: _____
Date: _____

ALTERNATIVES
No one can require you to participate in this study. Participation is entirely voluntary. If you choose not to participate in this study, then on the day of the study you will perform your ordinary activities. You alternative is to not participate.

QUESTIONS
If you have questions about this study or if at any time you think you have a research-related injury or illness, contact a researcher or call:

Larry D. Smith (Study Director) at 440-255-1954 (collect)
Or 440-554-2812 (24 hours)
Or
David Johnson, Ph.D. (sponsor contact) at 660-349-4601.

If you have any questions regarding your rights as a research volunteer, please contact Kim Lerner, Chairman of the Independent Investigational Review Board, Inc. at toll free (877) 888-iirb (4472) during regular working hours. The Independent Investigational Review Board is a committee established for the purpose of protecting the rights of volunteers in a research study.

IIRB is a group of people who perform independent review of research.

Do not sign this consent form unless you were able to ask questions and received satisfactory answers.

APPROVED BY
Independent IRB
Signature
3/4/08
Date

Initials: _____
Date: _____

CONSENT

I have read the information in this consent form and in the Product Risk Statement (or it has been read to me) in a language I understand well. All my questions about the study and about being in it have been answered. I freely consent to be in this study.

I authorize the release of my research records, including photographs and video recordings, to the sponsor, to the researchers, to government agencies in other states and/or countries, to EPA, to IIRB, and to other parties as required by law.

By signing this consent form, I have not given up any of my legal rights.

_____ _____
Date Subject's Name (print)

_____
Subject's Signature

_____
Subject's Unique Worker Code

I conducted the private consent meeting with the worker named above and confirm that consent was given voluntarily after being fully informed of the benefits, risks, and procedures. In addition, this worker has reviewed and signed the Product Risk Statement which I will store along with this signed consent form in a secure location:

_____ _____
Date Name of Person Conducting Informed Consent Discussion (print)

_____
Signature of Person Conducting Informed Consent Discussion

_____
Title and Affiliation of Person Conducting Informed Consent Discussion

APPROVED BY
Independent IRB

Signature 3/4/08 Date

Initials: _____
Date: _____

---------- Use the following only if applicable ----------

If this consent form is read to the worker because the worker is unable to read the form, an impartial witness (who is not associated with the researchers or who is not part of the management of the grower where the study is being conducted) must be present to witness this worker's consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and understood by, this worker. This worker freely consented to participate in the research study.

_____ _____
Date Impartial Witness' Name (print)

_____
Impartial Witness' Signature

_____
Title and Affiliation of Impartial Witness

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not read English.

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

APPROVED BY
Independent IRB
Signature 3/4/08 Date

Initials: _____
Date: _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Fyfanon® 8 lb. Emulsion (EPA Registration No. 5905-250-ZA)

Active Ingredient (AI): Malathion (insecticide, CAS No. 00121-75-5)

Formulation and Packaging: 8 lbs AI/gallon Emulsifiable Concentrate in 1 or 2.5 gallon plastic jugs

APPROVED BY
Independent IRB
Signature 3/4/08 Date

Initials: _____
Date: _____

You may handle up to: 12.5 gallons of product

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This malathion product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include moderate eye irritation, slight skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 2005
MSDS date: 1-5-05

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

Version: 3/4/08
Protocol: AHE55
Fyfanon® 8 lb. Emulsion

APPROVED BY
Independent IRB
Signature 3/4/08 Date

Initials: _____
Date: _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Fyfanon® (EPA Registration No. 5905-196)

Active Ingredient (AI): Malathion (insecticide, CAS No. 00121-75-5)

Formulation and Packaging: 5 lbs AI/gallon Emulsifiable Concentrate

You may handle up to: 20 gallons of product

APPROVED BY
Independent IRB
Signature 3/4/08 Date

Initials: _____
Date: _____

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves and protective eyewear. The gloves and protective eyewear must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This malathion product is classified as moderate toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include moderate eye irritation, slight skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 2005 MSDS date: 10-5-05

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

Version: 3/4/08
Protocol: AHE55
Fyfanon®

APPROVED BY
Independent IRB
Signature 3/4/08 Date

Initials: _____
Date: _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Gowan Malathion 8 (EPA Registration No. 10163-21)

Active Ingredient: Malathion (insecticide, CAS No. 121-75-5)

Formulation and Packaging: 8 lbs AI/gallon Emulsifiable Concentrate

You may handle up to: 12.5 gallons of product

APPROVED BY
Independent IRB
Signature 3/4/08 Date

Initials: _____
Date: _____

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This malathion product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye and/or skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label ID: 04-R0699
MSDS date: 2/1/07 (Gowan Malathion 8 Flowable)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

Version: 3/4/08
Protocol: AHE55
Gowan Malathion 8

APPROVED BY
Independent IRB
Signature 3/4/08 Date

Initials: _____
Date: _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Malathion 8-E Insecticide (EPA Registration No. 34704-452)

Active Ingredient (AI): Malathion (insecticide, CAS No. 121-75-5)

Formulation and Packaging: 8 lbs AI/gallon Emulsifiable Concentrate in 1 gallon plastic jugs

APPROVED BY
Independent IRB
Signature 3/4/08 Date

Initials: _____
Date: _____

You may handle up to: 12.5 gallons of product

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This malathion product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include moderate eye irritation, slight skin irritation, possible allergic skin reaction, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: None found
MSDS date: 6/8/06 (Loveland MSDS #000452-06-LPI)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

Version: 3/4/08
Protocol: AHE55
Malathion 8-E

APPROVED BY
Independent IRB
Signature 3/4/08 Date

Initials: _____
Date: _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Sevin® Brand 4F Carbaryl Insecticide (EPA Registration No. 264-349)

Active Ingredient (AI): Carbaryl (insecticide, CAS No. 63-25-2)

Formulation and Packaging: 4 lb AI/gallon Flowable liquid in 2.5 gallon plastic jugs

You may handle up to: 25 gallons of product

APPROVED BY
Independent IRB
Signature
3/4/08
Date

Initials: _____
Date: _____

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This carbaryl product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye irritation, minimal skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 9/27/04
MSDS date: 12/18/02 (No. 000000000194, Version 2.1)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

Version: 3/4/08
Protocol: AHE55
Sevin® Brand 4F

APPROVED BY
Independent IRB
Signature 3/4/08 Date

Initials: _____
Date: _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Sevin® Brand 80WSP Carbaryl Insecticide (EPA Registration No. 264-526)

Active Ingredient (AI): Carbaryl (insecticide, CAS No. 63-25-2)

Formulation and Packaging: 80% AI dry powder in a 1.25 lb water soluble pack

You may handle up to: 100 water soluble packs

APPROVED BY
Independent IRB
Signature
3/4/08
Date

Initials: _____
Date: _____

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear waterproof gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This carbaryl product is classified as moderate toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye irritation, minimal skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 9/23/04
MSDS date: 12/26/02 (number 000000001825; Version 1.1)

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

Version: 3/4/08
Protocol: AHE55
Sevin® Brand 80WSP

APPROVED BY
Independent IRB
Signature 3/4/08 Date

Initials: _____
Date: _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Sevin® Brand XLR Plus Carbaryl Insecticide (EPA Registration No. 264-333)

Active Ingredient (AI): Carbaryl (insecticide, CAS No. 63-25-2)

Formulation and Packaging: 4 lb AI/gallon Flowable liquid in 2.5 gallon plastic jugs

You may handle up to: 25 gallons of product

APPROVED BY
Independent IRB
Signature 3/4/08 Date

Initials: _____
Date: _____

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This carbaryl product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye irritation and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 9/21/04
MSDS date: 1/17/08 (Bayer MSDS 102000001927, Version 2.1)

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

Version: 3/4/08
Protocol: AHE55
Sevin® Brand XLR

APPROVED BY
Independent IRB
Signature 3/4/08 Date

Initials: _____
Date: _____

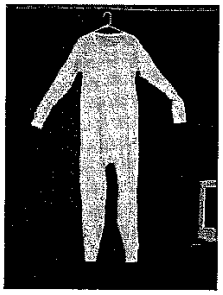
Research Study Volunteers

The Agricultural Handlers Exposure Task Force (AHETF) is a group of pesticide companies doing research to measure how much chemical gets on workers when they handle pesticides. They are looking for experienced airblast applicators to perform their usual work and let them collect exposure data.

To volunteer you must be:	You are not qualified if you:
• At least 18 years old with a government issued photo ID • Fluent in speaking English or Spanish • In good health • Not working for a pesticide manufacturer • Male or female (not pregnant or nursing) • Experienced and trained in handling pesticides	• Are less than 18 years of age • Do not have a government-issued photo identification card • Don't speak English or Spanish • Are not in good health • Work for a pesticide manufacturer • Are a pregnant or nursing female • Are cognitively impaired

You will be asked to do the following:

- Let us monitor you as you do your work for a day
- Sign a consent form before participating (in English or Spanish)
- Wear long underwear under your regular clothes
- Let us have the long underwear at the end of the day
- Let us wash your hands and wipe your face periodically with a mild soap solution



You should also know that:

- Participation is completely voluntary
- You can withdraw whenever you want
- Only non-invasive techniques are used, so you don't have to give urine or blood samples
- Information from the study will be used by EPA in assessing risks to agricultural workers.

If you are interested, please contact the Study Director:

Larry Smith
office phone 440-255-1954
cell phone 440-554-2812

He can answer any of your questions and give you more details.

APPROVED 3/4/08
Independent Investigational Review Board

"Ver. Research Study Volunteers"

Memorandum

DATE: March 12, 2008

TO: Larry D. Smith, PhD
Principal Investigator

FROM: Kim Lerner, Chairman or
Anita McSharry, Vice-Chairman
Independent Investigational Review Board, Inc.

SUBJECT: Certified Translation;

PROTOCOL: AHE55

The Independent Investigational Review Board, Inc. acknowledges receipt of the Certified Spanish Translation of the approved English Informed Consent Form, Fyfanon® 8 lb. Emulsion Product Risk Statement, Fyfanon® Product Risk Statement, Gowan Malathion 8 Product Risk Statement, Malathion 8-E Product Risk Statement, Sevin® Brand 4F Product Risk Statement, Sevin® Brand 80WSP Product Risk Statement and Sevin® Brand XLR Product Risk Statement Versions 3/4/08, Approved 3/4/08 and Advertisement Version "Research Study Volunteers" Approved 3/4/08 for the above noted research study. The Certification of translation and translator credentials meets the requirements of the Independent Investigational Review Board, Inc.

The Certified Spanish Translation of the approved English Informed Consent Form, Fyfanon® 8 lb. Emulsion Product Risk Statement, Fyfanon® Product Risk Statement, Gowan Malathion 8 Product Risk Statement, Malathion 8-E Product Risk Statement, Sevin® Brand 4F Product Risk Statement, Sevin® Brand 80WSP Product Risk Statement and Sevin® Brand XLR Product Risk Statement are identified as Versions 3/4/08 Approved 3/4/08 and Advertisement identified as Version "Research Study Volunteers" Approved 3/4/08 are consistant with the approved English versions and are acceptable for Spanish speaking volunteers. The Certified Spanish Translations of the English Informed Consent Form, Fyfanon® 8 lb. Emulsion Product Risk Statement, Fyfanon® Product Risk Statement, Gowan Malathion 8 Product Risk Statement, Malathion 8-E Product Risk Statement, Sevin® Brand 4F Product Risk Statement, Sevin® Brand 80WSP Product Risk Statement and Sevin® Brand XLR Product Risk Statement Versions 3/4/08, are Approved 3/4/08 and Advertisement Version "Research Study Volunteers" Approved 3/4/08 are accompanied with Certifications of Translations dated 3/12/08.

Thank you for your cooperation.
kl/ams/yc:

6738 West Sunrise Blvd. Suite 102 ♦ Plantation, FL, 33313
Tel: (954) 327-0778 ♦ Fax: (954) 327-5778
Email: INFO@IIRB.COM

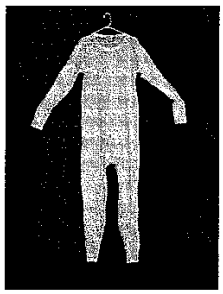
Voluntarios para un Estudio de Investigación Científica

La Agricultural Handlers Exposure Task Force (AHETF) es un grupo de compañías de pesticidas que están llevando a cabo investigación científica para medir cuánta substancia química se agarran los trabajadores cuando ellos manipulan pesticidas. Están buscando aplicadores experimentados de pulverización neumática [*airblast*] para que desempeñen su trabajo usual y dejar que se les recoja datos de la exposición.

Para ofrecerse como voluntario usted debe:	Usted no cumple con los requisitos si:
• Tener por lo menos 18 años y una identificación, con foto, emitida por el gobierno • Dominar el idioma inglés o el español • Gozar de buena salud • No trabajar para un fabricante de pesticidas • Ser hombre, o mujer (que no esté embarazada ni lactando) • Ser experimentado y estar entrenado en el manipuleo de pesticidas	• Es menor de 18 años de edad • Si no tiene una identificación con foto que sea emitida por el gobierno • Si no habla ni inglés ni español • Si no goza de un buen estado de salud • Si trabaja para un fabricante de pesticidas • Si es una mujer que está embarazada o lactando • Si tiene insuficiencia cognitiva

Le pedirán que haga lo siguiente:

- Que nos permita monitorearlo mientras que usted hace su trabajo, durante un día
- Que firme un formulario de consentimiento antes de participar (en inglés ó en español)
- Que use ropa interior larga debajo de sus ropas regulares
- Que nos deje tener la ropa interior larga al final del día
- Que nos deje lavarle las manos y frotarle la cara, periódicamente, con una solución de jabón suave



Usted debería saber que:

- La participación es completamente voluntaria
- Usted puede retirarse cuando quiera
- Se usan solamente técnicas no invasoras, de modo que usted no tiene que dar ni muestras de orina ni de sangre
- La información proveniente del estudio será usada por la EPA al evaluar los riesgos que corren los trabajadores agrícolas.

Si está interesado, por favor póngase en contacto con el Director del Estudio:

Larry Smith
teléfono de la oficina 440-255-1954
teléfono celular 440-554-2812

Él puede responder a cualquiera de sus preguntas y darle más detalles.

ver. "Research Study Volunteers"

APPROVED 3/4/08
Independent Investigational Review Board

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 12, 2008

To Whom It May Concern:
A Quién Corresponda:

This is to certify that the attached document from English into Spanish is an accurate representation of the informed consent form received by this office. This document is designated as:

Print Ad: (Research Study Volunteers) Approved 3/4/08
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: Research Study Volunteers) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

Aviso Impreso: (Voluntarios para Estudio de Investigación Científica) Approvado 3/4/08
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverización Neumática [*Airblast*] a las Cosechas, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: Voluntarios para Estudio de Investigación Científica) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Américo Gómez, who translated this document, is fluent in Spanish and standard North American English and qualified to translate. He attests to the following:

Américo Gómez, quien tradujo dicho documento, tiene dominio de los idiomas inglés norteamericano y español, y está capacitado para traducir. Él declara lo siguiente:

"To the best of my knowledge, the accompanying text is a true, full and accurate translation of the specified document".
«Según mi leal saber y entender, el texto que sigue a continuación es una traducción fiel y correcta del documento que se adjunta».

Signature of Américo Gómez/*Firma de Américo Gómez*

FORMULARIO DE INFORMACIÓN SOBRE LA INVESTIGACIÓN Y CONSENTIMIENTO INFORMADO

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverización Neumática [*Airblast*] a las Cosechas, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, PhD
P.O. Box 509
Macon, Missouri 63552

DIRECTOR DEL ESTUDIO: Larry D. Smith, PhD
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Teléfono: 440-255-1954
Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIÓN: _____
_____
_____

INTRODUCCIÓN y PROPÓSITO

Queda invitado a participar en un estudio de investigación científica porque usted tiene por lo menos 18 años de edad y posee experiencia en hacer aplicaciones de pulverización neumática [*airblast*] en cabinas cerradas. Para que usted pueda participar en este estudio, usted debe entender y firmar este formulario de consentimiento y una Declaración de Riesgo del Producto que describe los riesgos provenientes del pesticida. Si hemos usado palabras o presentado información que usted no entienda con claridad, por favor pídame que le explique. Usted puede llevarse a su casa una copia, sin firmar, de este formulario de consentimiento, para pensarlo o para hablar sobre esto con sus familiares o amigos, o investigadores, antes de tomar su decisión. Si usted se pone de acuerdo para estar en este estudio, le darán una copia firmada y fechada de este formulario de consentimiento y de la Declaración de Riesgo del Producto.

La Agricultural Handlers Exposure Task Force (AHETF) fue formada por un grupo de compañías de pesticidas. El propósito de este estudio es medir cuánto pesticida podría recibir usted en su piel y respirar, mientras que usted esté usando equipo de pulverización neumática de cabina cerrada. Se hará esto mediante la medición de residuos de pesticida en las muestras que nosotros recojamos de usted. Se

APROBADO POR
Independent IRB
Firma
4/marzo/08
Fecha

monitoreará a unas 5 personas en este estudio. Los resultados del estudio se usarán para estimar la exposición y los riesgos a los trabajadores que estén fumigando pesticidas con equipo de pulverización neumática [*airblast*] de cabina cerrada.

ELEGIBILIDAD

1. Experiencia en hacer aplicaciones de pulverización neumática [*airblast*] en cabina cerrada, en el transcurso del último año.
2. Proporcionar prueba de que tiene por lo menos 18 años de edad (identificación con foto, emitida por un ente gubernamental).
3. Confirmar que no trabaja para una compañía de pesticidas ni para un contratista de AHETF.
4. El estado de salud general es «lo suficientemente bueno como para hacer el trabajo». Díganos si tiene alguna afección [dolencia] médica que afecte a su capacidad para participar en el estudio.
5. Las mujeres quienes estén embarazadas o lactando [dándole el pecho a un niño], no pueden participar en este estudio. Si usted es mujer, usted debe hacerse una prueba de embarazo, de las de venta libre, antes del estudio. Esta prueba será supervisada por una investigadora. Usted no tiene que decirle a nadie si es que tiene una prueba positiva. Los resultados de una prueba negativa deben ser confirmados por la investigadora o usted no puede participar.
6. Confirmar que usted no usa, normalmente, equipo de protección personal que exceda los requisitos de la etiqueta para las aplicaciones de pulverización neumática [*airblast*] de cabina cerrada. Confirmar que usted seguirá las instrucciones de la etiqueta.
7. Tener una reunión privada con un investigador para repasar este formulario de consentimiento. El propósito es cerciorarse de que usted entienda con qué se está poniendo de acuerdo y que le respondan a sus preguntas. Usted puede tener a un amigo, a un miembro de su familia o a un asesor, con usted, durante la reunión. Si usted es un empleado, esta persona no puede ser de la gerencia de operaciones.
8. Usted entender inglés ó castellano [español].
9. Usted debe entender y firmar este formulario de consentimiento y Declaración de Riesgo del Producto.

LA DURACIÓN DEL ESTUDIO

La duración de su participación en este estudio es de aproximadamente 4-8 horas de uno de sus días normales de trabajo.

LOS PROCEDIMIENTOS

Si participa en este estudio, usted hará lo siguiente:

1. Proporcionar su nombre y años de experiencia haciendo aplicaciones de pulverización neumática [*airblast*] de cabina cerrada.

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2. Confirmar si usted ha recibido entrenamiento de seguridad en pesticidas o si está exento del entrenamiento de seguridad en pesticidas.
3. Permitirles a los investigadores que midan y registren su estatura [altura] y peso.
4. Permitirles a los investigadores que midan y registren su género, edad, e idioma preferido.
5. Permitirle al personal del estudio que tome notas sobre los debates, durante la sesión(es) del consentimiento informado.

Si usted lee solamente español, le proporcionarán una versión de los documentos en español, junto con un intérprete [traductor] durante nuestra reunión. Si usted tuviese problemas para leer estos documentos en el idioma que usted haya elegido (inglés ó español), entonces se los leerán a usted.

LOS PROCEDIMIENTOS EN EL DÍA DEL ESTUDIO

1. Lave su camisa de manga larga y pantalones largos, antes de participar en el estudio, para quitar cualquier residuo(s) del producto que estamos estudiando.
2. Báñese o dúchese en la noche o en la mañana, antes de participar en el estudio, para quitar cualquier residuo(s) del producto que estamos estudiando.
3. Use todo el equipo de protección personal requerido por la etiqueta del producto (vea la Declaración de Riesgo del Producto).
4. Trabaje alrededor de 4 u 8 horas aplicando un pesticida comercial, de acuerdo con sus prácticas normales y fumigue por lo menos 3 cargas.
5. Use ropa interior nueva debajo de su camisa de manga larga y pantalones largos. Use la ropa interior personal que usted desee, debajo de la ropa interior larga. La ropa interior larga se la suministrará AHETF y la recogerán al final del día. Le pedirán que se vista y se desvista con la asistencia de un investigador del mismo sexo. Le proporcionarán un área para cambiarse, por razones de privacidad. Cuando usted complete su participación, usted se pondrá sus propias ropas y regresará a su trabajo normal.
6. Le adjuntarán un tubo al cuello de su camisa y éste estará conectado a una bomba portátil de muestreo de aire, en un cinturón que usted usará alrededor de la cintura. La bomba es pequeña y liviana, alrededor del tamaño de una radio portátil.
7. Limpiarse la cara y cuello con almohadillas de gasa humedecidas con una mezcla de detergente suave y agua. Esto se llevará a cabo antes de que usted coma nada, en cualquier momento en el que usted normalmente se lavaría la cara y, al final del día.
8. Lavarse las manos con una mezcla de detergente suave y agua. Esto se llevará a cabo antes de que usted coma nada, en cualquier momento en el que usted normalmente se lavaría las manos (tal como cuando usa el cuarto de baño) y, al final del día.
9. Permitirles a los investigadores que observen todas sus actividades laborales [de trabajo] y que tomen notas acerca de lo que hace usted.

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10. Permitirles que saquen fotografías y grabaciones en vídeo. No lo fotografiarán ni lo grabarán en vídeo, mientras que se esté vistiendo o desvistiendo. AHETF será la propietaria exclusiva [con todos los derechos] de las fotografías y vídeos y puede usarlos con cualquier propósito. **Si usted no desea que lo fotografíen ni que lo graben en vídeo, usted no debería participar en este estudio**.

PRODUCTOS MANIPULADOS

Le pedirán que manipule un producto pesticida que está registrado por la Agencia Estadounidense de Protección Medioambiental (EPA) y aprobado para fumigar cítricos con equipo de pulverización neumática [*airblast*]. Podría usarse una variedad de ingredientes activos pesticidas y la administración de la granja elegirá el producto. No obstante, usted sabrá qué producto va a manipular, antes de que le pidan que firme este formulario de consentimiento.

Además del pesticida que usted fumigará, la administración de la granja pudiera requerir las mezclas de tanques con otros productos registrados o aprobados, de acuerdo con las instrucciones de la etiqueta. Antes de su participación, le dirán cuáles materiales habrá en la mezcla del tanque. Nosotros no tendremos conocimiento de ningún riesgo(s) para usted, aparte de aquellos que le hayan proporcionado a usted en las etiquetas de los productos existentes en la mezcla del tanque.

RIESGOS Y MOLESTIAS

En este estudio, usted correrá los riesgos usuales de manipular equipos de fumigación. Usted usará solamente equipos en los que tenga experiencia en operarlos.

Le pedirán que firme un documento separado, llamado Declaración de Riesgo del Producto, que identifica al producto que usted fumigará, que indica cuánto de ese producto usted podría manipular y, que especifica los riesgos del manipuleo de ese producto. También describe qué equipo de protección personal debe usar usted.

Usted revisará la etiqueta del producto junto con el personal de la investigación científica, para identificar las instrucciones y precauciones del uso de la pulverización neumática [*airblast*]. De la etiqueta y de la Declaración de Riesgo del Producto, usted se informará acerca de cualquier efecto(s) secundario(s) posible (tal como irritación en la piel) y las señales y síntomas de la sobre-exposición. Si usted sintiese cualquiera de las señales ó síntomas durante ó después del día de trabajo, ó si no se sintiese bien por cualquier razón, notifíqueselo inmediatamente a un investigador. Hay a su disposición, en cualquier momento en el que usted lo desee, una copia de la Hoja de Datos de Seguridad del Material (MSDN) del producto.

Debido a que usted usará ropa interior larga debajo de sus ropas normales de trabajo, usted corre un riesgo de enfermarse debido a que sienta mucho calor. A esto se le conoce como golpe de calor [*heat stress* ó *heat illness* en inglés] y puede ser grave o puede constituir una amenaza a la vida. Las señales y los síntomas tempranos

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incluyen la sensación de exceso de calor, cansancio, mareos, estar irritable y, la disminución de concentración. Si usted sintiese cualquiera de estas señales ó síntomas, durante ó después de un día de trabajo, notifíqueselo inmediatamente a un investigador. Si usted no se sintiese bien por cualquier razón, notifíqueselo inmediatamente a un investigador. Un investigador que esté tratando de detectar estos síntomas, va a estar observándolo a usted. AHETF detendrá su trabajo si el tiempo se pusiese muy cálido.

Como medida de precaución, AHETF tendrá un paramédico, asistente de médico, enfermera, ó un técnico en emergencias médicas, en el sitio durante el estudio. Si fuere necesario, este profesional también lo observará a usted para detectar señales de enfermedad y le proporcionará atención médica.

Usted pudiera tener otros riesgos o molestias, incluyendo:

- Irritación en los ojos o en la piel, proveniente de la mezcla de detergente y agua.
- Molestia debida al uso de una bomba portátil de muestreo de aire, alrededor de su cintura.
- Sentirse con vergüenza mientras que se esté vistiendo o desvistiendo.
- Estar preocupada acerca de tener que hacerse una prueba de embarazo de venta libre.
- El trabajar más tiempo de lo normal, debido al tiempo que lleva la recolección de muestras.

Pudiera haber otros riesgos que se desconozcan en estos momentos. Le dirán de manera puntual, tanto verbalmente como por escrito, acerca de cualquier información nueva que podría cambiar su decisión de estar en el estudio.

LESIÓN AL PARTICIPANTE

Si usted se lesionase o se enfermase durante o después del día de trabajo, habrá a su disposición tratamiento médico en su lugar de trabajo y en una instalación cercana de atención médica. Si fuere necesario, AHETF arreglará para que lo transporten para que reciba atención médica. Usted puede rehusar el tratamiento médico, al menos que usted se enferme debido a la demasiada exposición al pesticida o debido al excesivo calor, o si nosotros creyésemos que usted está demasiado enfermo como para tomar una decisión racional acerca de recibir tratamiento médico. AHETF cubrirá el costo de la atención médica razonable y apropiada, que no esté cubierta por su propio seguro o por el seguro que le proporcione su empleador. Los expedientes del tratamiento no se convertirán en parte de los expedientes de la investigación científica para este estudio. No obstante, AHETF tomará nota del evento y esto estará reportado en el informe del estudio. Para más información acerca de esto, usted puede llamar al Administrador de AHETF (David Jonson) al 660-349-4601.

Usted no renunciará a ninguno de sus derechos legales por firmar este formulario.

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CONFIDENCIALIDAD

Su nombre aparecerá en el formulario de consentimiento, en la Declaración de Riesgo del Producto y, en un formulario optativo para que usted solicite sus resultados personales del estudio. Toda la otra información proveniente del estudio, lo identificará a usted solamente por medio de un código único. Los expedientes que contengan su nombre se almacenarán en un archivo seguro, de acceso limitado.

La información acerca de su participación en este estudio no se le dará a su empleador.

AHETF escribirá un informe del estudio y estará a disposición de compañías miembro. Se le enviará a la Agencia Estadounidense de Protección Medioambiental (EPA). También pudiera ser enviada a agencias gubernamentales estatales y a gobiernos de otros países. Su nombre no estará incluido en ningún informe del estudio.

Nosotros no podemos prometerle a usted una confidencialidad absoluta debido a la necesidad de darles información a algunas organizaciones o a partes [a terceros] en acciones legales, según lo requiera la ley. Toda la información proveniente del estudio, incluyendo los expedientes que lo identifiquen a usted, pueden ser mirados o copiados por el patrocinador y por cualquier consultor(es) que esté trabajando con el patrocinador, por la EPA o por otras agencias gubernamentales y, por el Independent Investigational Review Board, Inc. (IIRB). El IIRB es un grupo de personas quienes revisan y monitorean la investigación científica para cerciorarse de que las personas quienes participen en ella, estén protegidas.

Usted puede pedirle, al Director del Estudio, una copia de sus resultados personales provenientes de este estudio. Usted va a necesitar proporcionar su nombre y una dirección postal o de correo electrónico [*e-mail*].

COSTOS

No habrá costos para usted por la participación en este estudio.

BENEFICIOS

Usted no se beneficiará, directamente, de la participación en el estudio. El propietario de la granja pudiera beneficiarse del producto usado en el estudio, dado que AHETF lo reembolsará al propietario por ese producto. La información proveniente de este estudio se usará para mejorar la calidad de las evaluaciones de seguridad en los pesticidas, para los trabajadores que estén usando equipo de pulverización neumática [*airblast*] de cabina cerrada.

EL PAGO POR LA PARTICIPACIÓN

Le pagarán $20 si usted se reúne en privado con un investigador para repasar este consentimiento informado. Usted recibirá el dinero si usted decide participar o no. Usted recibirá el dinero en efectivo enseguida de la reunión.

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Le pagarán $80 adicionales por el día que usted participe en el muestreo. Le pagarán $80 por completar el día de muestreo y por permitirnos recoger sus muestras. Si usted decide retirarse durante el muestreo, aún le pagarán los $80. Si nosotros lo hiciésemos retirarse del estudio, usted aún recibirá los $80. El pago se efectuará en efectivo al final del día de muestreo.

Usted también recibirá su pago normal de su empleador.

Si hubiese más voluntarios de los que necesitamos, algunos participantes pudieran ser seleccionados al azar (por ejemplo, por lotería). Usted pudiera, o no, ser seleccionado. Si no fuese seleccionado, usted no recibirá los $80.

LA PARTICIPACIÓN / EL RETIRO VOLUNTARIOS

Su empleador se ha puesto de acuerdo en permitirnos llevar a cabo la investigación científica y ha confirmado que él/ella no lo anima ni lo desanima a usted para participar en este estudio. Su decisión de estar en este estudio es voluntaria y queda librada enteramente a usted. Si usted decide participar, usted pudiera, más adelante, cambiar de manera de pensar y abandonar el estudio en cualquier momento y por cualquier razón. Una decisión de no participar, o de retirarse del estudio después de que éste haya empezado, no tendrá efecto sobre su trabajo ni sobre su pago, ni incluirá ninguna multa ni pérdida de beneficios a los cuales usted pueda tener derecho.

Si usted se retirase, la ropa interior larga y la bomba de muestreo de aire se los removerán, y las muestras de las manos y cara/cuello pudieran recogerse con su consentimiento.

Su participación en este estudio pudiera ser detenida en cualquier momento por los investigadores o por el patrocinador. La ropa interior larga y la bomba de muestreo de aire se los removerán, y las muestras de las manos y cara/cuello pudieran recogerse con su consentimiento.

Si usted se retirase del estudio, o si lo quitasen del estudio, o si el estudio no durase un día entero de trabajo, a usted lo dejarán que reanude sus actividades usuales.

ALTERNATIVAS

Nadie puede requerirle a usted que participe en este estudio. La participación es enteramente voluntaria. Si usted opta por no participar en este estudio, entonces en el día del estudio usted desempeñará sus actividades normales y corrientes. Su alternativa es la de no participar.

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PREGUNTAS

Si tiene preguntas acerca de este estudio o si en cualquier momento usted tuviese una lesión o enfermedad relacionada con el estudio, póngase en contacto con un investigador o llame a:

Larry D. Smith (Director del Estudio) al 440-255-1954 (llamada a cobrar; *collect*)
Ó 440-554-2812 (las 24 horas)
Ó
David Johnson, PhD (contacto del patrocinador) al 660-349-4601.

Si usted tiene cualquier pregunta(s) en lo concerniente a sus derechos en calidad de voluntario de una investigación científica, por favor póngase en contacto con la señora Kim Lerner, Presidenta del Independent Investigational Review Board, Inc. llamando al número gratuito (877) 888-iirb (4472) durante horas regulares de trabajo. El Independent Investigational Review Board es un comité que se ha establecido con el propósito de proteger los derechos de los voluntarios en un estudio de investigación científica.

El IIRB es un grupo de personas quienes desempeñan la revisión independiente de la investigación científica.

No firme este formulario al menos que usted haya podido hacer preguntas y que haya recibido respuestas satisfactorias.

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CONSENTIMIENTO

Yo he leído la información existente en este formulario de consentimiento y en la Declaración de Riesgo del Producto (ó me la han leído) en un idioma que entiendo bien. Todas mis preguntas acerca del estudio y acerca del hecho de estar en él, me las han respondido. Yo consiento libremente a estar en este estudio.

Yo autorizo la divulgación de mis expedientes de la investigación científica, incluyendo fotografías y grabaciones de vídeo, al patrocinador, a los investigadores, a agencias gubernamentales en otros estados y/ó países, a la EPA, al IIRB, y a otras partes, según lo requiera la ley.

Al firmar este formulario de consentimiento, yo no he renunciado a ninguno de mis derechos legales.

Fecha _____ Nombre del Sujeto (en letra de molde; de imprenta) _____

Firma del Sujeto _____

Código Único de Trabajador, del Sujeto _____

Yo dirigí la reunión privada del consentimiento, con el trabajador mencionado anteriormente y confirmo que el consentimiento fue dado voluntariamente después de haber sido informado acerca de los beneficios, riesgos y procedimientos. Además, este trabajador ha revisado y firmado la Declaración de Riesgo del Producto, la cual yo almaceno junto con este formulario de consentimiento firmado, en un lugar seguro:

Fecha _____ Nombre de la Persona que está Dirigiendo la Discusión del Consentimiento Informado (en letra de molde; de imprenta) _____

Firma de la Persona que está Dirigiendo la Discusión del Consentimiento Informado _____

Título y Afiliación de la Persona que está Dirigiendo la Discusión del Consentimiento Informado. _____

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---------- Use lo siguiente solamente si fuere pertinente ----------

Si este formulario de consentimiento se le lee al trabajador debido a que el trabajador no puede leer el formulario, debe estar presente un testigo imparcial (quien no esté asociado con los investigadores ó quien no forme parte de la administración del cultivador donde el estudio se esté llevando a cabo) para atestiguar el consentimiento de este trabajador y firmar la siguiente declaración:

Yo confirmo que la información existente en este formulario de consentimiento y cualquier otra información escrita, le fue explicada con precisión a este trabajador y éste la entendió. Este trabajador consintió libremente a participar en el estudio de investigación científica.

Fecha	Nombre del Testigo Imparcial (en letra de molde; de imprenta)
	Firma del Testigo Imparcial
	Título y Afiliación del Testigo Imparcial

Nota: Este bloque de firmas no puede usarse para las traducciones a otro idioma. Se necesita un formulario de consentimiento, traducido, para inscribir a sujetos quienes no lean inglés.

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08

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Independent IRB
Firma
4/marzo/08
Fecha

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 12, 2008

To Whom It May Concern:
A Quién Corresponda:

This is to certify that the attached document from English into Spanish is an accurate representation of the informed consent form received by this office. This document is designated as:

(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/4/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverización Neumática [*Airblast*] a las Cosechas, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 4/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Américo Gómez, who translated this document, is fluent in Spanish and standard North American English and qualified to translate. He attests to the following:

Américo Gómez, quien tradujo dicho documento, tiene dominio de los idiomas inglés norteamericano y español, y está capacitado para traducir. Él declara lo siguiente:

"To the best of my knowledge, the accompanying text is a true, full and accurate translation of the specified document".
«Según mi leal saber y entender, el texto que sigue a continuación es una traducción fiel y correcta del documento que se adjunta».

Signature of Américo Gómez/*Firma de Américo Gómez*

Declaración de Riesgo del Producto
Riesgo de Toxicidad del Producto Pesticida Manipulado
(Debe adjuntarse al Formulario de Consentimiento Informado)

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverización Neumática [*Airblast*] a las Cosechas, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, PhD
P.O. Box 509
Macon, Missouri 63552

DIRECTOR DEL ESTUDIO: Larry D. Smith, PhD
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Teléfono: 440-255-1954
Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIÓN: _____
_____
_____

Introducción
Usted se ha puesto de acuerdo para participar en el estudio de referencia. El formulario de consentimiento informado que usted firmó, enunciaba que se le informaría verbalmente y por escrito, acerca de cualquier riesgo(s) que podría influir sobre su disposición para participar en el estudio.

Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Fyfanon® 8 lb. Emulsión (Registro de EPA № 5905-250-ZA)

Ingrediente Activo (AI): Malathion (insecticida, CAS № 00121-75-5)

Formulación y Embalaje: 8 lbs. AI/galón Concentrado Emulsionante en jarras de plástico de 1 ó 2,5 galones.

Usted puede manipular hasta: 12,5 galones del producto

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Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes a las substancias químicas. Debe quitarse los guantes antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Basándose en la etiqueta más reciente del producto y en la Hoja de Datos de Seguridad del Material (acerca de la cual se hablará con usted y estará a su disposición para que la repase), podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto malathion está clasificado como de baja toxicidad para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación moderada de los ojos, irritación ligera de la piel, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Fecha de la etiqueta: 2005
Fecha de la MSDS: enero-5-05

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma del Testigo Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08

APROBADO POR
Independent IRB
Firma 4/marzo/08 Fecha

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 12, 2008

To Whom It May Concern:
A Quién Corresponda:

This is to certify that the attached document from English into Spanish is an accurate representation of the informed consent form received by this office. This document is designated as:

Fyfanon® 8 lb. Emulsion
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/4/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

Fyfanon® Emulsión de 8 libras
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverización Neumática [*Airblast*] a las Cosechas, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 4/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Américo Gómez, who translated this document, is fluent in Spanish and standard North American English and qualified to translate. He attests to the following:

Américo Gómez, quien tradujo dicho documento, tiene dominio de los idiomas inglés norteamericano y español, y está capacitado para traducir. Él declara lo siguiente:

"To the best of my knowledge, the accompanying text is a true, full and accurate translation of the specified document".
«Según mi leal saber y entender, el texto que sigue a continuación es una traducción fiel y correcta del documento que se adjunta».

Signature of Américo Gómez/*Firma de Américo Gómez*

Declaración de Riesgo del Producto
Riesgo de Toxicidad del Producto Pesticida Manipulado
(Debe adjuntarse al Formulario de Consentimiento Informado)

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverización Neumática [*Airblast*] a las Cosechas, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, PhD
P.O. Box 509
Macon, Missouri 63552

DIRECTOR DEL ESTUDIO: Larry D. Smith, PhD
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Teléfono: 440-255-1954
Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIÓN: _____
_____
_____

Introducción
Usted se ha puesto de acuerdo para participar en el estudio de referencia. El formulario de consentimiento informado que usted firmó, enunciaba que se le informaría verbalmente y por escrito, acerca de cualquier riesgo(s) que podría influir sobre su disposición para participar en el estudio.

Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Fyfanon® (Registro de EPA № 5905-196)

Ingrediente Activo (AI): Malathion (insecticida, CAS № 00121-75-5)

Formulación y Embalaje: 5 lbs. AI/galón Concentrado Emulsionante.

Usted puede manipular hasta: 20 galones del producto

APROBADO POR
Independent IRB
Firma
4/marzo/08
Fecha

Iniciales: _____
Fecha: _____

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes a las substancias químicas y anteojos protectores para los ojos. Debe quitarse los guantes y los anteojos protectores para los ojos, antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Basándose en la etiqueta más reciente del producto y en la Hoja de Datos de Seguridad del Material (acerca de la cual se hablará con usted y estará a su disposición para que la repase), podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto malathion está clasificado como de toxicidad moderada para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación moderada de los ojos, irritación ligera de la piel, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Fecha de la etiqueta: 2005 Fecha de la MSDS: octubre-5-05

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma del Testigo Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08

APROBADO POR
Independent IRB
Firma 4/marzo/08 Fecha

Iniciales: _____
Fecha: _____

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March 12, 2008

To Whom It May Concern:
A Quién Corresponda:

This is to certify that the attached document from English into Spanish is an accurate representation of the informed consent form received by this office. This document is designated as:

Fyfanon®
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/4/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

Fyfanon®
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverización Neumática [*Airblast*] a las Cosechas, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 4/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
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«Según mi leal saber y entender, el texto que sigue a continuación es una traducción fiel y correcta del documento que se adjunta».

Signature of Américo Gómez/*Firma de Américo Gómez*

Declaración de Riesgo del Producto
Riesgo de Toxicidad del Producto Pesticida Manipulado
(Debe adjuntarse al Formulario de Consentimiento Informado)

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverización Neumática [*Airblast*] a las Cosechas, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, PhD
P.O. Box 509
Macon, Missouri 63552

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LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
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Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIÓN: _____
_____
_____

Introducción
Usted se ha puesto de acuerdo para participar en el estudio de referencia. El formulario de consentimiento informado que usted firmó, enunciaba que se le informaría verbalmente y por escrito, acerca de cualquier riesgo(s) que podría influir sobre su disposición para participar en el estudio.

Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Insecticida Malathion 8-E (Registro de EPA № 34704-452)

Ingrediente Activo (AI): Malathion (insecticida, CAS № 121-75-5)

Formulación y Embalaje: 8 lbs. AI/galón Concentrado Emulsionante en jarras de plástico de 1 galón.

Usted puede manipular hasta: 12,5 galones del producto

APROBADO POR
Independent IRB
Firma 4/marzo/08 Fecha

Iniciales: _____
Fecha: _____

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes a las substancias químicas. Debe quitarse los guantes antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Basándose en la etiqueta más reciente del producto y en la Hoja de Datos de Seguridad del Material (acerca de la cual se hablará con usted y estará a su disposición para que la repase), podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto malathion está clasificado como de baja toxicidad para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación moderada de los ojos, irritación ligera de la piel, posible reacción alérgica en la piel, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Fecha de la etiqueta: no se ha encontrado
Fecha de la MSDS: junio-8-06 (Loveland MSDS № 000452-06-LPI)

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma del Testigo Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08

Versión: 4/marzo/08
Protocolo: AHE55
Malathion 8-E

APROBADO POR
Independent IRB
Firma 4/marzo/08 Fecha

Iniciales: _____
Fecha: _____

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 12, 2008

To Whom It May Concern:
A Quién Corresponda:

This is to certify that the attached document from English into Spanish is an accurate representation of the informed consent form received by this office. This document is designated as:

Malathion® 8 E
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/4/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

Malathion® 8 E
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverización Neumática [*Airblast*] a las Cosechas, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 4/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
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Signature of Américo Gómez/*Firma de Américo Gómez*

Declaración de Riesgo del Producto
Riesgo de Toxicidad del Producto Pesticida Manipulado
(Debe adjuntarse al Formulario de Consentimiento Informado)

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverización Neumática [*Airblast*] a las Cosechas, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
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c/o David R. Johnson, PhD
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Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIÓN: _____
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Introducción
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Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Gowan Malathion 8 (Registro de EPA № 10163-21)

Ingrediente Activo: Malathion (insecticida, CAS № 121-75-5)

Formulación y Embalaje: 8 lbs. AI/galón Concentrado Emulsionante.

Usted puede manipular hasta: 12,5 galones del producto

APROBADO POR
Independent IRB
Firma
4/marzo/08
Fecha

Iniciales: _____
Fecha: _____

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes a las substancias químicas. Debe quitarse los guantes antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Basándose en la etiqueta más reciente del producto y en la Hoja de Datos de Seguridad del Material (acerca de la cual se hablará con usted y estará a su disposición para que la repase), podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto malathion está clasificado como de baja toxicidad para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación ligera de los ojos y/ó piel, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Identificación de la etiqueta: 04-R0699
Fecha de la MSDS: febrero-1-07 (Gowan Malathion 8 que fluye)

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma del Testigo Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08

Versión: 4/marzo/08
Protocolo: AHE55
Gowan Malathion 8

APROBADO POR
Independent IRB
Firma 4/marzo/08 Fecha

Iniciales: _____
Fecha: _____

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435 NE 23rd Street
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March 12, 2008

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A Quién Corresponda:

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Malathion® 8
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/4/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

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Malathion® 8
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverización Neumática [*Airblast*] a las Cosechas, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
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Signature of Américo Gómez/*Firma de Américo Gómez*

Declaración de Riesgo del Producto
Riesgo de Toxicidad del Producto Pesticida Manipulado
(Debe adjuntarse al Formulario de Consentimiento Informado)

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverización Neumática [*Airblast*] a las Cosechas, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
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Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Insecticida Servin® Brand 4F Carbaryl (Registro de EPA № 264-349)

Ingrediente Activo (AI): Carbaryl (insecticida, CAS № 63-25-2)

Formulación y Embalaje: 4 lbs. AI/galón líquido fluyente en jarras de plástico de 2,5 galones.

Usted puede manipular hasta: 25 galones del producto

APROBADO POR
Independent IRB
Firma 4/marzo/08 Fecha

Iniciales: _____
Fecha: _____

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes a las substancias químicas. Debe quitarse los guantes antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Basándose en la etiqueta más reciente del producto y en la Hoja de Datos de Seguridad del Material (acerca de la cual se hablará con usted y estará a su disposición para que la repase), podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto carbaryl está clasificado como de baja toxicidad para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación ligera de los ojos, irritación mínima de la piel, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Fecha de la etiqueta: septiembre-27-04
Fecha de la MSDS: diciembre-18-02 (№ 000000000194, Versión 2.1)

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma del Testigo Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08

APROBADO POR
Independent IRB
Firma 4/marzo/08 Fecha

Iniciales: _____
Fecha: _____

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 12, 2008

To Whom It May Concern:
A Quién Corresponda:

This is to certify that the attached document from English into Spanish is an accurate representation of the informed consent form received by this office. This document is designated as:

SevinBrand® 4 F
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/4/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

SevinBrand® 4 F
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverización Neumática [*Airblast*] a las Cosechas, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 4/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Américo Gómez, who translated this document, is fluent in Spanish and standard North American English and qualified to translate. He attests to the following:

Américo Gómez, quien tradujo dicho documento, tiene dominio de los idiomas inglés norteamericano y español, y está capacitado para traducir. Él declara lo siguiente:

"To the best of my knowledge, the accompanying text is a true, full and accurate translation of the specified document".
«Según mi leal saber y entender, el texto que sigue a continuación es una traducción fiel y correcta del documento que se adjunta».

Signature of Américo Gómez/*Firma de Américo Gómez*

Declaración de Riesgo del Producto
Riesgo de Toxicidad del Producto Pesticida Manipulado
(Debe adjuntarse al Formulario de Consentimiento Informado)

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverización Neumática [*Airblast*] a las Cosechas, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, PhD
P.O. Box 509
Macon, Missouri 63552

DIRECTOR DEL ESTUDIO: Larry D. Smith, PhD
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Teléfono: 440-255-1954
Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIÓN: _____
_____
_____

Introducción
Usted se ha puesto de acuerdo para participar en el estudio de referencia. El formulario de consentimiento informado que usted firmó, enunciaba que se le informaría verbalmente y por escrito, acerca de cualquier riesgo(s) que podría influir sobre su disposición para participar en el estudio.

Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Insecticida Servin® Brand 80 WSP Carbaryl (Registro de EPA № 264-526)

Ingrediente Activo (AI): Carbaryl (insecticida, CAS № 63-25-2)

Formulación y Embalaje: 80% AI polvo seco en un paquete soluble en agua de 1,25 libras.

Usted puede manipular hasta: 100 paquetes solubles en agua

APROBADO POR
Independent IRB
Firma 4/marzo/08 Fecha

Iniciales: _____
Fecha: _____

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes al agua. Debe quitarse los guantes antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Basándose en la etiqueta más reciente del producto y en la Hoja de Datos de Seguridad del Material (acerca de la cual se hablará con usted y estará a su disposición para que la repase), podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto carbaryl está clasificado como de toxicidad moderada para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación ligera de los ojos, irritación mínima de la piel, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Fecha de la etiqueta: septiembre-23-04
Fecha de la MSDS: diciembre-26-02 (Número 000000001825; Versión 1.1)

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma de la Persona que está dirigiendo la discusión del Formulario de Consentimiento Informado Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08

APROBADO POR
Independent IRB
Firma 4/marzo/08 Fecha

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 12, 2008

To Whom It May Concern:
A Quién Corresponda:

This is to certify that the attached document from English into Spanish is an accurate representation of the informed consent form received by this office. This document is designated as:

SevinBrand® 80 WSP
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/4/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

SevinBrand® 80 WSP
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverización Neumática [*Airblast*] a las Cosechas, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 4/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Américo Gómez, who translated this document, is fluent in Spanish and standard North American English and qualified to translate. He attests to the following:

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"To the best of my knowledge, the accompanying text is a true, full and accurate translation of the specified document".
«Según mi leal saber y entender, el texto que sigue a continuación es una traducción fiel y correcta del documento que se adjunta».

Signature of Américo Gómez/*Firma de Américo Gómez*

Declaración de Riesgo del Producto
Riesgo de Toxicidad del Producto Pesticida Manipulado
(Debe adjuntarse al Formulario de Consentimiento Informado)

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverización Neumática [*Airblast*] a las Cosechas, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, PhD
P.O. Box 509
Macon, Missouri 63552

DIRECTOR DEL ESTUDIO: Larry D. Smith, PhD
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7919 Champaign Dr.
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Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIÓN: _____
_____
_____

Introducción
Usted se ha puesto de acuerdo para participar en el estudio de referencia. El formulario de consentimiento informado que usted firmó, enunciaba que se le informaría verbalmente y por escrito, acerca de cualquier riesgo(s) que podría influir sobre su disposición para participar en el estudio.

Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Insecticida Servin® Brand XLR Plus Carbaryl (Registro de EPA № 264-333)

Ingrediente Activo (AI): Carbaryl (insecticida, CAS № 63-25-2)

Formulación y Embalaje: 4 lbs. AI/galón de líquido fluyente en jarras plásticas de 2,5 galones.

Usted puede manipular hasta: 25 galones del producto

APROBADO POR
Independent IRB
Firma 4/marzo/08 Fecha

Iniciales: _____
Fecha: _____

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes a substancias químicas. Debe quitarse los guantes antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Basándose en la etiqueta más reciente del producto y en la Hoja de Datos de Seguridad del Material (acerca de la cual se hablará con usted y estará a su disposición para que la repase), podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto carbaryl está clasificado como de baja toxicidad para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación ligera de los ojos, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Fecha de la etiqueta: septiembre-21-04
Fecha de la MSDS: enero-17-08 (Bayer MSDS 102000001927; Versión 2.1)

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma de la Persona que está dirigiendo la discusión del Formulario de Consentimiento Informado Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08

APROBADO POR
Independent IRB
Firma 4/marzo/08 Fecha

Iniciales: _____
Fecha: _____

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 12, 2008

To Whom It May Concern:
A Quién Corresponda:

This is to certify that the attached document from English into Spanish is an accurate representation of the informed consent form received by this office. This document is designated as:

SevinBrand® XLR Plus
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/4/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

SevinBrand® XLR Plus
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverización Neumática [*Airblast*] a las Cosechas, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 4/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
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Signature of Américo Gómez/*Firma de Américo Gómez*

LS Consulting

From: Robert Roogow [rroogow@iirb.com]
Sent: Friday, March 07, 2008 3:56 PM
To: lsconsulting@oh.rr.com
Subject: Protocol AHE55
Attachments: Sevin Brand XLR Plus.doc; AHE55.Smith. ICF.doc; Fyfanon 8 lb.doc; Fyfanon.doc; Malathion 8 E.doc; Malathion 8.doc; Sevin Brand 4F.doc; Sevin Brand 80WSP.doc

Larry,

I have attached electronic copies of the consent form and product risk statements with tracked changes. Please let me know if you have any questions or concerns.

Regards,

Robert Roogow, MS, CIM
Director of Operations
Independent Investigational Review Board, Inc.
Ph: 954-327-0778
Fax: 954-327-5778
rroogow@iirb.com

LS Consulting

From: Robert Roogow [rroogow@iirb.com]
Sent: Wednesday, March 12, 2008 11:25 AM
To: lsconsulting@oh.rr.com
Subject: Protocol AHE55
Attachments: 3-4-2008 (AHE55).doc

Dear Larry,

Please find attached the portion of the minutes that pertains to the review of the AHE55 protocol last week. The EPA already has copies of our most current Policies & Procedures and Membership List. Please let me know if you should need anything additional.

Regards,
Robert Roogow, MS, CIM
Director of Operations
Independent Investigational Review Board, Inc.
Ph: 954-327-0778
Fax: 954-327-5778
rroogow@iirb.com

LS Consulting

From: LS Consulting [lsconsulting@oh.rr.com]
Sent: Wednesday, March 12, 2008 12:36 PM
To: 'rroogow@iirb.com'
Subject: RE: Protocol AHE55

Robert,

Thanks, I appreciate the update. We haven't received the approval documents. Would you mind confirming they were sent last Friday and to whom.

Also, please let me know if the new protocol and documents will be reviewed by the board on Thursday.

Regards,

Larry D. Smith, Ph.D.

From: Robert Roogow [mailto:rroogow@iirb.com]
Sent: Wednesday, March 12, 2008 11:25 AM
To: lsconsulting@oh.rr.com
Subject: Protocol AHE55

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Regards,
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Director of Operations
Independent Investigational Review Board, Inc.
Ph: 954-327-0778
Fax: 954-327-5778
rroogow@iirb.com

LS Consulting

From: Robert Roogow [rroogow@iirb.com]
Sent: Wednesday, March 12, 2008 1:45 PM
To: lsconsulting@oh.rr.com
Subject: RE: Protocol AHE55

Larry,

They were sent addressed to you via USPS as per your request on the study set form. I will have Yessenia send you a PDF copy of the documents. We will be sending the AHE56 documents via FedEx so we will be able to track those documents.

Regards,

Robert Roogow, MS, CIM
Director of Operations
Independent Investigational Review Board, Inc.
Ph: 954-327-0778
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Director of Operations
Independent Investigational Review Board, Inc.
Ph: 954-327-0778
Fax: 954-327-5778
rroogow@iirb.com

LS Consulting

From: Yesenia Crespo [ycrespo@iirb.com]
Sent: Wednesday, March 12, 2008 1:54 PM
To: lsconsulting@oh.rr.com
Subject: AHE55
Attachments: smith.pdf; smith-1.pdf

Please see attached the Spanish translations that are being sent out today and the English documents that were sent out on Friday.

Please let me know if I can help you with anything else.

Best Regards,

Yesenia Crespo
Independent Investigational Review Board INC.
6738 West Sunrise Blvd. Suite 102
Plantation, Florida 33313
Tel. (954) 327-0778
Fax. (954) 327-5778
email: ycrespo@iirb.com

LS Consulting

From: LS Consulting [lsconsulting@oh.rr.com]
Sent: Wednesday, March 12, 2008 2:09 PM
To: 'rroogow@iirb.com'
Subject: RE: Protocol AHE55

Robert,

Thanks again for your diligence. I just received Yessenia's email.

Larry

From: Robert Roogow [mailto:rroogow@iirb.com]
Sent: Wednesday, March 12, 2008 1:45 PM
To: lsconsulting@oh.rr.com
Subject: RE: Protocol AHE55

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Director of Operations
Independent Investigational Review Board, Inc.
Ph: 954-327-0778
Fax: 954-327-5778
rroogow@iirb.com

Formatted

RESEARCH INFORMATION AND INFORMED CONSENT FORM

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

Deleted: AHE55

SPONSOR AND SOURCE OF FUNDING:

Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

INTRODUCTION and PURPOSE

You are invited to participate in a research study because you are at least 18 years old and have experience making closed cab airblast applications. For you to participate in this study, you must understand and sign this consent form and a Product Risk Statement that describes the risks from the pesticide. If we have used words or presented information you do not clearly understand, please ask me to explain. You may take home an unsigned copy of this consent form to think about or discuss with family or friends or researchers before making your decision. If you agree to be in this study, you will be given a signed and dated copy of this consent form and the Product Risk Statement.

Deleted: .

The Agricultural Handlers Exposure Task Force (AHETF) was formed by a group of pesticide companies. The purpose of this study is to measure how much pesticide you might get on your skin and breathe in while you spray using closed cab airblast equipment. This will be done by measuring pesticide residues in the samples we collect from you. About 5 people will be monitored in this study. The results of the study will be used to estimate exposure and risks to workers spraying pesticides with closed cab airblast equipment.

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

ELIGIBILITY

1. Experience making closed cab airblast applications in the last year.
2. Provide proof you are at least 18 years old (government-issued photo ID).
3. Confirm you do not work for a pesticide company or a contractor of AHETF.
4. General health status is "good enough to do the work". Tell us whether you have any medical conditions that affect your ability to participate in the study.
5. Pregnant or nursing women cannot participate in the study. If you are female, you must take an over-the-counter urine pregnancy test before the study. This test will be supervised by a female researcher. You do not have to tell anyone if you have a positive test. Results of a negative test must be confirmed by the female researcher or you cannot participate.
6. Confirm that you do not normally wear personal protective equipment in excess of the label requirements for closed cab airblast applications. Confirm that you will follow label directions.
7. Have a private meeting with a researcher to go over this consent form. The purpose is to make sure you understand what you are agreeing to and to have your questions answered. You may have a friend, family member or advisor with you during the meeting. If you are an employee, this person may not be from the operation's management.
8. You must understand English or Spanish.
9. You must understand and sign this consent form and Product Risk Statement.

STUDY DURATION

The duration of your participation in this study is approximately 4-8 hours of one of your normal workdays.

PROCEDURES

If you participate in this study, you will do the following:

1. Provide your name and years of experience making closed cab airblast applications.
2. Confirm whether you have received pesticide safety training or are exempt from pesticide safety training.
3. Allow researchers to measure and record your height and weight.
4. Allow researchers to record your gender, age, and preferred language.
5. Allow study staff to take notes on the discussions during the informed consent session(s).

If you read only Spanish, a Spanish version of the documents will be provided, along with a translator during our meeting. If you have trouble reading these documents in your language of choice (English or Spanish), it will be read to you.

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

PROCEDURES ON THE DAY OF THE STUDY

1. Wash your long-sleeved shirt and long pants before participating in the study to remove any residues of the product we are studying.
2. Bathe or shower the evening or morning before participating in the study to remove any residues of the product we are studying.
3. Wear all personal protection equipment required by the product label (see Product Risk Statement).
4. Work about 4 to 8 hours applying a commercial pesticide according to your normal practices and spray at least 3 loads.
5. Wear new long underwear underneath your long-sleeved shirt and long pants. Wear your choice of personal undergarments under the long underwear. The long underwear will be supplied by AHETF and collected at the end of the day. You will be asked to dress and undress with the assistance of a researcher of the same sex. A changing area will be provided for privacy. When you complete your participation, you will put on your own clothes and return to your normal work.
6. Have a tube attached to your shirt collar and connected to a portable air-sampling pump on a belt worn around your waist. The pump is small and light about the size of a portable radio.
7. Have your face and neck wiped with gauze pads moistened with a mild detergent and water mixture. This will be done before you eat anything, any time you would normally wash your face, and at the end of the day.
8. Have your hands washed in a mild detergent and water mixture. This will be done before you eat anything, any time you would normally wash your hands (such as when you use the toilet), and at the end of the day.
9. Allow researchers to watch all of your work activities and take notes on what you do.
10. Allow photographs and video recordings to be taken. You will not be photographed or video recorded while dressing or undressing. AHETF will own all rights to the photos and videos and may use them for any purpose. **If you do not want to be photographed or recorded you should not participate in this study.**

Deleted: <#>With the long underwear, you have a risk of becoming overheated and suffering heat illness.¶

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This may be uncomfortable or annoying.

Deleted: <#>There is a risk of eye or skin irritation from the detergent and water.¶

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Deleted: <#>There is a risk of skin irritation from the detergent and water.¶

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PRODUCTS HANDLED

You will be asked to handle a pesticide product that is registered by the US Environmental Protection Agency (EPA) and approved for spraying citrus with airblast equipment. A variety of pesticide active ingredients might be used and farm management will select the product. However, you will know what product you will handle before you are asked to sign this consent form.

In addition to the pesticide you will spray, farm management may require tank-mixes with other registered or approved products according to label directions. You will be told before your participation which materials will be in the tank mix. We will have no

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Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

knowledge of any risks to you other than those provided to you on the tank-mix product labels.

RISKS AND DISCOMFORTS

In this study you will have the usual risks of handling the spray equipment. You will only use equipment you have experience operating.

You will be asked to sign a separate document, called the Product Risk Statement, that identifies the product you will spray, indicates how much of that product you might handle, and specifies the risks of handling that product. It also describes what personal protection equipment you must wear.

You will review the product label with the research staff to identify the airblast use directions and precautions. From the label, and Product Risk Statement, you will learn of any possible side-effects (such as skin irritation) and the signs and symptoms of overexposure. If you feel any of the signs or symptoms during or after the workday, or do not feel well for any reason, notify a researcher immediately. A copy of the product Material Safety Data Sheet (MSDS), is available for your review and discussion any time you desire.

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Deleted: Otherwise, there are no reasonably foreseeable harmful effects related to handling the test products or tank-mixed products.

Because you will wear long underwear underneath your normal work clothing, you have a risk of becoming sick from being too hot. This is known as heat stress or heat illness and can be serious or life threatening. Early signs and symptoms include feeling overheated, tired, dizzy, irritable, and having decreased concentration. If you feel any of these signs or symptoms during or after the workday notify a researcher immediately. If you don't feel well for any reason, notify a researcher immediately. You will be observed by a researcher watching for these symptoms. AHETF will stop your work if the weather gets too hot.

As a precaution, AHETF will have a paramedic, physician's assistant, nurse, or emergency medical technician on site during the study. If needed, this professional will also observe you for signs of illness and will provide medical attention.

You may have other risks or discomforts, including:

- Eye or skin irritation from the detergent and water mixture
- Discomfort from wearing a portable air sampling pump around your waist
- Being embarrassed during dressing and undressing
- Being concerned about taking an over-the-counter pregnancy test
- Working longer than normal because of the time it takes for sample collection

There may be other risks that are unknown at this time. You will be told in a timely manner both verbally and in writing of any new information that might change your decision to be in the study.

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Signature Date

Initials: _____
Date: _____

INJURY TO PARTICIPANT

If you are injured or get sick during or after the workday, medical treatment will be available at your workplace and at a nearby health care facility. If necessary, AHETF will arrange transportation for you to receive medical attention. You may refuse medical treatment unless you get sick from too much pesticide exposure or from getting too hot, or if we believe you are too sick to make a rational decision about receiving medical treatment. AHETF will cover the cost of reasonable and appropriate medical attention that is not covered by your own insurance or insurance provided through your employer. Treatment records will not become part of the research records for this study. However, AHETF will make note of the event and this will be reported in the study report. For further information about this, you may call the AHETF Manager (David Johnson) at 660-349-4601.

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Deleted: (David Johnson)

You will not give up any of your legal rights by signing this form.

CONFIDENTIALITY

Your name will appear on the consent form, the Product Risk Statement, and an optional form for you to request your personal study results. All other study information will identify you only by a unique code. Records with your name will be stored in a secure, limited access archive.

Information about your participation in this study will not be given to your employer.

A study report will be written by AHETF and will be available to member companies. It will be sent to the US Environmental Protection Agency (EPA). It may also be sent to state government agencies and to governments of other countries. Your name will not be included in any study report.

We cannot promise you absolute confidentiality because of the need to give information to some organizations or to parties in legal actions, as required by law. All study information, including records which identify you, may be looked at or copied by the sponsor and any consultants working with the sponsor, by EPA or other government agencies, and by the Independent Investigational Review Board, Inc. (IIRB). IIRB is a group of people who review and monitor research to make sure the people who participate in it are protected.

You may ask the Study Director for a copy of your personal results from this study. You will need to provide your name and a mail or e-mail address.

COSTS

There will be no costs to you for participation in this study.

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Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

BENEFITS
You will not directly benefit from your participation in the study. The farm owner may benefit from the product used in the study since AHETF will reimburse the owner for that product. Information from this study will be used to improve the quality of pesticide safety assessments for workers using closed cab airblast equipment.

PAYMENT FOR PARTICIPATION
You will be paid $20 if you meet privately with a researcher to review this informed consent. You will receive the money whether you decide to participate or not. You will receive the money in cash right after the meeting.

You will be paid an additional $80 for the day you participate in sampling. You will be paid $80 for completing the sampling day and allowing us to collect your samples. If you decide to withdraw during the sampling, you will still be paid the $80. If we remove you from the study, you will still receive the $80. Payment will be in cash at the end of the sampling day.

You will also receive your normal pay from your employer.

If more people volunteer than we need, some participants may be selected randomly (for example, by lottery). You may or may not be selected. If not selected, you will not receive the $80.

VOLUNTARY PARTICIPATION / WITHDRAWAL
Your employer has agreed to let us do the research and has confirmed he/she does not encourage or discourage you to participate in this study. Your decision to be in this study is voluntary and entirely up to you. If you decide to participate, you may change your mind later and drop out of the study at any time and for any reason. A decision not to participate, or to withdraw from the study after it begins, will have no effect on your job or pay or include any penalty or any loss of benefits to which you may be entitled.

If you withdraw, the long underwear and air sampling pump will be removed, and the hand and face/neck samples may be collected with your consent.

Your participation in this study may be stopped at any time by the researchers or the sponsor. The long underwear and air sampling pump will be removed, and the hand and face/neck samples may be collected with your consent.

If you withdraw or are removed from the study, or if the study does not last an entire workday, you will be released to resume your usual activities.

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Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

ALTERNATIVES

No one can require you to participate in this study. Participation is entirely voluntary. If you choose not to participate in this study, then on the day of the study you will perform your ordinary activities. You alternative is to not participate.

QUESTIONS

If you have questions about this study or if at any time you think you have a research-related injury or illness, contact a researcher or call:

Larry D. Smith (Study Director) at 440-255-1954 (collect)
Or 440-554-2812 (24 hours)
Or
David Johnson, Ph.D. (sponsor contact) at 660-349-4601.

If you have any questions regarding your rights as a research volunteer, please contact Kim Lerner, Chairman of the Independent Investigational Review Board, Inc. at toll free (877) 888-iirb (4472) during regular working hours. The Independent Investigational Review Board is a committee established for the purpose of protecting the rights of volunteers in a research study.

Deleted: If you have questions about your rights as a research subject, you may contact:¶
¶

Deleted: Independent Investigational Review Board (IIRB)¶
6738 West Sunrise Blvd. Suite 102¶
Plantation, Florida 33313¶
Telephone: 954-327-0778¶
E-mail: info@IIRB.com¶

IIRB is a group of people who perform independent review of research.

Do not sign this consent form unless you were able to ask questions and received satisfactory answers.

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

CONSENT

I have read the information in this consent form and in the Product Risk Statement (or it has been read to me) in a language I understand well. All my questions about the study and about being in it have been answered. I freely consent to be in this study.

I authorize the release of my research records, including photographs and video recordings, to the sponsor, to the researchers, to government agencies in other states and/or countries, to EPA, to IIRB, and to other parties as required by law.

By signing this consent form, I have not given up any of my legal rights.

_____ _____
Date Subject's Name (print)

_____
Subject's Signature

_____
Subject's Unique Worker Code

I conducted the private consent meeting with the worker named above and confirm that consent was given voluntarily after being fully informed of the benefits, risks, and procedures. In addition, this worker has reviewed and signed the Product Risk Statement which I will store along with this signed consent form in a secure location:

_____ _____
Date Name of Person Conducting Informed Consent Discussion (print)

_____
Signature of Person Conducting Informed Consent Discussion

_____
Title and Affiliation of Person Conducting Informed Consent Discussion

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Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

---------- Use the following only if applicable ----------

If this consent form is read to the worker because the worker is unable to read the form, an impartial witness (who is not associated with the researchers or who is not part of the management of the grower where the study is being conducted) must be present to witness this worker's consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and understood by, this worker. This worker freely consented to participate in the research study.

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_____ _____
Date Impartial Witness' Name (print)

_____
Impartial Witness' Signature

_____
Title and Affiliation of Impartial Witness

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not read English.

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

Deleted: Product-Specific Risk Statement¶
(Must be attached to the Informed Consent Form)¶

Deleted: AHE55

SPONSOR AND SOURCE OF FUNDING:

Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction

You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

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This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

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Deleted: Informed Consent Form Addendum

The product you will handle is identified as follows:

Name: Sevin® Brand 80WSP Carbaryl Insecticide (EPA Registration No. 264-526)

Active Ingredient (AI): Carbaryl (insecticide, CAS No. 63-25-2)

Formulation and Packaging: 80% AI dry powder in a 1.25 lb water soluble pack

You may handle up to: 100 water soluble packs

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Independent IRB

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Signature Date

Initials: _____
Date: _____

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Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear waterproof gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

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User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This carbaryl product is classified as moderate toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye irritation, minimal skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 9/23/04
MSDS date: 12/26/02 (number 000000001825; Version 1.1)

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

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APPROVED BY
Independent IRB
_____ 3/4/08
Signature Date

Initials: _____
Date: _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

Deleted: Product-Specific Risk Statement¶
(Must be attached to the Informed Consent Form)¶

Deleted: AHE55

SPONSOR AND SOURCE OF FUNDING:

Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
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Introduction

You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

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This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

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The product you will handle is identified as follows:

Name: Sevin® Brand 4F Carbaryl Insecticide (EPA Registration No. 264-349)

Active Ingredient (AI): Carbaryl (insecticide, CAS No. 63-25-2)

Formulation and Packaging: 4 lb AI/gallon Flowable liquid in 2.5 gallon plastic jugs

You may handle up to: 25 gallons of product

APPROVED BY
Independent IRB

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Signature **Date**

Initials: _____
Date: _____

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Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

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User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This carbaryl product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye irritation, minimal skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 9/27/04
MSDS date: 12/18/02 (No. 000000000194, Version 2.1)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

APPROVED BY
Independent IRB
_____ 3/4/08
Signature Date

Initials: _____
Date: _____

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Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR: Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Malathion 8-E Insecticide (EPA Registration No. 34704-452)

Active Ingredient (AI): Malathion (insecticide, CAS No. 121-75-5)

Formulation and Packaging: 8 lbs AI/gallon Emulsifiable Concentrate in 1 gallon plastic jugs

APPROVED BY
Independent IRB
_____ 3/4/08
Signature Date

Initials: _____
Date: _____

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You may handle up to: 12.5 gallons of product

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This malathion product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include moderate eye irritation, slight skin irritation, possible allergic skin reaction, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: None found
MSDS date: 6/8/06 (Loveland MSDS #000452-06-LPI)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

Version: 3/4/08
Protocol: AHE55
Malathion 8-E

APPROVED BY
Independent IRB
_____ 3/4/08
Signature Date

Initials: _____
Date: _____

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Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR: Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
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Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Gowan Malathion 8 (EPA Registration No. 10163-21)

Active Ingredient: Malathion (insecticide, CAS No. 121-75-5)

Formulation and Packaging: 8 lbs AI/gallon Emulsifiable Concentrate

You may handle up to: 12.5 gallons of product

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Independent IRB

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Signature Date

Initials: _____
Date: _____

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

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User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This malathion product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye and/or skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label ID: 04-R0699
MSDS date: 2/1/07 (Gowan Malathion 8 Flowable)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

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APPROVED BY
Independent IRB
_____ 3/4/08
Signature Date

Initials: _____
Date: _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

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SPONSOR AND SOURCE OF FUNDING:

Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
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Introduction

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This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

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The product you will handle is identified as follows:

Name: Fyfanon® 8 lb. Emulsion (EPA Registration No. 5905-250-ZA)

Active Ingredient (AI): Malathion (insecticide, CAS No. 00121-75-5)

Formulation and Packaging: 8 lbs AI/gallon Emulsifiable Concentrate in 1 or 2.5 gallon plastic jugs

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

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You may handle up to: 12.5 gallons of product

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Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This malathion product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include moderate eye irritation, slight skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 2005
MSDS date: 1-5-05

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

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Version: 3/4/08
Protocol: AHE55
Fyfanon® 8 lb. Emulsion

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR: Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
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Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
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Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Fyfanon® (EPA Registration No. 5905-196)

Active Ingredient (AI): Malathion (insecticide, CAS No. 00121-75-5)

Formulation and Packaging: 5 lbs AI/gallon Emulsifiable Concentrate

You may handle up to: 20 gallons of product

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves and protective eyewear. The gloves and protective eyewear must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This malathion product is classified as moderate toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include moderate eye irritation, slight skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 2005 MSDS date: 10-5-05

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

Version: 3/4/08
Protocol: AHE55
Fyfanon®

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus

Deleted: Product-Specific Risk Statement¶
(Must be attached to the Informed Consent Form)¶

Deleted: AHE55

SPONSOR AND SOURCE OF FUNDING:

Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction

You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

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This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

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The product you will handle is identified as follows:

Name: Sevin® Brand XLR Plus Carbaryl Insecticide (EPA Registration No. 264-333)

Active Ingredient (AI): Carbaryl (insecticide, CAS No. 63-25-2)

Formulation and Packaging: 4 lb AI/gallon Flowable liquid in 2.5 gallon plastic jugs

You may handle up to: 25 gallons of product

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

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Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), the following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This carbaryl product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye irritation and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 9/21/04
MSDS date: 1/17/08 (Bayer MSDS 102000001927, Version 2.1)

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

Version: 3/4/08
Protocol: AHE55
Sevin® Brand XLR

APPROVED BY
Independent IRB
_____ 3/4/08
Signature Date

Initials: _____
Date: _____

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Volume VIII, Part C:

Protocol Revisions Submitted 3-21-08 and 3-24-08

LS Consulting

From: LS Consulting [lsconsulting@oh.rr.com]
Sent: Friday, March 21, 2008 10:32 AM
To: 'rroogow@iirb.com'
Subject: AHETF Request IIRB Review AHE55 Document Amendments
Importance: High
Attachments: AHE55 Proposed Amendments.zip

Robert,

I have attached amended documents for which AHETF is seeking IIRB review and approval. The documents are presented with MS Word tracked changes and changes accepted for your convenience. The documents include the following which were approved on 3-4-2008:

AHE55 Protocol 2-27-2008
AHE55.Smith.ICF
Fyfanon 8 lb PRS Amendments 3-20-2008
Fyfanon PRS Amendments 3-20-2008
Malathion 8 E PRS Amendments 3-20-2008
Malathion 8 PRS Amendments 3-20-2008
Sevin Brand 4F PRS Amendments 3-20-2008
Sevin Brand 80WSP PRS Amendments 3-20-2008
Sevin Brand XLR Plus PRS Amendments 3-20-2008

The amendments are the result of an EPA review and represent an effort to clarify the AHETF exposure monitoring program prior to submission to the HSRB. The changes are minor and do not reflect changes of the intent of the original documents. Nor do the changes reflect any additional risks to the study participants.

Since amendments are requested for the ICF and the Product Risk Statements, AHETF is requesting IIRB arrange Spanish translation of these documents.

AHETF has very urgent deadlines and hopes to have these amendments reviewed and approved at the IIRB meeting of 3/25/2008. Please, call me if you anticipate any delay or have any questions.

Regards,

Larry

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, OH 44060
440/255-1954

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AGRICULTURAL HANDLERS EXPOSURE TASK FORCE (AHETF)

STUDY No. AHE55

Study Title: Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

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PROTOCOL AUTHORIZATION

Read and Approved by:

AHETF Sponsor Representative: David R. Johnson, Ph.D.

Signature _____

Date _____

Study Director: Larry D. Smith, Ph.D.

Signature _____

Date _____

TABLE OF CONTENTS

1.0 GENERAL INFORMATION

1.1 Study Title

Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

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1.2 Study No. AHE55

1.3 Objective

The objective of this study is to develop data to determine the potential exposure for workers making closed cab airblast applications in Florida citrus.

1.4 Timeline

Proposed Experimental Start Date: August, 2008

Proposed Experimental Termination (Field Phase) Date: April, 2009

Proposed Experimental Termination (Analytical Phase) Date: October, 2009

Proposed Final Report Issue Date: December, 2009

1.5 Good Laboratory Practice

This study will be conducted in compliance with the US EPA FIFRA Good Laboratory Practice (GLP) Standards (40 CFR 160) and will adhere to applicable AHETF and/or field facility standard operating procedures (SOPs) and field work practices.

1.6 Pesticide Assessment Guideline

This study is based upon EPA's guidance documents for dermal and inhalation exposure measurement under Series 875: Occupational and Residential Exposure Test Guidelines. Data reporting will follow the requirements defined in these guidelines.

1.7 Institutional Review Board

Independent Investigational Review Board Inc. (IIRB)
6738 West Sunrise Blvd. Suite 102
Plantation, FL 33313
Telephone: 954-327-0778
E-mail: info@IIRB.com

1.8 Testing Facility, Sponsor's Representative and Sponsor

Agricultural Handlers Exposure Task Force, LLC
c/o David R. Johnson, Ph.D.
1720 Prospect Dr.
Macon, MO 63552
(660) 395-9590
davejohn@marktwain.net

1.9 Study Director

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, OH 44060
(440) 255-1954
lsconsulting@oh.rr.com

1.10 Principal Field Investigators

Principal Field Investigators may include:

Brian Lange
Access Research and Consulting, Inc.
4720 W. Jennifer Ave., Suite 106
Fresno, CA 93722
Phone: 559-277-5272
brian@accessrc.com

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Tami Belcher
Grayson Research, LLC
1040 Grayson Farm Road
Creedmoor, NC 27522
Phone: 919-528-5508
tbelcher@graysonfarm.com

Aaron Rotondaro
Paragon Research Services, Inc.
6773 Woodcliff Circle

Zionsville, IN 46077
Phone: 317-733-1243
arotondaro@indy.rr.com

During the consent process, each study participant will be informed of which of the above researchers will be involved with monitoring his/her exposure.

1.11 Field Facilities

Southeast Ag Research
86 Jim Moore Rd.
Chula, GA 31733
Phone: 229-386-8989
smith@seagr.com

1.12 Principal Analytical Investigator and Analytical Facility

To be determined and amended to the protocol prior to initiation of the field phase of the study.

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1.15 Quality Assurance Unit

Compliance Assessment and Training, Inc.
Randy Fuller
2309 Patton Ct.
Lexington, KY 40509
Phone: 859-264-8844
randyfuller@windstream.net

2.0 ETHICAL CONSIDERATIONS

This study will be conducted in accordance with EPA's final regulation published at 40 CFR Part 26 that establishes requirements for the protection of subjects in human research. The protocol, informed consent form, and other required documentation for this study will be approved by an institutional review board (IRB) and submitted to the EPA as required by 40 CFR 26.1125. The report of the completed research is subject to 40 CFR 26.1303 requirements to document its ethical conduct.

The proposed research described by this protocol, the informed consent form, and all recruitment materials, such as handouts or visual aids, shall be reviewed and approved by Independent Investigational Review Board Inc. (IIRB) of Plantation, Florida. Complete records of the IRB review as required by 40 CFR 26.1125 will be submitted to EPA for review along with this protocol and other documents.

Researchers that participate in the study and interact with study participants must undergo ethics training (SOP AHETF-1.B). The training shall include successful completion of the course from the National Institutes of Health (NIH; Human Participant Protections Education for Research Teams) and/or the Basic Collaborative IRB Training Initiative Course (CITI; The Protection of Human Research Subjects). Copies of the certificates of completion for the ethics courses will be submitted to the IRB and stored in the respective personnel files (maintained by the AHETF and all contract facilities.)

2.1 Inclusion and Exclusion Criteria

AHETF has established the following inclusion and exclusion criteria for this closed cab airblast application study.

Participants in this study must meet the following inclusion criteria;

- Be freely willing to participate and to understand and sign the consent form
- Handle pesticides as part of their job
- Be trained in safe pesticide handling practices in accordance with the Worker Protection Standard (WPS), or be exempt from such training
- Have experience within the past year with making airblast applications to citrus using closed cab tractors and airblast sprayers (including the particular equipment to be used)
- Be at least 18 years old with a government-issued ID to verify age
- Consider themselves to be in good general health with no medical conditions that could impact their ability to participate in the study
- Be willing to follow all label and WPS requirements

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In addition, potential subjects who meet the following exclusion criteria will not be allowed to participate in this study:

- Are pregnant females
- Are nursing mothers
- Normally wear personal protective equipment (PPE) that is not required by the label, such as chemical-resistant clothing
- Don't understand Spanish or English
- Are employed by a pesticide manufacturer or a contractor to AHETF (except employees of the Local Site Coordinator)

2.2 Remuneration of Subjects

During recruitment, workers will be offered an opportunity to take part in a group meeting with the Study Director or other designated member of the study team (but without the workers' supervisors) to learn about participating

in this study (Section 6.2). No remuneration is offered for this introductory meeting. Workers who are still interested will attend a private meeting with a researcher who will obtain the informed consent of the worker (Section 2.7). Workers will be paid $20 for their attendance right after the consent meeting, whether or not they decide to participate in the study. Workers who decide to participate in the study will be paid an additional $80 each time they suit up (i.e., put on the long underwear) to participate in the study. Usually, workers will participate in the study on only one day unless their participation is terminated due to weather or other unexpected occurrences. The additional $80 is provided in cash at the end of the monitoring period or at the time the volunteer withdraws from the study. All workers who participate will receive the payment, even if they withdraw or their participation is terminated by the study team.

2.3 Risks to Subjects

Six kinds of risks are associated with the conduct of the current exposure monitoring study. These are:

- The risk of heat-related illness
- The risk of exposure to surrogate chemicals
- The risk associated with scripting of field activities
- Psychological risks
- The risk of exposure to detergents
- The background risk of injury associated with agricultural work

In this study risks to subjects are classified as "greater than minimal", primarily since agricultural work is considered a high risk occupation where the likelihood of harm or discomfort is greater than what is encountered in ordinary daily life. In particular, this study involves the operation of tractors and airblast sprayers which present risks of accidents and physical injury, as well as the use of chemicals (pesticides, fertilizers, additives, etc.) which presents a risk of adverse health effects. In addition, AHETF believes the risk of heat-related illness (resulting from wearing an extra layer of clothing to trap chemical) will be increased due to study participation. AHETF has adopted an extensive program to minimize these risks. All of the risk minimization procedures, as described in AHETF SOPs, will be followed during the conduct of the study.

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2.3.1 Risk of Heat-Related Illness

This study involves the application of liquid sprays to citrus crops using airblast equipment and tractors with a closed cab. All airblast applications will be made outdoors and some locations and dates are likely to result in hot and/or humid conditions. AHETF expects most tractors to be air conditioned, thus reducing the potential for heat-

related illness. AHETF will not accept tractors without properly operating air conditioners. Researchers will inquire of the participants whether or not the air conditioner units function in their tractors. All participants in the study will be wearing an extra layer of clothing (i.e., long underwear under their WPS-required clothing) that they would not normally wear under such conditions. For these reasons, the study will likely involve an increased risk of heat-related illness due to study participation. AHETF researchers will therefore be vigilant in following the extensive educational and monitoring procedures designed to minimize the risk of heat-related illness that are detailed in SOP AHETF-11.G.

Since heat-related illness may occur during the conduct of the study, Study Directors shall have first aid training that includes recognition of signs and symptoms of heat-related illness. A copy of the certificate of completion of this training will be included in the Study Director's personnel file, maintained by the AHETF.

The following procedures will be followed by researchers to minimize the risk of heat-related illness in study participants:

- Ensure plenty of water and sports drinks are available for the workers.
- During worker orientation immediately before participation in the study, remind the workers of the risk of heat stress, suggest they drink some water before they start work, and let them know how/where they can get water during the monitoring period.
- Urge workers to drink water during the monitoring period and remind them that thirst does not give a good indication of how much water a person needs to drink.
- Observe workers during the monitoring period and be aware of the signs and symptoms of heat-related illness.
- Require workers to take rest breaks when early signs or symptoms of heat illness are present.
- Monitor the heat index (based on air temperature and relative humidity) at least hourly whenever ambient temperature is at or above 70 ºF.
- In cases where the worker has exited the air conditioned cab for a period exceeding 30 minutes, stop the worker activity when the heat index (adjusted for direct sunlight, if applicable) reaches 120^{0}F and/or move the worker to a cooler environment until monitoring can be resumed.
- Have a medical professional on site to observe for signs of heat-related illness
- Know the location of the nearest medical facility

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AHETF anticipates that applicators who participate in the study will spend the bulk of their time in the closed cab tractor; driving the tractor and making applications. This is a "sedentary" activity as defined by the North American Free Trade Association (NAFTA) Technical Working Group on pesticides (1998), so physical exertion is low which will reduce the likelihood of heat-related illness. However, each participant will be required to spray at least three loads of pesticide spray, so there will also be some time spent at a mixing/loading site waiting while another (non-study) worker prepares the next load. During these times, the study participant may exit the cab and be exposed to ambient temperatures and humidity which will increase the likelihood of heat-related illness. Applicators may also exit the cab periodically to adjust or repair equipment, if that becomes necessary.

Since workers may exit the cab, AHETF will monitor ambient conditions outside the cab to determine the heat index and base monitoring decisions on the external heat index. A heat index of 120°F is the cutoff, as measured outside the cab. When the worker is inside an air conditioned closed cab the external heat index will not be applicable to that subject and exposure monitoring will not necessarily stop if the heat index cutoff is reached or exceeded. A worker will be allowed to exit the cab for short periods of time even if the heat index cutoff is exceeded; however, if the duration of exiting becomes prolonged (more than 30 minutes), the Study Director or other researcher shall stop the monitoring and/or move the worker to a cooler environment until monitoring can be resumed. For example, a worker who exits an air conditioned cab to adjust the airblast sprayer (e.g., nozzles, deflectors, pressure, etc.) might spend only a few minutes doing so and monitoring would not need to be stopped. On the other hand, if a worker exits to make a repair of the equipment, and it takes more than a half-hour, researchers will stop the monitoring and/or require the worker to move into a cooler environment (e.g., back into the air conditioned cab or into a cooler building).

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In addition to the procedures discussed above, it is possible that some monitoring will take place at night or early in the morning to avoid excessively hot and humid conditions. Discussions with orchard airblast applicators in Florida and Georgia (July, 2007) indicate this is often preferred by workers since winds tend to be lower than during the day and temperatures tend to be cooler. AHETF will encourage this practice when daytime conditions are expected to approach the heat index cutoff of 120º F (adjusted for direct sun, if applicable).

2.3.2 Risk of Exposure to Surrogate Chemicals

The short duration of study participation for a subject (generally only one day) limits the risk of toxicity from surrogate chemicals to acute toxic effects (i.e., the potential for chronic effects is negligible). The active ingredients proposed for use in this study have been reviewed to determine the relative acute toxicity risks and status of reregistration at EPA. This study could involve either of two active ingredients: carbaryl or malathion.

The pesticide products containing these active ingredients and potentially used in this study are currently registered for airblast applications to citrus crops. AHETF will only monitor workers making applications in accordance with all label and Worker Protection Standard (WPS) requirements. Margins of Exposure (MOEs) are presented below for the highest amount of active ingredient that will be handled in this scenario (100 lb ai/day). For each of the active ingredients that may be used in this scenario the calculated MOEs greatly exceeded the required MOE for both the individual dermal and inhalation routes of exposure, as well as for the combined exposure, and their use is acceptable for this scenario.

Margins of Exposure for Closed-cab Airblast Application:

	Carbaryl	Malathion
Max. Daily Amount Handled	100 lb ai/day	100 lb ai/A
Dermal MOE	**3,308**	**4,885**
Inhalation MOE	**1,719**	**40,313**
Combined MOE	**1,130**	**4,400**

Level of concern (LOC) dermal = 100
LOC inhalation = 100 (carbaryl) or 1000 (malathion)
LOC combined = 100

The potential surrogates are listed below. All include minimal PPE requirements, especially the need for only a single layer of clothing. A summary of the signs and symptoms of acute overexposure to these products is presented in the following table. Additional detailed information is presented in the Product Risk Statements for these products (attached to the Informed Consent Form).

Product	Signal Word	Acute Toxicity Summary
Sevin® brand 80WSP Carbaryl Insecticide	CAUTION	• Slight eye irritation • Low toxicity for oral, dermal, and inhalation routes • Cholinesterase inhibition
Sevin® brand XLR Plus Carbaryl Insecticide	CAUTION	
Sevin® brand 4F Carbaryl Insecticide	CAUTION	
Fyfanon® 8 lb. Emulsion	CAUTION	• Moderate skin irritation • Moderate eye irritation • Possible allergic skin reactions • Low toxicity for oral, dermal, and inhalation routes • Cholinesterase inhibition
Fyfanon®	CAUTION	
Malathion 8-E	CAUTION	• Moderate eye irritation • Slight skin irritation • Possible allergic skin reaction • Low toxicity for oral, dermal, and inhalation routes • Cholinesterase inhibition
Gowan Malathion 8 Flowable	CAUTION	

AHETF will make an effort to select growers who would normally be using one of these products regardless of their participation in the monitoring study. However, some growers might agree to use one of the listed surrogate products as a substitute for their usual product. In all cases, AHETF will ensure the workers are informed of the risks associated with the specific surrogate product during the informed consent process and prior to participation by reviewing the product label with the worker. In addition, attached to the informed consent form will be a Product Risk Statement that details the signs and symptoms of overexposure for the specific product that each worker will handle. This risk statement must be understood and signed by the subject during the consent process.

The risk of acute toxicity will be minimized by reminding workers of safe handling practices prior to participation in the study, ensuring that worker clothing meets WPS requirements prior to participation, and enforcing the use of label-specified PPE (especially the use of gloves outside the cab if contacting contaminated surfaces) during participation.

For this application study, participants will only be exposed to product that has been diluted in water. The closed cab will likely provide significant protection from both dermal and inhalation exposure. In

addition, dermal exposure potential will be reduced since the long underwear will intercept chemical that might otherwise reach the subject's skin. Therefore, the likelihood of acute overexposure to the test substance during this study is expected to be very low.

2.3.3 Risk Associated with Scripting of Field Activities

AHETF may script certain participant activities to achieve diversity in some factors that might have an impact on exposure potential for a scenario. In particular, for this closed cab airblast application study scripting may be needed to ensure that at least three loads are handled or that certain amounts of active ingredient are handled. However, workers will not be asked to use equipment they do not have recent experience with (i.e., within the past year).

In order to ensure all MUs involve handling at least three loads, AHETF may ask some workers to use a smaller tank size or a higher spray volume than they would normally select. This might lead to a slightly longer work period for those workers which may increase the risks of acute toxicity to the surrogate chemical and of heat-related illness. This type of scripting is only likely for MUs involving the lower amounts of active ingredient handled (AaiH) in the study, such as 5 to 9 or 10 to 17 pounds of AaiH (Section 7.8). If spray volume is increased, the worker's exposure would be to a more dilute spray solution. The increased work period might increase the risk of heat-related illness, but this scripting is likely to result in work periods of only about 4 hours. In summary, scripting to ensure at least three loads are handled involves MUs with relatively low chemical exposure and relatively short work days, so this type of scripting is not likely to result in increased risk.

In order to achieve diversity in AaiH at the high end, AHETF may ask some workers to use larger tank sizes or a lower spray volume per acre than they would normally select. These changes might result in longer work periods and greater chemical exposure than would otherwise occur and this may increase the risks of acute toxicity to the surrogate chemical or heat-related illness. With regard to the increased risk of heat-related illness, this will primarily depend on local environmental conditions. For these MUs, researchers must be extra vigilant in following the guidance discussed above for minimizing the risks of chemical exposure and heat-related illness.

Deleted: Therefore, AHETF believes the risk of chemical toxicity for this study is low relative to other approved label uses.

2.3.4 Psychological Risks

Participating in AHETF exposure monitoring studies involves activities that are unusual and might cause subjects psychological

distress. These include:

- Performing an over-the-counter pregnancy test prior to participation (females only)
- Allowing a researcher to assist with removing long underwear

Minimizing the risk of psychological harm related to pregnancy tests involves providing a private place for women to take the test and following procedures outlined in SOP AHETF-11.D to ensure the confidentiality of a positive result. Minimizing the risk of embarrassment during undressing involves providing a private dressing area and ensuring a worker of the same gender will be available to assist in the process.

2.3.4 Risk of Exposure to Detergents During Face/Neck Wipe and Hand Wash Sampling

A very dilute detergent solution (0.01% v/v Aerosol® OT in water) is used as a surfactant for face/neck wipes and hand washes for all MUs. The only variation between MUs is in the duration of exposure since longer work periods or frequent eating breaks can lead to multiple hand washes and/or face/neck wipes. This surfactant is in a very dilute solution and its use represents a very short exposure period, but the undiluted surfactant causes mild to moderate skin and eye irritation in animals. This risk is minimized by making fresh solutions shortly before monitoring, being careful to avoid accidental exposure to the eyes during face/neck wipes, and having an eye rinse station on hand in case of an accidental exposure.

A long history of using this mild detergent solution in pesticide exposure monitoring studies indicates the likelihood of skin or eye irritation is negligible.

2.3.5 Background Risk of Injury Associated with Agricultural Work

Agriculture remains one of the country's most dangerous occupations (i.e., farm occupations, see Bureau of Labor Statistics). It perennially ranks in the top ten occupations measured by fatality rate (on-the-job deaths divided by total number of workers) or injury/illness rate. The most common risks for serious injury to farmers are vehicular accidents (especially tractor rollovers, but also accidents while driving machinery on roads) and entanglement with moving parts of farm machinery. Farm workers are also commonly exposed to a variety of chemical products that present increased risks compared to the general public. These include pesticides, fertilizers, solvents, lubricants, fuels,

etc.

For this closed cab airblast application study, the risk of injury will involve the use of mechanical equipment for all MUs (the tractor as well as the airblast sprayer) and for some MUs will likely involve the use of chemicals in addition to the AHETF surrogate chemical, such as spray adjuvants or other pesticide products. These risks are discussed below.

This study will require workers to utilize two pieces of equipment: a closed cab tractor and an airblast sprayer. AHETF will have very little input on the choice of equipment that workers utilize during exposure monitoring since it is generally dictated by the crop involved and the size of the farm or operation. However, AHETF will require that all participants have experience operating the particular equipment they will utilize in the study. Workers will operate their usual tractor unless researchers determine the closed cab is not intact. If that happens, the worker can use another suitable tractor with which he has experience. Workers will use their usual sprayer unless AHETF requests a different tank size. If that happens, the worker can use a more suitable sprayer with which he has experience, but if no such sprayer is available another worker will be selected who has the necessary experience with that equipment. These practices are designed to ensure the risk of injury from equipment is not increased by asking a worker to use equipment he is not familiar with.

Growers often choose to include chemicals other than the pesticide product in their tank mixes, such as anti-foam agents, spreaders, stickers, other pesticides, or fertilizers. This is likely to be the case during this study, but it is impossible to know in advance, since some decisions are made at the last moment depending on agronomic conditions. AHETF will allow the use of such tank mix "partners" so long as they are legal uses, don't interfere with chemical analysis of the AHETF surrogate pesticide being applied, and do not require the worker to wear any additional PPE. Prior to allowing the use of tank mix partners AHETF researchers will ensure that none of these situations exists. Since AHETF does not require addition of tank mix products, any risks associated with exposure to such products would not result from a worker's participation in this research, and would simply be among the background risks normally experienced as part of the job. Nevertheless, a researcher will review the label precautions for all tank mix products with the worker prior to their handling the products. This discussion will be documented by the researcher and ensures the workers are informed of the risks associated with these tank mix products.

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In summary, this study will likely involve a risk of physical injury based on the nature of the agricultural work involved and possibly an increased risk of heat illness. The following practices, designed to minimize these risks and respond to injuries, will be followed during this study:

- Selecting only experienced pesticide handlers
- Requiring experience operating the equipment to be used
- Reminding workers of safe chemical handling practices
- Identifying nearby hospitalization facilities in case of emergency
- Monitoring the heat index and stopping the study if conditions warrant
- Providing transportation to medical treatment and covering the costs of treatment
- Having a medical professional on site to observe the workers and provide urgent care
- Observing study participants throughout the monitoring period
- Ensuring that all tank mix products are used according to approved label (s) and do not require any additional PPE

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2.4 Benefits

The risks and likely benefits of the study described in this protocol will be reviewed with potential participants during the consenting process. There are no personal benefits to the study participants. Growers who allow the study to be conducted using their equipment, crops and facilities will be reimbursed for the pesticides used for the study. While this is beneficial to the grower, it is considered a minor benefit when compared to the costs of running their businesses. The AHETF member companies will likely realize a benefit by addressing regulatory data requirements generically, at lower cost (and using fewer human subjects), than if they conducted similar studies for individual pesticide ingredients.

Data from the AHETF exposure monitoring program has the potential to improve the ability of EPA and other regulatory agencies to accurately assess occupational risks associated with spraying pesticides using airblast equipment and closed-cab tractors. The knowledge likely to be obtained from this study is generalizable and will contribute to assessments of the risks of both new and existing pesticides.

Since there are no existing data suitable for use in a generic database describing the exposure of closed-cab airblast application workers, society will likely benefit from data generated by this study through the improved risk assessments by EPA and other regulatory agencies.

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2.5 Risk/Benefit Balance

By monitoring exposure to professional agricultural handlers who follow their normal practices, but wear an additional layer of clothing (as an inner dosimeter which traps chemical that penetrates the work clothing), this study presents a greater than minimal risk to participants. The primary risk comes from their employment as an agricultural worker where accidents and chemicals contribute to injury and illness. In particular, this scenario involves the use of mechanical equipment that could cause physical injury and handling chemicals that could cause adverse health effects. However, workers will be experienced with the equipment they will be using and will follow their usual practices while handling pesticides approved for this use pattern.

Participating in this study increases the risk of heat-related illness, but this risk is mitigated by a medical management program which emphasizes prevention measures and guidelines for stopping participation when warranted based on environmental conditions.

The likely benefit to agricultural workers as a whole and to society in general, in the form of more accurate measurements of potential exposure to pesticides, must be weighed against the risks to participants. Airblast applications are common in both orchard and trellis crops across the country, and a wide variety of experts consulted by AHETF reported that closed cabs are most common now, and are becoming even more common. Exposure data for this scenario meeting contemporary standards of reliability and quality will likely provide a significant benefit to society. Because the margins of exposure (MOEs) calculated for the exposures in this research indicate that subjects are very unlikely to experience acute toxic effects, and because extensive procedures will be in place to minimize these and other risks to participants, the likelihood of serious adverse effects is very small. In sum, AHETF believes the risks to study participants from participating in this study are reasonable in light of the likely benefit to society of the knowledge to be gained.

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2.6 Respect for Subjects

2.6.1 Subject Privacy

The AHETF employs many procedures, summarized below, to protect subject privacy during recruitment, consent, study conduct, and maintenance of study records. The consent form also summarizes important confidentiality issues for subjects.

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Initial contact with workers during recruitment will be made without the presence of their employer as described in detail in Sections 2.7

and 6.2 of this protocol. If workers are interested in participating, a private meeting with the Study Director or his/her designee will be used to explain the study further, address any questions, and seek the candidate's consent to participate.

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Pregnancy tests, required for female participants, must be conducted within 24 hours of the start of the monitoring period. These will be self-administered in a private restroom, but under the supervision of a female researcher. Positive results from pregnancy tests will not be documented or given to a woman's employers or co-workers. If a female volunteer has a positive pregnancy test result, she must withdraw from participation but can do so without stating a reason. Consent forms and all other records associated with the worker will be promptly shredded (SOP AHETF-11.D). Negative results must be confirmed by a female researcher and recorded in the study files.

Certain worker information will be collected during the course of this worker exposure monitoring study. The information collected, such as notes taken by study observers, will not be available to a participant's employer. Most information identifies subjects only by a unique worker identifier. Forms and paperwork that contain personal information (including a worker's name or address) will be kept confidential in a sealed envelope while in the field. After the study is completed, this confidential envelope will be sent to AHETF archives with the other raw data. Unrestricted access to this confidential information is allowed only to the AHETF Administrative Chair (SOP AHETF-6.B).

The information collected in this study may, under certain regulatory circumstances, be given to the U.S. Environmental Protection Agency (EPA) or to state governmental agencies and other countries. Participants in the study will be informed that their names will not be disclosed, but that absolute confidentiality cannot be guaranteed because of the need to give information to these parties.

The results of this research may be presented at meetings or in publications; however, only a unique worker identification number will identify each worker in reports or presentations.

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2.6.2 Freedom to Withdraw

The absolute right for subjects to withdraw from the research is the cornerstone of protection of human subjects. Prospective and enrolled subjects will be informed of their right to withdraw without consequence prior to and during the conduct of the research.

Any volunteer expressing a need or desire to withdraw from the

research after exposure monitoring begins will be paid $80 and allowed to return to their normal work duties for their employer. If a participant withdraws while being monitored, the long underwear and air sampling pump will be removed, and the hand and face/neck samples will be collected with the worker's consent. The Study Director will decide whether these samples will be analyzed (SOP AHETF-8.K).

2.7 Informed Consent

The Study Director or designated member of the study team will obtain informed consent from all study volunteers prior to their participation in the study. The consenting process is conducted in a private meeting between the researcher and the volunteer (and possibly other individuals as described below). Depending on the circumstances, consenting may occur several days prior to the study up to the day of the study. The volunteer will be given a copy of the consent form to review at least one day before the consent meeting, and advised of study provisions to accommodate their language preference, the need for readers, witnesses, and their desire to have a confidant or counselor present during an informed consent meeting. For example, the volunteer may feel more comfortable with a confidant or counselor in the consent meeting with him/her.

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Study participation will be limited to English or Spanish speakers. When Spanish speakers are involved, a bilingual researcher will conduct the interview. Potential participants that have limited reading ability will have the consent form verbally explained in their preferred language (English or Spanish) with an impartial witness (bilingual as appropriate) present. Witnesses must have no association with AHETF, its member companies, researchers, growers, or workers. Witnesses must have some familiarity with farming and will be recruited from any appropriate source such as a university, grower association, or other organization. The witness cannot serve as the interpreter or an advisor to the volunteer. The witness will sign the consent form to acknowledge that the study participant apparently understood the information presented to him/her.

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During the private consent meeting the worker will be provided with a full explanation of the study, its requirements, any potential risks, and its likely benefits. Workers will be informed that the grower or their employer will be reimbursed for the product used in the conduct of the study on their farms. Workers will be advised of their right to withdraw from the study at any time and for any reason without jeopardizing their normal position with their employers. Each volunteer will be provided a copy of the supervisor's signed Employer's Cooperation Statement (in the worker's preferred language) that states they will not suffer any consequence if they decide to participate or not and they will receive their usual pay for the day when the study is conducted.

The volunteer will be informed that he/she will receive the $20 remuneration payment even if he/she decides not to participate.

The volunteer will be provided information about the risk of the particular product he/she will handle, including signs and symptoms of acute overexposure. The product and its risks will be identified in a Product Risk Statement that is an attachment to the consent form. Appropriate sections of the product label and Material Safety Data Sheet will be discussed by the person conducting the consent meeting and made available for review by the volunteer. WPS requirements, especially proper use of clothing, personal protection equipment, and cleaning facilities will be discussed.

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The Study Director or designated member of the study team will discuss the germane aspects of the AHETF medical management plan with the prospective participants. Information will be provided about the risk of heat stress, including signs and symptoms, and ways to prevent it.

The IRB-approved consent form will be presented in the preferred language (English or Spanish) of the volunteer. All sections of the consent form including the test substance Product Risk Statement will be discussed in detail.

During the discussions with potential participants, ample time will be provided for questions and any additional information or clarification that is requested will be provided. When the Study Director or designated member of the study team is satisfied that the volunteer understands the requirements and risks of the study, and if the worker still wants to participate, he/she will be asked to sign and date the informed consent form and the Product Risk Statement. The member of the study team conducting the interviews (and witness, if applicable) will also sign the consent form and provide a copy of the signed form (and signed attachments) to the worker. The worker will be informed of the impending date of the study and paid $20 for their participation in the private meeting.

When the pool of available worker volunteers at a site, or a particular citrus grove, exceeds the number of MUs required, a simple random selection of equivalent participants will be made. The names of the volunteers will be written on slips of paper of equal size and placed into a container and mixed thoroughly. The required number of slips will be drawn from the container to fill the MUs. All potential participants will be informed of the possibility of not being selected for this reason. Volunteer workers who decide against participation or who are not selected will be paid $20 for meeting with the study team member and released to resume their normal activities.

In all situations, if the AHETF interviewer is not comfortable that the worker fully understands the discussions and the contents of the consent form, the worker will be excluded from consideration to participate in the study. This

will be ascertained by providing repeated opportunities to ask questions and by asking questions of the potential volunteers that would require a response that indicates understanding of key issues for all sections of the consent form. These responses will be documented and if necessary the person conducting the consent meeting will re-explain topics until the volunteer demonstrates an appropriate understanding.

2.8 Study Procedures

During the consenting process the Study Director or designated researcher will inform each volunteer of the procedures used during the study. Volunteers will be informed if they participate in this study, they will do the following:

1. Provide their name and years of experience making closed cab airblast applications.
2. Confirm whether they have received pesticide safety training or are exempt from pesticide safety training.
3. Allow researchers to measure and record their height and weight.
4. Allow researchers to record their gender, age, and preferred language.
5. Allow the researcher to take notes on the discussions during the informed consent session(s).

Volunteers will also be informed about the procedures to expect on the day of their participation in the study. The Study Director or designated researcher will explain the following procedures to each volunteer during the consenting process. Participants must do the following on the day of the study:

1. Arrive at the study site approximately 1 hour before starting their work.
2. Wash their long-sleeved shirt and long pants before participating in the study to remove any residues of the product we are studying.
3. Bathe or shower the evening or morning before participating in the study to remove any residues of the product we are studying.
4. Wear all personal protection equipment required by the product label (see Product Risk Statement).
5. Work about 4 to 8 hours applying a commercial pesticide according to their normal practices and spray at least 3 loads. Participants will apply the pesticide according to the product label.
6. Wear new long underwear underneath their long-sleeved shirt and long pants. Participants may wear their choice of personal undergarments under the long underwear. The long underwear will be supplied by AHETF and collected at the end of the day. Participants will be asked to dress and undress with the assistance of a researcher of the same sex. A changing area will be provided for privacy. When participants complete their work in the study, they will put on their own clothes and return to their normal work. Participants will be informed there is a risk of becoming overheated and suffering heat illness.

7. Have a tube attached to their shirt collar and connected to a portable air-sampling pump on a belt worn around the waist. Participants will be informed that the pump may be uncomfortable or annoying.
8. Have their face and neck wiped with gauze pads moistened with a mild detergent and water mixture. This will be done before they eat anything, any time they would normally wash their face, and at the end of the workday. Participants will be informed there is a risk of eye or skin irritation from the detergent and water.
9. Have their hands washed in a mild detergent and water mixture. This will be done before they eat anything, any time they would normally wash their hands (such as before using the toilet), and at the end of the day. Participants will be informed there is a risk of skin irritation from the detergent and water.
10. Allow researchers to watch all of their work activities and take notes on what they do.
11. Allow photographs and video recordings to be taken. Participants will not be photographed or video recorded while dressing or undressing. AHETF will own all rights to the photos and videos and may use them for any purpose.

2.9 Post-Exposure Follow-Up

During the consenting process each volunteer will be provided the opportunity to request a summary of their personal results from the study. This will require the worker to provide a name and address (mail or e-mail). The results will include the distribution of chemical exposure among the various body areas measured so the worker can be aware of where most dermal exposure occurs. Results are typically available six to nine months after monitoring occurs. The personal information related to this follow-up will be retained in the confidential envelope described above (SOP AHETF-6.B).

Just prior to the completion of the worker's participation in the study, a researcher will remind the participant he/she should bathe or shower as soon as practical and that they have received a copy of the signed consent form with phone numbers for reporting any health changes they think might be related to participation in the study. Post-study inquiries will be forwarded to the Study Director who will deal with the situation as appropriate and notify AHETF management (SOP AHETF-11.B).

3.0 SITE OF THE FIELD PHASE OF THE STUDY

The site for the field phase of the study will be commercial citrus groves in Polk and Hillsborough counties in Florida. These counties were selected because Polk is highest in orange production and Hillsborough is an adjacent county accessible to major transportation routes. In addition, AEHTF has already expended resources to

discuss airblast applications with the handler community in Florida citrus (Bruce, et. al. 2007) and identified a suitable Local Site Coordinator. These counties are typical of citrus producing areas of Florida that utilize conventional closed cab airblast equipment to maintain the groves. The counties are also adjacent to other citrus producing counties that can be contacted if suitable test conditions cannot be found in these two.

Exposure monitoring will be conducted in at least three citrus groves and require at least three citrus growers within the identified counties.

Researchers will identify eligible growers using a random method as described below.

The primary considerations for site selection will be the availability of citrus crops sprayed with airblast equipment, suitable growers that are willing to use the AHETF surrogate compounds and are willing to participate in the study, and the availability of a Local Site Coordinator with experience conducting similar studies and a familiarity with agricultural practices in the area. Full details of the site selection process and actual sites will be recorded in the study file.

4.0 ELIGIBLE GROWER POOL SELECTION

4.1 Use of Local Resources to Identify Potential Eligible Local Growers

AHETF researchers will contact local resources from each of the following categories in Polk and Hillsborough counties in Florida:

- Local Site Coordinator (LCS)
- Commercial Applicator Firms that service citrus groves
- University Agricultural Researchers / County Extension Agents
- Crop Consultants (e.g., pest control advisors or commercial applicators) that service citrus groves
- Chemical Dealers or Sales Representatives
- Citrus Grower Associations

The researchers will briefly explain the AHETF Exposure Monitoring Program to the local resources who are then asked for a list of growers in Polk and Hillsborough counties who are commercial citrus producers and might utilize airblast equipment in their operations. The list of growers from all of the resources will be compiled and duplicate names eliminated. All local resource contacts shall be documented in a detailed record that shall be maintained in the study file.

4.2 Random Selection of Eligible Growers

The compiled list of growers from local resources shall be placed in random order for further consideration. The randomization process will be

documented and maintained in the study file.

The growers shall be contacted, one at a time, following the random order, to determine whether the grower is 'eligible' to participate in this study. Researchers making the contacts will briefly explain the AHETF Exposure Monitoring Program including the need for the proper equipment, potential worker volunteers, ethical aspects of the study, and reimbursement for the products they supply for the conduct of the study on their farms. Growers are considered eligible who:

- Are willing to cooperate with AHETF, including the ethical aspects of the research,
- Are commercial citrus producers,
- Spray their crop(s) with conventional airblast equipment with closed cabs,
- Have at least one worker with experience making closed cab airblast applications,
- Are willing to allow AHETF to recruit his/her worker(s) for the study
- Have sufficient acreage so the minimum AaiH stratum can reasonably be handled by a worker in one day, and
- Are willing to use at least one of the surrogate active ingredients listed in the study protocol and agree to be reimbursed only for the products utilized in the course of the study on their farm.

Growers who meet the criteria above but indicate they use commercial applicators to make airblast applications to their crop will be asked to identify their preferred commercial applicator(s) and researchers will contact them to screen them for willingness to cooperate by providing suitable equipment and workers to spray that specific grower's crop. This step in the procedure ensures that first the crop acreage is identified and then equipment and workers associated with that acreage are identified. The actual worker involved could be the grower himself, the grower's employee, or an employee of a commercial applicator that services that grower.

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Each grower identified as eligible (sometimes with an associated commercial applicator) is placed into a working pool and the following information is assembled to allow construction of an efficient MU selection design:

- Crop(s) available, with acreage that might be treated
- Specific location of crop(s) that might be treated
- Description of equipment available (e.g., number, type, and size)
- Surrogate chemical(s) that might be utilized
- Approximate timing of surrogate applications
- Number of workers available
- AaiH those workers might be able to handle in a day

Screening of the growers (in the order of the random list) continues until the

pool of eligible growers (and/or commercial applicators) contains at least 10 workers who may potentially volunteer for the study, and at least 2 workers are available for each of the AaiH strata. This pool will include more growers and more workers than are ultimately needed for the study.

This process results in a random sample of eligible growers and, by association, a random pool of potential workers associated with eligible growers. All grower contact discussions and decisions made during this eligibility screening will be documented in a detailed study notebook provided by AHETF or kept in files bearing the study number.

5.0 EFFICIENT MU DESIGN

The Study Director and Local Site Coordinator will assemble the information obtained from the pool of eligible growers to construct a plan to efficiently assign all MUs in the study. Details of the potentially available MUs will be used to identify one configuration of MUs (i.e., growers, chemicals, workers, AaiH, timing) that will result in an efficient study. The efficient configuration will be comprised of a group of at least three growers that are near each other, can provide separate workers for all the five strata of AaiH, utilize some diversity in equipment, and plan to make applications within a narrow time frame. The growers and/or commercial applicators in the chosen configuration provide the pool of workers from which study participants will be recruited.

6.0 PARTICIPANT SELECTION

6.1 Site Inspection

The Study Director and/or Local Site Coordinator shall arrange to visit growers from the pool of eligible growers to confirm the suitability of their operation for the study. In accordance with SOP AHETF-11.B the individual growers will be asked to sign a non-coercion statement (Employer Cooperation Statement) affirming to their workers and AHETF that they will not coerce or unduly influence their workers to either participate or not participate in the study. Growers must also certify that alternate work will be provided on study days for workers who choose not to volunteer; and that the employee's decision to participate or not will have no impact on their employment. For grower/owners or grove operators/managers or commercial applicators that do not have a supervisor, but who are eligible handlers themselves, this form is not applicable and will not be used.

6.2 Initial Potential Participants Recruitment

AHETF will follow standard procedures (see SOP AHETF-11.B) to recruit

potential participants for this closed cab airblast application study. Individual workers will be recruited during an initial site inspection or subsequent visit(s) to an eligible grower facility.

The Study Director or designated researcher will seek permission from the eligible grower to approach his/her employees to recruit volunteers for the study. Depending on the number of employees and size of the grower facility the Study Director or researcher may contact employees through the use of an informational recruitment flyer posted in a common work area. Such a flyer will briefly describe the research study and provide contact information for employees who may have an interest in participation in the study. The flyer shall have been previously reviewed and approved by an IRB.

Alternatively, or subsequent to the use of a flyer, the Study Director or researcher will arrange a meeting with the grower's employees who express an interest in participation. Such meetings will always occur without the grower or supervisors being present (SOP AHETF-11.B). The Study Director or researcher shall make a presentation describing the AHETF Exposure Monitoring Program, the goals of the research study, the procedures used in exposure monitoring, and the risks and benefits to participants. Contact information will be provided, and individuals will be encouraged to contact AHETF if they desire additional information about the study or are interested in participating in the study. All presentation materials, such as handouts or visual aids, shall be reviewed and approved by an IRB prior to use in recruiting subjects.

The Study Director or researcher shall continue conducting site inspections and potential participant recruitment as described above until an adequate number of eligible growers and potential participants have been secured for an efficient configuration of all MUs in the study. During this process, the following restrictions will be maintained:

- At least 10 workers who may potentially volunteer for the study
- At least 2 workers available for each of the AaiH strata
- No more than 2 MUs from any one grower (this effectively requires at least 3 different growers since 5 MUs are desired)
- No workers may be used more than once
- No piece of equipment (tractor plus sprayer) may be used more than once

As indicated above, the efficient configuration must include enough eligible growers and potential participants to fill all MUs in the study, even in cases where growers or participants are not available at the last minute for the time interval scheduled for the field phase of the study.

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6.3 Participant Selection and Consenting

The Study Director or designated researcher will establish a pool of eligible growers and workers (potential participants) from those in the efficient configuration who shall be contacted prior to initiating the field phase of the study to confirm their availability and interest in being in the study. Individual volunteers will be informed of study provisions to accommodate their language preference, the need for readers, witnesses, and their desire to have a confidant or counselor present during an informed consent meeting.

The Study Director or designated researcher will arrange a place and schedule to conduct consent meetings with individual volunteers from the eligible pool. Prior to such meetings, accommodations will have been made for interpreters, witnesses, and ancillary personnel who must be present for the meeting. Consent meetings shall be conducted as described above in Section 2.7.

7.0 FIELD MATERIALS AND METHODS

7.1 Test System Identification - Workers

The test system for this study is the worker handling pesticides according to label directions. Workers may include farm owners, farm operators, farm employees, contract applicator employees, or employees of agricultural research facilities. Passive dermal dosimetry methods will be used to determine potential exposure of experienced workers handling the test substance. Inclusion/exclusion criteria have been enumerated in Section 2.1 of this protocol. The recruitment and consenting process will follow the procedures presented in Sections 2.7, 6.2, and 6.3 of this protocol. Details are provided in SOP AHETF-11.B. A total of five applicators are anticipated for this study.

7.2 Justification of the Test System and Test Substances

Experienced agricultural workers handling pesticide products using commercial product packaging and typical handling procedures will be monitored. Monitoring these workers provides the best estimate of potential dermal and inhalation exposure for handlers applying pesticides with conventional airblast equipment using closed cab equipment.

The test substances selected for this study are registered and approved for use in a wide variety of agricultural settings, including airblast application to citrus crops. The justification for their possible use in this study is that they have each been deemed suitable by the Sponsor as surrogate compounds for generating exposure data appropriate for a generic database. In addition, the analytical methods have been validated and these products have the requisite degree of stability under field, storage, and transit conditions.

7.3 Mixing/Loading Stations and Application Area

Field maps and/or sketches will be provided in the raw data showing the exact locations where mixing/loading and application occur. Relative distances between mix/load areas and application areas will be recorded. These will include area and local maps or sketches for all sites involved in the study.

7.4 Study Personnel – Field

The study team will be comprised of a sufficient number of people to conduct the following activities:

1. Monitoring the workers and environmental conditions to ensure safe working conditions
2. Assisting with the donning and collection of all dosimeters in a time-efficient manner to minimize the time from completion of the work cycle to sampling (requires a female researcher if there will be female participants)
3. Fortifying field recovery samples
4. Calibrating air sampling pumps and recording beginning and ending flow rates
5. Observing and recording all work practices, recording site details and treatment details
6. Taking a photographic record of representative study-related activities
7. Evaluating the working order and condition of application equipment
8. Monitoring by a Quality Assurance Officer of operations for compliance with the GLP regulations
9. Providing a medical professional on site to observe the workers and provide urgent care

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7.5 Test Substances

7.5.1 Approved Test Substances

The test substances approved for use in this study are listed in Section 2.3.2 above and Table 1 below. The most appropriate test substance, based largely on the preference of the grower, will be used at each of the individual locations. A different test substance may be used at each location and by each worker within a location if appropriate.

Selection of the exact test substance is determined as the product selected by an eligible grower for his crop on the day of the study. As previously described, eligible growers are selected from an efficient configuration of MUs who plan to use or are willing to use one of the products approved by the AHETF. As the time approaches to conduct the field phase of the study, the grower will confirm the actual product

he will be using on the day of the study. The researchers will insure a sufficient amount of the test substance product will be available at the grower site. The AHETF will reimburse the grower for the product used in the study at the completion of the study on his farm.

The product name, active ingredient and nominal concentration, EPA registration number, CAS number, lot number, formulation type, package type, and package size will be recorded for each product used by monitored workers.

Table 1. Approved Test Substances for AHE55

Test Substance	Active Ingredient	Type	Activity
Sevin® brand 80WSP	Carbaryl	Powder in water soluble bags	Insecticide
Sevin® brand XLR Plus	Carbaryl	Liquid flowable	Insecticide
Sevin® brand 4F	Carbaryl	Liquid flowable	Insecticide
Fyfanon® 8 Lb Emulsion	Malathion	Emulsifiable concentrate	Insecticide
Fyfanon®	Malathion	Emulsifiable concentrate	Insecticide
Malathion 8-E	Malathion	Emulsifiable concentrate	Insecticide
Gowan Malathion 8 Flowable	Malathion	Liquid flowable	Insecticide

7.5.2 Active Ingredient Stability

The stability of the test substances under recommended storage conditions will be documented before the start of the study. Generally, AHETF will rely on data supplied by the product registrant that were submitted to support the EPA registration of the test substance. Study researchers will record the storage conditions, including temperature, during the days of use of the products at the eligible grower's facility.

7.5.3 Purity Analysis

A sample of each lot of test substance used by each worker in the study at each location will be collected and sent to a designated laboratory for GLP purity analysis (content of active ingredient in the test substance). Purity analysis will be conducted concurrently with analytical phase of the study. Documentation of such analyses will be retained in the study raw data.

7.5.4 Retention Samples

Retained samples from each lot of the test substance(s) used in the study will be sent to the AHETF archive facility.

7.6 Application Parameters

Carrier:	Water
Target application rate:	Products will be applied at a rate specified on the label for the particular crop. Rates depend on target crop and field needs. Actual application rates will be documented in study raw data.
Target application volume:	Application volume will comply with the product label. Volumes depend on target crop and field needs. Actual application volumes will be documented in study raw data.
Route of application:	Applications will be made using available common airblast application equipment.

7.7 Equipment Accuracy Verification

Mixing/Loading equipment accuracy will be verified according to field testing facility SOPs prior to use in this study. This will include equipment used to pump or meter the carrier during the mixing/loading process.

Copies of relevant facility maintenance records (if available) for all mixing/loading and application equipment used for this study will be obtained and retained with the field raw data. The Study Director or designated member of the study team will assure equipment operation is acceptable according to SOP AHETF-10.D.

Workers will only be allowed to handle equipment for which they are familiar and have used recently. This will help ensure the safety of the worker when handling equipment and ensure that the procedures followed by the worker are normal and typical of their usual job function.

7.8 Amount of Material Handled

The amount of test substance that is mixed and loaded for each applicator

worker will be determined and recorded in the raw data. Each worker will handle an amount of active ingredient designed to achieve a within-cluster diversification of AaiH following the standard approach of partitioning the practical AaiH range for the scenario into five strata. These strata are:

(1) 5 to 9 pounds ai handled
(2) 10 to 17 pounds ai handled
(3) 18 to 30 pounds ai handled
(4) 31 to 55 pounds ai handled
(5) 56 to 100 pounds ai handled

A single MU will be conducted in this study from each of the five strata.

Each MU shall consist of a period of at least 4 hours of spraying and at least 3 tank loads of the spray mixture. The application volume, gallons per acre, may be adjusted by ground speed and output volume to achieve a stratum-assigned range of pounds ai handled. The application volume applied shall be in accordance with the product label. The volume of spray mixture applied will be determined and recorded in the field raw data, along with other critical measurements including application area and duration. Upon completion of spraying each load of diluted product, the amount of spray volume remaining in the tank(s) will be determined and recorded in the raw data. Disposal of excess spray mixture will occur in accordance with applicable regulations.

7.9 Rationale for the Route of Administration

The above handling procedures represent typical agricultural practices for each particular location and test substance.

8.0 DERMAL EXPOSURE SAMPLING

Full details of procedures for dermal and inhalation exposure sampling, and sample removal, are specified in the most recent versions of SOPs AHETF-8.A, 8.B, 8.C, and 8.D. At the completion of the monitoring period, exposure samples will be taken in the following order to minimize cross contamination: inhalation samples (discussed in the next section), then hand washes, then face/neck wipes, and finally inner dosimeters as described below and in SOP AHETF-10.E.

Workers will wear the clothing and PPE required by the product label. Depending on the particular product, this may include long pants, long-sleeved shirts, waterproof gloves, chemical resistant gloves, protective eyewear, shoes, and socks. The clothing can be provided by each worker as long as the Study Director agrees they are compliant with the WPS. All items worn must be compliant with the WPS, and the clothing must have been laundered since being worn while handling pesticides, or be new. Any clothing items deemed unacceptable by the Study Director will be replaced by alternate clothing (see SOP AHETF-8.F). Upon approval by the Study Director,

workers may wear a hat or cap.

Workers will wear one layer of work clothing over the inner dosimeters. The inner dosimeter will consist of 100% white cotton long underwear, pre-washed and provided by the AHETF. The inner dosimeter is designed to represent the worker's skin and will act as a collection medium that will be analyzed. It will be worn throughout the period of monitoring and removed at the end of the work period, with the assistance of a member of the monitoring team.

Workers' hands will be washed just prior to the exposure monitoring period as described below. This assures that the worker hands are free of pesticide and provides an opportunity for researchers to ensure the worker understands how to assist with the hand washing procedure. The face and neck area will also be wiped just prior to the exposure monitoring period. All of the pre-monitoring hand wash and face/neck samples will be discarded.

At the end of the monitoring period (and after the inhalation exposure equipment is removed as described below), the worker will first remove his/her PPE (e.g. waterproof gloves) and shoes, then enter a clean, private area for collecting the remaining samples. Once inside the private area, the worker will remove his/her outer clothing and socks. The outer layer of clothing and socks will not be collected or analyzed. To reduce the potential for cross contamination, each set of outer work garments will be used only once. Dermal exposure samples will be collected in the following order: final hand wash sample, final face/neck wipe sample, and the inner dosimeter.

Hand exposure will be measured by having the worker wash their hands in a 0.01% Aerosol OT solution according to a standardized washing procedure described in the most recent version of SOP AHETF-8.B. Interim hand wash samples will be collected whenever a worker would normally wash his/her hands (e.g., before using the toilet, etc.). These interim hand wash samples will be numbered sequentially, as described in SOP AHETF-8.F. After an MU is completed (i.e., at the end of the monitoring period) one final hand wash will be collected from each worker. The post-activity hand wash sample for each MU will be the final hand wash sample for the monitoring period and receive the final sequence number for the MU. This sample will be clearly marked as the post-activity hand wash. All hand washes collected during and at the end of the work period will be treated as separate samples. All hand wash samples will be poured into pre-labeled containers and placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will be maintained in frozen storage until analysis.

Face/neck exposure will be measured by wiping the entire face and neck areas (front and back of neck) with two gauze sponges, sequentially, that have been wetted with 0.01% Aerosol OT as described in the most recent version of SOP AHETF-8.C. Interim face/neck wipe samples (consisting of two gauze sponges) will be collected prior to eating. After each MU is completed, a final face/neck wipe sample will be collected from each worker after the hand wash sample is collected and before

removal of the whole body dosimeters. Face/neck wipe samples will be wrapped in aluminum foil prior to placement in pre-labeled re-sealable plastic bags. All wipes collected during the study for a worker will be combined in the same container, resulting in a single sample for analysis. If more than two samples (4 sponges) are in a sample container, the laboratory must be notified as to the number in the container. All face/neck wipe samples will be placed in pre-labeled containers and placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will be maintained in frozen storage until analysis.

Finally, the inner layer of clothing (inner dosimeter) will be removed with the assistance of a member of the study team and sectioned into two sections for all MUs (upper body and lower body). The sections will be individually wrapped in aluminum foil, placed in pre-labeled containers and placed into temporary frozen storage as soon as possible for transport to the analytical facility. Samples will be maintained in frozen storage until analysis.

9.0 INHALATION EXPOSURE SAMPLING

Full details of the personal air-sampling method, attachment of pumps, monitoring of workers, and pump calibration are given in the most recent versions of SOP AHETF-8.D and 10.A. Suitable low-volume personal air-sampling pumps and OVS tubes with a glass fiber filter and the appropriate sorbent for the test substance being used are required. Valid calibration equipment, specified in SOP AHETF-10.A, and Tygon® (or equivalent) tubing are also required. The pumps and calibration equipment will be uniquely labeled and this information recorded in the raw data records.

Before the work commences, the sampling pump will be attached to a belt around the waist of the worker to be monitored. Tygon® tubing (or equivalent) attached to the inlet valve of the pump will be placed over the shoulder of the worker and attached to the air-sampling tube. A clip will be used to attach the tube to the collar of the worker, thus positioning it in the breathing zone of the worker. The inlet of the air-sampling tube will be facing downward, similar to the nasal passage of a worker.

Each pump will be calibrated, as specified in SOP AHETF-10.A, to a nominal sample flow rate of approximately 2 L/min and will operate for the duration of the exposure monitoring period. Flow rates will be measured before and after each exposure monitoring period and detailed records of flow rates and sampling durations will be maintained in the raw data records.

The pumps will be turned on immediately prior to the start of the monitoring period and will operate continuously until the end of the period. Detailed time logs will be maintained to allow the length of the exposure period to be calculated.

Periodically throughout the monitoring period, the pumps will be inspected to ensure they are still running and the tubing checked to ensure that there are no kinks. Workers will be instructed to inform a study team member if the pump fails to

operate or the tubing becomes kinked.

If a pump stops operating during the work cycle, it will be replaced with a pre-calibrated replacement pump or given fresh batteries as soon as possible. Only the pump or batteries will be changed, the same sampling tube and tubing will continue to be used. At the conclusion of each exposure monitoring period, after the final flow rate has been recorded, the OVS tube will be disconnected from the tubing leading to the pump. The OVS tube will be sealed at both ends, placed in a pre-labeled container, and placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will be maintained in frozen storage until analysis (SOP AHETF-8.A).

10.0 CONTROL OF BIAS

Sampling bias will be controlled by sampling multiple workers over a period representative of a typical work day, and by sampling over the entire body of each worker. Quality control samples in the field and in the laboratory also act as methods for controlling bias.

11.0 FIELD RECOVERY EVALUATION

11.1 Fortification Procedures

Full details regarding field recovery evaluation procedures for all sampling media are given in the most recent version of SOP AHETF-8.E. The SOP instructions for "spiking using vialed spikes" and analytical standard in solvent will be followed.

Sample matrix fortifications designed to assess the stability of the active ingredient during field, storage and transit conditions in or on the sampling materials (inner dosimeters, hand wash solutions, face/neck wipes, and air sampling matrices) will be conducted on a minimum of one day of exposure monitoring at each location, or more days as appropriate for environmental conditions.

Fortification vials with solutions of active ingredient in appropriate solvent will be shipped and stored under frozen conditions until used in the field. The entire contents of the fortification vials will be applied to the sampling media. The OVS tubes will be pre-spiked with the active ingredient (generally in an organic solvent) at the analytical laboratory and kept frozen until their use in the field.

Storage conditions of the individual vials used for fortifications, and of the fortified OVS tubes, will be specified by the analytical laboratory and the actual storage details will be recorded in the study file.

After fortification, the inner dosimeters and OVS tubes will be exposed to ambient conditions (i.e., weathered) for the longest expected exposure monitoring period in a location away from possible contamination (e.g., upwind of mixing/loading and application operations). Inner dosimeter samples will be covered with a single layer of shirt material during weathering. Segments representing any body area may be used for inner dosimeter fortification samples. An air sampling system will be set up in a manner similar to that of the workers, in which a pump will continuously draw air through the pre-fortified filter and OVS tube for the entire duration of the work period.

Hand wash and face/neck wipe samples will be fortified and immediately placed in frozen storage without exposure to ambient conditions. In addition, on each fortification day, duplicate samples of the inner dosimeters fortified in the field at the highest level, and duplicate OVS tubes fortified in the laboratory at the highest fortification level, will be processed for immediate frozen storage and used as travel spikes. These travel spikes will be analyzed only if deemed necessary by the Study Director, for example to help determine the cause of unusually low field fortification recovery results.

Finally, on each fortification day, two untreated control samples of each matrix will be processed similar to the field fortification samples (i.e., some are weathered). Packaging, storage and shipment of the field fortification samples will be the same as for the worker exposure samples.

11.2 Field Fortification Levels

Matrices will be fortified in triplicate at the following levels:

Matrix:	Fortification Levels (µg/sample):
Inner Dosimeters	5, 100, and 2,000
Face/neck Wipes	5, 100, and 2,000
Hand Wash	5, 100, and 2,000
OVS Tubes	0.05, 0.5, and 5.0

12.0 OBSERVATIONS

Observations will be recorded according to SOP AHETF-10.C throughout the monitoring period while the workers perform their tasks. Any specific occurrences that could affect exposure will be noted on the observation forms. Measurements will be made of the amount of test substance handled. A detailed time log will be

maintained for all activities. A photographic record will be taken of representative study-related activities during exposure monitoring.

13.0 ENVIRONMENTAL MONITORING

Exposure monitoring will not be conducted under meteorological conditions inappropriate for the conduct of the activity (e.g., excessive precipitation, excessive wind speed or other adverse condition). Adequate protection from the elements will be provided for handling worker exposure samples and field fortifications in case of inclement weather.

Environmental conditions, including air temperature, relative humidity, wind speed, and wind direction will be recorded by means of an on-site, portable weather station during exposure monitoring. Measuring equipment will be calibrated as per the field contractor's SOP. Additionally, observations concerning pertinent weather conditions, such as amount of cloud cover, degree of sunshine, rainfall, relative humidity, etc. for each day of monitoring will be recorded in the field raw data.

Most importantly, environmental conditions will be monitored regularly by the Study Director or designated members of the study team to evaluate the risk to workers of heat-related illness according to SOP AHETF-11.G and Section 2.3.1 of this protocol. These temperature, relative humidity, and heat index values will be recorded in the field raw data.

14.0 SAMPLE IDENTIFICATION, SHIPPING AND STORAGE

14.1 Sample Identification

The sample identification process is described in the most recent version of SOP AHETF-8.F. Samples will be identified and tracked by unique sample numbers assigned by AHETF. During the analytical phase of the study, the laboratory may assign its own sample numbers as long as the AHETF number is cross-referenced and included in the documentation of the sample.

14.2 Shipping

Samples will be shipped frozen to the analytical laboratory designated for the specific active ingredient used at each location. Full chain of custody record will be available for all samples.

14.3 Storage

All samples will be placed into frozen storage as soon as possible after collection; the analytical laboratory will store samples under frozen conditions until analysis. Freezers will be monitored and the temperatures documented.

15.0 ANALYTICAL PROCEDURES

Experimental exposure and field recovery samples will be analyzed according to the analytical methods for the active ingredient in the specified test substance used in the field. The methodology will have been validated for use in the relevant matrices prior to the initiation of the sample analyses.

15.1 Reference Substance(s)

The reference substance for this study is the analytical standard used by the analytical laboratory to prepare analytical standard solutions.

The Study Director or an authorized representative will obtain analytical standard from the registrant or suitable commercial supplier. Receipt of the standard will be documented, including label identification, date of receipt, person receiving the standard, and the amount received. Preparation of all stock and serially diluted solutions will be documented.

The stability of the analytical standard (reference substance) will be documented before the start of the study. Generally, AHETF will rely on data supplied by the product registrant that were submitted to support the EPA registration of the technical grade active ingredient. An expiration date and recommended storage conditions will be based on the stability data to ensure the analytical standard strength does not change appreciably during conduct of the study. Analytical standards are to be stored under the recommended conditions.

GLP determination of the percent ai analysis (content of ai in the reference substance) will be performed for each lot of reference substance used in the study prior to the use of that substance for sample analyses. Documentation of such analyses will be retained in the study raw data file.

15.2 Analytical Methods

The latest revisions of the following validated analytical methods will be used:

Analytical Method No. ARTF-AM-005 entitled, "Determination of Diazinon and Malathion in Inner Dosimeters."

Analytical Method No. ARTF-AM-006 entitled, "Determination of Diazinon and Malathion in Hand Wash Solutions."

Analytical Method No. ARTF-AM-009 entitled, "Determination of Diazinon and Malathion in OVS Air Sampling Tubes."

Analytical Method No. ARTF-AM-010 entitled, "Determination of Diazinon and Malathion in Facial/Neck Wipes."

ARTF-AM-011, "Determination of Carbaryl in Dermal Dosimeters" by Gary Westberg, Revision 4, September 2003

ARTF -AM-012, "Determination of Carbaryl in Hand Wash Solutions" by Gary Westberg, Revision 2, June 1998

ARTF-AM-013, "Determination of Carbaryl in OVS Air Sampling Tubes" by Gary Westberg, February 1997

ARTF-AM-014, "Determination of Carbaryl in Cotton Facial/Neck Wipes" by Gary Westberg, Revision 2, April 1998

Equivalent instrumentation, apparatus, and reagents may be substituted for those specified in the method. All substitutions must be clearly documented in the raw data.

15.3 Analytical Design

All analytical procedures, techniques and matrices will be provided by the AHETF. Procedures and techniques will be followed as rigidly as possible. No changes are permitted without the prior approval of the AHETF Analytical Monitor and the Study Director.

All data will be measured against a standard curve (five-point minimum) that brackets the levels of the matrix spikes. If necessary, a solvent blank for the standard solutions will be injected prior to the standard solutions for each run.

Analytical data sets for the study will be considered acceptable if the following criteria are met. If these criteria cannot be met, the analytical monitor must be contacted immediately.

1) The limit of determination, r^2, or the regression coefficient, r, must be reported for all curves to demonstrate sufficient linearity of detector response in the range of residues quantified. All r^2 values must be 0.90 or greater or all r values must be 0.94 or greater.

2) Back calculations of the standard to the calculated curve which is based on the standards run in a set of samples will be performed for all analytical sets. The back calculations of the standards to the curve will be around +/-15% for all standards but the lowest concentration standard may back calculate to around +/-20%. No standard will be discarded from a set unless there is a good reason for its being discarded and not without consultation with the analytical monitor.

A minimum of two laboratory spikes must be included in each analytical set. For large analytical sets, include approximately one spike for every ten field samples. The spiking concentrations will bracket the expected levels in the

field samples. The LOQ is defined in each analytical method.

For all samples wrapped in aluminum foil, the inner surface of the foil wrapping will be rinsed with at least 50 mL of extraction solvent, which will be added to the total extract volume. The final volume of solvent used must be documented.

The filter, plus front and rear sorbent sections of the OVS tubes, (along with the retainer ring and sorbent section separators) will be analyzed together as one unit.

15.4 Analytical Statistical Methods

Chromatographic quantification (either GC or HPLC depending on the method) will be achieved using a standard curve obtained from peak heights or areas of injections of several concentrations of standards. The standard curve will be a least squares fit unless otherwise approved by the AHETF Analytical Subcommittee. Means and standard deviations (arithmetic and/or geometric), and coefficients of variation may be calculated on the limited data set generated in this study.

16.0 STUDY RECORDS

16.1 Field Records

Raw data will be obtained to cover all aspects of the study, including but not limited to the following:

1. Test and reference substance lot numbers, receipt and storage location(s) use records
2. Crop description and growth stage, if applicable
3. Mixing/loading equipment details, if applicable
4. Application equipment details, if applicable
5. If available, application equipment maintenance records (retained in the study file)
6. Environmental conditions for the entire monitoring period, including data used for making determinations of potential heat stress indices
7. Approvals from the Institutional Review Board covering the protocol and the Informed Consent document, and all amendments to either document
8. All correspondence with the Institutional Review Board
9. Personal details of workers, including consent forms and documentation of consent process (which will be maintained under confidential conditions as per SOP AHETF-6.D)
10. Trial location maps, including description, dimensions, and exact locations of plots and mixing/loading stations

11. Pounds active ingredient handled, monitoring time, acres treated, and volume of liquid applied
12. Dermal exposure sampling information
13. Inhalation exposure sampling information, including pump identification, calibration, flow rates and times of sampling
14. Field recovery procedure information for all sampling media
15. Test and reference substance, and sample storage temperature records
16. Observations on work practices, including photographs
17. Sample information (including inventory and chain of custody)

Field raw data will be recorded directly into the study notebook provided by AHETF. All data generated during this study will be kept in files bearing the study number. All forms and paperwork that contain personal information (including a worker's name and address) will be kept confidential in a sealed envelope while in the field. After the study is completed, this confidential envelope will be sent to AHETF archives with the other raw data (SOP AHETF-6.B).

16.2 Analytical Records

All study-specific original documents and data generated in the course of this study, including but not limited to the following, will be maintained and turned over to the AHETF when requested, or at the completion of the study.

1. Analytical worksheets, chromatograms, methods, residue calculation sheets and other pertinent analytical data
2. Laboratory notebooks or bench sheets used to record details of the analyses
3. Chromatograms and/or machine-generated analysis reports and data
4. Spreadsheets and other calculated data
5. Chain of custody records

In addition to the above study-specific raw data, the following records must also be kept, and true copies submitted with the raw data:

a. Storage conditions for reference substances and samples
b. Reference substance use log
c. Balance and instrument log book pages
d. Communications logs or records

Following completion of the field or analytical portion of the study, copies of the relevant records will be indexed and sent to the Study Director for preparation of the final report. All original raw data will be transferred directly to the AHETF-designated GLP study archive at Quality Associates, Inc., 8161 Maple Lawn Boulevard, Suite 200, Fulton, MD 20759.

17.0 DATA HANDLING

17.1 Communication of Results

Results will be communicated from Principal Field and Analytical Investigators to the Study Director and the designated AHETF Study Monitor(s) on a regular and timely schedule. Volunteer subjects will have an opportunity to fill out a form to request their personal study results when they are available. Individual results requested by subjects will be communicated in accordance with SOP AHETF-11.B.

AHETF has an adverse effects reporting procedure in place and will submit reports to EPA, IIRB, and appropriate state authorities if potential adverse effects to workers are found (see SOP AHETF-1.F and AHETF-11.F). The Study Director has the primary responsibility for identifying potential adverse effects during study conduct and as exposure results are obtained.

Deleted: 17.2 Statistical Methods ¶
Detailed statistical evaluations of exposure data from this study and any existing data will be conducted by AHETF for each use scenario in its generic database.¶
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18.0 QUALITY ASSURANCE

AHETF intends that all regulatory studies are conducted in accordance with the FIFRA GLP Standards (40 CFR part 160). Field and analytical aspects of this study will be monitored by the relevant quality assurance unit(s) (QAU) while this study is in progress to ensure compliance with the FIFRA GLP regulation and adherence to this protocol and relevant SOPs. The QAU(s) will submit copies of its/their inspection reports to the Study Director and AHETF Sponsor Representative (40 CFR part 160.35 [4]). The final report will be audited by the QAU specified in Section 1.15 to ensure that the contents of the report accurately describe the conduct and findings of the study.

The final report will contain a Quality Assurance Statement from the QAU of each contributing laboratory conducting QA audits, and from the QAU specified in Section 1.15.

19.0 WORKER SAMPLE RETENTION

All sample extracts, extracted sample matrices, unanalyzed fortification matrices, and analytical standards will be retained until the Study Director and Analytical Monitor determine they are no longer useful. These materials are the property of the AHETF and will be stored or disposed of in a safe and lawful manner by the appropriate authorized personnel with the approval of AHETF and with QA verification at the performing facility.

20.0 PHASE REPORTS

Separate final reports will be prepared for the field and analytical phases of the study.

20.1 Field Report

Upon completion of the field phase at each individual location, the field investigators will submit reports for individual locations to the AHETF and the Study Director in a format specified by the AHETF. Each field report will describe the procedures followed at that location and must contain, but is not limited to, the following:

1. Identification of the locations of the study, and the general environmental conditions during the exposure monitoring periods
2. A field laboratory QAU statement giving dates of inspections and dates that findings were reported to the Study Director and AHETF Management
3. A summary of the worker recruitment and consent process
4. A description of the workers and handling activities
5. A summary of worker observations identifying any specific occurrences that may contribute to unusual worker exposure
6. A detailed summary of the amount of test substance handled by each worker
7. A detailed summary of the length of time each worker was monitored
8. A complete description of the field recovery procedure with a summary of specific handling and weathering of all field samples
9. A complete description of collection, handling, storage, and shipping of field samples

20.2 Analytical Report

At the completion of the analytical phase, each analytical laboratory that analyzed samples for this study will submit a report to the AHETF and the Study Director in a format specified by the AHETF. Each analytical report will describe the procedures followed for analysis of sample matrices and must contain, but is not limited to, the following:

1. Results of analyses
2. An analytical laboratory QAU statement giving dates of inspections and dates that findings were reported to the Study Director and AHETF Management
3. A detailed description of the methods
4. Example calculations
5. A summary of the concurrent lab recovery data
6. Representative chromatograms of control, treated, fortified samples and calibration standards
7. A typical standard curve

21.0 FINAL STUDY SUMMARY REPORT

A final summary report will be prepared according to a standardized format provided by AHETF. The report will contain a description of the conduct of the studies that comprise this scenario as well as a statistical analysis of the exposure data for the scenario. The original signed copy of the summary report will be archived at the AHETF GLP study archive.

22.0 PROTOCOL CHANGES

22.1 Amendments

Amendments to this protocol during the course of the study are permissible and subject to review and approval by the Study Director, the Sponsor representative and the IRB prior to implementation, except where necessary to eliminate apparent immediate hazards to the human subjects (40 CFR 26.1108(a)(4)). Protocol amendments shall to be documented in accordance with SOP AHETF-2.C and reported in the Field Report, Analytical Report and Summary Reports.

22.2 Deviations

GLP deviations are to be documented on the "Statement of GLP Compliance" in the summary report. A description of any changes to the protocol must appear in the Field Report, Analytical Report and Summary Reports. Any deviations to the protocol, lab SOPs or GLPs, or situations that may affect the integrity of the study must be communicated to the Study Director in a timely manner. Any deviations affecting the safety or rights of the subjects must also be reported to the IRB. Protocol deviations are to be documented in accordance with SOP AHETF-2.C.

23.0 REFERENCES

Bruce, E., L. Smith and V. Standart. 2007. Report of workplace meetings with citrus and pecan growers and employees. With attached: AHETF exposure studies: input from the local workplace community. Georgia and Florida, July 2007. Prepared for the Agricultural Handlers Exposure Task Force, 8 August 2007.

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RESEARCH INFORMATION AND INFORMED CONSENT FORM

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

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SPONSOR AND SOURCE OF FUNDING:

Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

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STUDY DIRECTOR: Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

FIELD LOCATIONS: 3 to 5 Orange Orchards in Florida

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INTRODUCTION and PURPOSE

The Agricultural Handlers Exposure Task Force (AHETF) was formed by a group of pesticide companies. The purpose of this study is to measure how much pesticide you might get on your skin and breathe in while you spray using closed cab airblast equipment. This will be done by measuring pesticide residues in the samples we collect from you. About 5 people will be monitored in this study. The results of the study will be used to estimate exposure and risks to workers spraying pesticides with closed cab airblast equipment.

For you to participate in this study, you must understand and sign this consent form and a Product Risk Statement that describes the risks from the pesticide. If we have used words or presented information you do not clearly understand, please ask me to explain. You may take home an unsigned copy of this consent form to think about or discuss with family or friends or researchers before making your decision. If you agree to be in this study, you will be given a signed and dated copy of this consent form and the Product Risk Statement.

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Deleted: The Agricultural Handlers Exposure Task Force (AHETF) was formed by a group of pesticide companies. The purpose of this study is to measure how much pesticide you might get on your skin and breathe in while you spray using closed cab airblast equipment. This will be done by measuring pesticide residues in the samples we collect from you. About 5 people will be monitored in this study. The results of the study will be used to estimate exposure and risks to workers spraying pesticides with closed cab airblast equipment.¶

Version: 3/4/08
Protocol: AHE55

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

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Date: _____

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ELIGIBILITY

To be eligible to participate in this study you must:

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1. Have made airblast applications using a closed cab tractor within the last year.
2. Provide proof you are at least 18 years old (government-issued photo ID).
3. Confirm you do not work for a pesticide company or a contractor of AHETF, except an employee of the Local Site Coordinator for this study.
4. Consider your general health status to be "good enough to do the work". Tell us if you have any medical conditions that affect your ability to participate in the study.
5. Not be pregnant or nursing women cannot participate in the study. If you are female, you must take an over-the-counter urine pregnancy test before the study. This test will be supervised by a female researcher. You do not have to tell anyone if you have a positive test. Results of a negative test must be confirmed by the female researcher or you cannot participate.
6. Confirm that you do not normally wear personal protective equipment in excess of the label requirements for closed cab airblast applications. Confirm that you will follow label directions.
7. Have a private meeting with a researcher to go over this consent form. The purpose is to make sure you understand what you are agreeing to and to have all your questions answered. You may have a friend, family member or advisor with you during the meeting. If you are an employee, this person may not be from the operation's management.
8. Understand English or Spanish.
9. Understand and sign this consent form and Product Risk Statement.

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STUDY DURATION

The duration of your participation in this study is approximately 4-8 hours of one of your normal workdays.

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

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PROCEDURES BEFORE THE DAY OF THE STUDY

If you participate in this study, you will do the following:

1. Tell us your name and how many years you have been making closed cab airblast applications.
2. Allow researchers to measure and record your height and weight.
3. Allow researchers to record your gender, age, and preferred language.
4. Confirm whether you have received pesticide safety training or are exempt from pesticide safety training.
5. Allow us to take notes on the discussions during the informed consent session(s).

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If you read only Spanish, a Spanish version of the documents will be provided, along with a translator during our meeting. If you have trouble reading these documents in your language of choice (English or Spanish), it will be read to you.

PROCEDURES ON THE DAY OF THE STUDY

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1. Bathe or shower the evening or morning before you come to work.
2. Wear a freshly laundered long-sleeved shirt and long pants.
3. Put on new long underwear (which we will provide) under your long-sleeved shirt and long pants. Wear your choice of personal undergarments under the long underwear. The long underwear will be collected at the end of the day. You will be asked to dress and undress with the assistance of a researcher of the same sex. A changing area will be provided for privacy. When you complete your participation, you will put on your own clothes and return to your normal work.
4. Wear a tube attached to your shirt collar and connected to a portable air-sampling pump on a belt worn around your waist. The pump is small and light about the size of a portable radio. This may be uncomfortable or annoying.
5. Wear all personal protection equipment required by the product label (see Product Risk Statement).
6. Work about 4 to 8 hours applying a commercial pesticide according to your normal practices and spray at least 3 loads.

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Deleted: <#>Bathe or shower the evening or morning before participating in the study to remove any residues of the product we are studying.¶
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Signature Date

Initials: _____
Date: _____

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7. Have your face and neck wiped with gauze pads moistened with a mild detergent and water mixture. This will be done before you eat anything, any time you would normally wash your face, and at the end of the day.

8. Have your hands washed in a mild detergent and water mixture. This will be done before you eat anything, any time you would normally wash your hands (such as when you use the toilet), and at the end of the day.

9. Allow researchers to watch all of your work activities and take notes on what you do.

10. Allow photographs and video recordings to be taken. You will not be photographed or video recorded while dressing or undressing. AHETF will own all rights to the photos and videos and may use them for any purpose. **If you do not want to be photographed or recorded you should not participate in this study.**

Deleted: <#>Wear new long underwear underneath your long-sleeved shirt and long pants. Wear your choice of personal undergarments under the long underwear. The long underwear will be supplied by AHETF and collected at the end of the day. You will be asked to dress and undress with the assistance of a researcher of the same sex. A changing area will be provided for privacy. When you complete your participation, you will put on your own clothes and return to your normal work.¶
<#>Have a tube attached to your shirt collar and connected to a portable air-sampling pump on a belt worn around your waist. The pump is small and light about the size of a portable radio.¶

PRODUCTS HANDLED

You will be asked to apply a pesticide product that is registered by the US Environmental Protection Agency (EPA) and approved for spraying citrus with airblast equipment. The active ingredient will be carbaryl or malathion and farm management will select the product. However, you will know which product you will handle before you are asked to sign this consent form.

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In addition to the pesticide you will spray, farm management may require tank-mixes with other registered or approved products according to label directions. You will be told before your participation which materials will be in the tank mix.

Deleted: We will have no knowledge of any risks to you other than those provided to you on the tank-mix product labels.

RISKS AND DISCOMFORTS

In this study you will have the usual risks of using the spray equipment. You will only use equipment you have experience operating.

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You will be asked to sign another document, the Product Risk Statement, that identifies the product you will spray, indicates how much of that product you might handle, and specifies the risks of handling that product. It also describes what personal protection equipment you must wear.

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You will review the product label with the research staff to identify the airblast use directions and precautions. From the label, and Product Risk Statement, you will learn of any possible side-effects (such as skin irritation) and the signs and symptoms of overexposure. If you feel any of the signs or symptoms during or after the workday, or do not feel well for any reason, notify a researcher immediately. A

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Signature Date

Initials: _____
Date: _____

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copy of the product Material Safety Data Sheet (MSDS), is available for your review and discussion any time you desire.

Because you will wear long underwear underneath your normal work clothing, you have a risk of becoming sick from being too hot. This is known as heat stress or heat illness and can be serious or life threatening. Early signs and symptoms include feeling overheated, tired, dizzy, irritable, and having decreased concentration. If you feel any of these signs or symptoms during or after the workday notify a researcher immediately. If you don't feel well for any reason, notify a researcher immediately. You will be observed by a researcher watching for these symptoms. AHETF will stop your work if the weather gets too hot.

As a precaution, AHETF will have a paramedic, physician's assistant, nurse, or emergency medical technician on site during the study. If needed, this professional will also observe you for signs of illness and will provide medical attention.

You may have other risks or discomforts, including:

- Eye or skin irritation from the detergent and water mixture used to rinse your hands, face and neck
- Discomfort from wearing a portable air sampling pump around your waist
- Being embarrassed during dressing and undressing
- Being concerned about taking an over-the-counter pregnancy test
- Working longer than normal because of the extra time it takes to collect samples for analysis

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There may be other risks that are unknown at this time. You will be told in a timely manner both verbally and in writing of any new information that might change your decision to be in the study.

INJURY TO PARTICIPANTS

If you are injured or get sick during or after the day of the study, medical treatment will be available at your workplace and at a nearby health care facility. If necessary, AHETF will arrange transportation for you to receive medical attention. You may refuse medical treatment unless you get sick from too much pesticide exposure or from getting too hot, or if we believe you are too sick to make a rational decision about receiving medical treatment. AHETF will cover the cost of reasonable and appropriate medical attention that is not covered by your own insurance or insurance provided through your employer. Treatment records will not become part of the research records for this study. However, AHETF will make note of the event and this will be reported in the study report. For further information about this, you may call the AHETF Manager (David Johnson) at 660-349-4601.

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Independent IRB

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Signature Date

Initials: _____
Date: _____

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You will not give up any of your legal rights by signing this form.

CONFIDENTIALITY

Your name will appear on the consent form, the Product Risk Statement, and an optional form for you to request your personal study results. All other study information will identify you only by a unique code. Records with your name will be stored in a secure, limited access archive.

Information about your participation in this study will not be given to your employer.

A study report will be written by AHETF and will be available to member companies. It will be sent to the US Environmental Protection Agency (EPA). It may also be sent to state government agencies and to governments of other countries. Your name will not be included in any study report.

We cannot promise you absolute confidentiality because of the need to give information to some organizations or to parties in legal actions, as required by law. All study information, including records which identify you, may be looked at or copied by the sponsor and any consultants working with the sponsor, by EPA or other government agencies, and by the Independent Investigational Review Board, Inc. (IIRB). IIRB is a group of people who review and monitor research to make sure the people who participate in it are protected.

You may ask the Study Director for a copy of your personal results from this study. You will need to provide your name and a mail or e-mail address.

COSTS

There will be no costs to you for participation in this study.

BENEFITS

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You will not directly benefit from your participation in the study. The farm owner may benefit from the product used in the study since AHETF will reimburse the owner for that product. Information from this study will be used to improve the quality of pesticide safety assessments for workers using closed cab airblast equipment.

PAYMENT FOR PARTICIPATION

You will be paid $20 if you meet privately with a researcher to review this informed consent. You will receive the money whether you decide to participate or not. You will receive the money in cash right after the meeting.

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_____ 3/4/08
Signature Date

Initials: _____
Date: _____

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You will be paid an additional $80 for the day you participate in sampling. You will be paid $80 for completing the sampling day and allowing us to collect your samples. If you decide to withdraw during the sampling, you will still be paid the $80. If we remove you from the study, you will still receive the $80. Payment will be in cash at the end of the sampling day.

You will also receive your normal pay from your employer.

If more people volunteer than we need, we will decide which volunteers participate by drawing names from a container. You may or may not be selected to participate; if not selected, you will not receive the $80.

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VOLUNTARY PARTICIPATION / WITHDRAWAL

Your employer has agreed to let us do the research and has confirmed that he/she does not care whether you to participate in this study. Your decision to be in this study is voluntary and entirely up to you. If you decide to participate, you may change your mind later and drop out of the study at any time and for any reason. A decision not to participate, or to withdraw from the study after it begins, will have no effect on your job or pay or include any penalty or any loss of benefits to which you may be entitled.

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If you withdraw, the long underwear and air sampling pump will be removed, and the hand and face/neck samples may be collected with your consent.

Your participation in this study may be stopped at any time by the researchers or the sponsor. The long underwear and air sampling pump will be removed, and the hand and face/neck samples may be collected with your consent.

If you withdraw or are removed from the study, or if the study does not last an entire workday, you will be released to resume your usual activities.

ALTERNATIVES

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No one can require you to participate in this study. Participation is entirely voluntary. If you choose not to participate in this study, then on the day of the study you will perform your ordinary activities. Your alternative is to not participate.

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

QUESTIONS

If you have questions about this study or if at any time you think you have a research-related injury or illness, contact a researcher or call:

Larry D. Smith (Study Director) at 440-255-1954 (collect)
Or 440-554-2812 (24 hours)
Or
David Johnson, Ph.D. (sponsor contact) at 660-349-4601 ext #1.

If you have any questions regarding your rights as a research volunteer, please contact Kim Lerner, Chairman of the Independent Investigational Review Board, Inc. at toll free (877) 888-iirb (4472) during regular working hours. The Independent Investigational Review Board is a committee established for the purpose of protecting the rights of volunteers in a research study.

IIRB is a group of people who perform independent review of research.

Do not sign this consent form unless you were able to ask questions and received satisfactory answers.

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

CONSENT

I have read the information in this consent form and in the Product Risk Statement (or it has been read to me) in a language I understand well. All my questions about the study and about being in it have been answered. I freely consent to be in this study.

I authorize the release of my research records, including photographs and video recordings, to the sponsor, to the researchers, to government agencies in other states and/or countries, to EPA, to IIRB, and to other parties as required by law.

By signing this consent form, I have not given up any of my legal rights.

_____ _____
Date Subject's Name (print)

_____
Subject's Signature

_____
Subject's Unique Worker Code

I conducted the private consent meeting with the worker named above and confirm that consent was given voluntarily after being fully informed of the benefits, risks, and procedures. In addition, this worker has reviewed and signed the Product Risk Statement which I will store along with this signed consent form in a secure location:

_____ _____
Date Name of Person Conducting Informed Consent Discussion (print)

_____
Signature of Person Conducting Informed Consent Discussion

_____
Title and Affiliation of Person Conducting Informed Consent Discussion

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

---------- Use the following only if applicable ----------

If this consent form is read to the worker because the worker is unable to read the form, an impartial witness (who is not associated with the researchers or who is not part of the management of the grower where the study is being conducted) must be present to witness this worker's consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and understood by, this worker. This worker freely consented to participate in the research study.

_____ _____
Date Impartial Witness' Name (print)

_____
Impartial Witness' Signature

_____
Title and Affiliation of Impartial Witness

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not read English.

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

Amended 3-20-2008 Page 1 of 2

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

Deleted: to Crops

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

Formatted: French (France)

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Sevin® Brand 80WSP Carbaryl Insecticide (EPA Registration No. 264-526)

Active Ingredient (AI): Carbaryl (insecticide, CAS No. 63-25-2)

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Formulation and Packaging: 80% AI dry powder in a 1.25 lb water soluble pack

You may handle up to: 100 water soluble packs

Version: 3/4/08
Protocol: AHE55
Sevin® Brand 80WSP

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear waterproof gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

Deleted: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), t

This carbaryl product is classified as moderate toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye irritation, minimal skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 9/23/04
MSDS date: 12/26/02 (number 000000001825; Version 1.1)

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

Version: 3/4/08
Protocol: AHE55
Sevin® Brand 80WSP

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

Amended 3-20-2008

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

Deleted: to Crops

SPONSOR AND SOURCE OF FUNDING:

Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

Formatted: French (France)

STUDY DIRECTOR:

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction

You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Sevin® Brand 4F Carbaryl Insecticide (EPA Registration No. 264-349)

Active Ingredient (AI): Carbaryl (insecticide, CAS No. 63-25-2)

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Formulation and Packaging: 4 lb AI/gallon Flowable liquid in 2.5 gallon plastic jugs

You may handle up to: 25 gallons of product

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Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

Amended 3-20-2008 Page 2 of 2

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

Deleted: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), t

This carbaryl product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye irritation, minimal skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 9/27/04
MSDS date: 12/18/02 (No. 000000000194, Version 2.1)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

Version: 3/4/08
Protocol: AHE55
Sevin® Brand 4F

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

Amended 3-20-2008

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

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SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

Formatted: French (France)

STUDY DIRECTOR: Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Gowan Malathion 8 (EPA Registration No. 10163-21)

Active Ingredient: Malathion (insecticide, CAS No. 121-75-5)

Formulation and Packaging: 8 lbs AI/gallon Emulsifiable Concentrate

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You may handle up to: 12.5 gallons of product

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Independent IRB

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Signature Date

Initials: _____
Date: _____

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This malathion product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye and/or skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label ID: 04-R0699
MSDS date: 2/1/07 (Gowan Malathion 8 Flowable)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

APPROVED BY
Independent IRB
_____ 3/4/08
Signature Date

Initials: _____
Date: _____

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Amended 3-20-2008 Page 1 of 2

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

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SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

Formatted: French (France)

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
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This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Malathion 8-E Insecticide (EPA Registration No. 34704-452)

Active Ingredient (AI): Malathion (insecticide, CAS No. 121-75-5)

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Formulation and Packaging: 8 lbs AI/gallon Emulsifiable Concentrate in 1 gallon plastic jugs

Version: 3/4/08
Protocol: AHE55
Malathion 8-E

APPROVED BY
Independent IRB

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Signature Date

Initials: _____
Date: _____

You may handle up to: 12.5 gallons of product

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

Deleted: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), t

This malathion product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include moderate eye irritation, slight skin irritation, possible allergic skin reaction, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: None found
MSDS date: 6/8/06 (Loveland MSDS #000452-06-LPI)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

Version: 3/4/08
Protocol: AHE55
Malathion 8-E

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

Amended 3-20-2008

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

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SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

Formatted: French (France)

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
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This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Fyfanon® (EPA Registration No. 5905-196)

Active Ingredient (AI): Malathion (insecticide, CAS No. 00121-75-5)

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Formulation and Packaging: 5 lbs AI/gallon Emulsifiable Concentrate

You may handle up to: 20 gallons of product

Version: 3/4/08
Protocol: AHE55
Fyfanon®

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves and protective eyewear. The gloves and protective eyewear must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

Deleted: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), t

This malathion product is classified as moderate toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include moderate eye irritation, slight skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 2005 MSDS date: 10-5-05

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

Version: 3/4/08
Protocol: AHE55
Fyfanon®

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

Amended 3-20-2008

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

Deleted: to Crops

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

Formatted: French (France)

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Fyfanon® 8 lb. Emulsion (EPA Registration No. 5905-250-ZA)

Active Ingredient (AI): Malathion (insecticide, CAS No. 00121-75-5)

Formulation and Packaging: 8 lbs AI/gallon Emulsifiable Concentrate in 1 or 2.5 gallon plastic jugs

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

You may handle up to: 12.5 gallons of product

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

Deleted: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), t

This malathion product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include moderate eye irritation, slight skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 2005
MSDS date: 1-5-05

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

Version: 3/4/08
Protocol: AHE55
Fyfanon® 8 lb. Emulsion

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

Amended 3-30-2008 Page 1 of 2

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

Deleted: to Crops

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

Formatted: French (France)

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Sevin® Brand XLR Plus Carbaryl Insecticide (EPA Registration No. 264-333)

Active Ingredient (AI): Carbaryl (insecticide, CAS No. 63-25-2)

Formulation and Packaging: 4 lb AI/gallon Flowable liquid in 2.5 gallon plastic jugs

You may handle up to: 25 gallons of product

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

Amended 3-30-2008 Page 2 of 2

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

Deleted: Based on the most recent product label and Material Safety Data Sheet (which will be discussed with you and be available for your review), t

This carbaryl product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye irritation and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 9/21/04
MSDS date: 1/17/08 (Bayer MSDS 102000001927, Version 2.1)

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08

Version: 3/4/08
Protocol: AHE55
Sevin® Brand XLR

APPROVED BY
Independent IRB

_____ 3/4/08
Signature Date

Initials: _____
Date: _____

LS Consulting

From: LS Consulting [lsconsulting@oh.rr.com]
Sent: Monday, March 24, 2008 10:20 AM
To: 'rroogow@iirb.com'
Cc: 'David R Johnson'
Subject: Additional Amendments to Protocols AHE55 and AHE56
Importance: High
Attachments: Additional Amendments to AHE55 Protocol 3-24-2008.doc; Additional Amendments to AHE56 Protocol 3-24-08.doc; 10 G 0 from AHETF SOP Manual 052406-2.pdf; 8 G 2 from AHETF SOP Manual 052406.pdf

Robert,

As we discussed earlier I have made additional amendments in the protocols for AHE55 and AHE56 that correct certain SOP citations in these documents. For clarity I have accepted the changes in the protocol amendment documents submitted to you last Friday, 3-21-2008. The current corrections are tracked in the attached documents.

Since these corrections to the protocols include citations to two previously unsubmitted AHETF SOPs, I have included these in this submission.

Thank you for your assistance. Please call me if you have any questions about these submissions.

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, OH 44060
440/255-1954

AGRICULTURAL HANDLERS EXPOSURE TASK FORCE (AHETF)

STUDY No. AHE55

Study Title: Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

PROTOCOL AUTHORIZATION

Read and Approved by:

AHETF Sponsor Representative: David R. Johnson, Ph.D.

Signature _____

Date _____

Study Director: Larry D. Smith, Ph.D.

Signature _____

Date _____

TABLE OF CONTENTS

1.0 GENERAL INFORMATION

1.1 Study Title

Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

1.2 Study No. AHE55

1.3 Objective

The objective of this study is to develop data to determine the potential exposure for workers making closed cab airblast applications in Florida citrus.

1.4 Timeline

Proposed Experimental Start Date: August, 2008

Proposed Experimental Termination (Field Phase) Date: April, 2009

Proposed Experimental Termination (Analytical Phase) Date: October, 2009

Proposed Final Report Issue Date: December, 2009

1.5 Good Laboratory Practice

This study will be conducted in compliance with the US EPA FIFRA Good Laboratory Practice (GLP) Standards (40 CFR 160) and will adhere to applicable AHETF and/or field facility standard operating procedures (SOPs) and field work practices.

1.6 Pesticide Assessment Guideline

This study is based upon EPA's guidance documents for dermal and inhalation exposure measurement under Series 875: Occupational and Residential Exposure Test Guidelines. Data reporting will follow the requirements defined in these guidelines.

1.7 Institutional Review Board

Independent Investigational Review Board Inc. (IIRB)
6738 West Sunrise Blvd. Suite 102
Plantation, FL 33313
Telephone: 954-327-0778
E-mail: info@IIRB.com

1.8 Testing Facility, Sponsor's Representative and Sponsor

Agricultural Handlers Exposure Task Force, LLC
c/o David R. Johnson, Ph.D.
1720 Prospect Dr.
Macon, MO 63552
(660) 395-9590
davejohn@marktwain.net

1.9 Study Director

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, OH 44060
(440) 255-1954
lsconsulting@oh.rr.com

1.10 Principal Field Investigators

Principal Field Investigators may include:

Brian Lange
Access Research and Consulting, Inc.
4720 W. Jennifer Ave., Suite 106
Fresno, CA 93722
Phone: 559-277-5272
brian@accessrc.com

Tami Belcher
Grayson Research, LLC
1040 Grayson Farm Road
Creedmoor, NC 27522
Phone: 919-528-5508
tbelcher@graysonfarm.com

Aaron Rotondaro
Paragon Research Services, Inc.
6773 Woodcliff Circle

Zionsville, IN 46077
Phone: 317-733-1243
arotondaro@indy.rr.com

During the consent process, each study participant will be informed of which of the above researchers will be involved with monitoring his/her exposure.

1.11 Field Facilities

Southeast Ag Research
86 Jim Moore Rd.
Chula, GA 31733
Phone: 229-386-8989
smith@seagr.com

1.12 Principal Analytical Investigator and Analytical Facility

To be determined and amended to the protocol prior to initiation of the field phase of the study.

1.15 Quality Assurance Unit

Compliance Assessment and Training, Inc.
Randy Fuller
2309 Patton Ct.
Lexington, KY 40509
Phone: 859-264-8844
randyfuller@windstream.net

2.0 ETHICAL CONSIDERATIONS

This study will be conducted in accordance with EPA's final regulation published at 40 CFR Part 26 that establishes requirements for the protection of subjects in human research. The protocol, informed consent form, and other required documentation for this study will be approved by an institutional review board (IRB) and submitted to the EPA as required by 40 CFR 26.1125. The report of the completed research is subject to 40 CFR 26.1303 requirements to document its ethical conduct.

The proposed research described by this protocol, the informed consent form, and all recruitment materials, such as handouts or visual aids, shall be reviewed and approved by Independent Investigational Review Board Inc. (IIRB) of Plantation, Florida. Complete records of the IRB review as required by 40 CFR 26.1125 will be submitted to EPA for review along with this protocol and other documents.

Researchers that participate in the study and interact with study participants must undergo ethics training (SOP AHETF-1.B). The training shall include successful completion of the course from the National Institutes of Health (NIH; Human Participant Protections Education for Research Teams) and/or the Basic Collaborative IRB Training Initiative Course (CITI; The Protection of Human Research Subjects). Copies of the certificates of completion for the ethics courses will be submitted to the IRB and stored in the respective personnel files (maintained by the AHETF and all contract facilities.)

2.1 Inclusion and Exclusion Criteria

AHETF has established the following inclusion and exclusion criteria for this closed cab airblast application study.

Participants in this study must meet the following inclusion criteria;

- Be freely willing to participate and to understand and sign the consent form
- Handle pesticides as part of their job
- Be trained in safe pesticide handling practices in accordance with the Worker Protection Standard (WPS), or be exempt from such training
- Have experience within the past year with making airblast applications to citrus using closed cab tractors and airblast sprayers (including the particular equipment to be used)
- Be at least 18 years old with a government-issued ID to verify age
- Consider themselves to be in good general health with no medical conditions that could impact their ability to participate in the study
- Be willing to follow all label and WPS requirements

In addition, potential subjects who meet the following exclusion criteria will not be allowed to participate in this study:

- Are pregnant females
- Are nursing mothers
- Normally wear personal protective equipment (PPE) that is not required by the label, such as chemical-resistant clothing
- Don't understand Spanish or English
- Are employed by a pesticide manufacturer or a contractor to AHETF (except employees of the Local Site Coordinator)

2.2 Remuneration of Subjects

During recruitment, workers will be offered an opportunity to take part in a group meeting with the Study Director or other designated member of the study team (but without the workers' supervisors) to learn about participating

in this study (Section 6.2). No remuneration is offered for this introductory meeting. Workers who are still interested will attend a private meeting with a researcher who will obtain the informed consent of the worker (Section 2.7). Workers will be paid $20 for their attendance right after the consent meeting, whether or not they decide to participate in the study. Workers who decide to participate in the study will be paid an additional $80 each time they suit up (i.e., put on the long underwear) to participate in the study. Usually, workers will participate in the study on only one day unless their participation is terminated due to weather or other unexpected occurrences. The additional $80 is provided in cash at the end of the monitoring period or at the time the volunteer withdraws from the study. All workers who participate will receive the payment, even if they withdraw or their participation is terminated by the study team.

2.3 Risks to Subjects

Six kinds of risks are associated with the conduct of the current exposure monitoring study. These are:

- The risk of heat-related illness
- The risk of exposure to surrogate chemicals
- The risk associated with scripting of field activities
- Psychological risks
- The risk of exposure to detergents
- The background risk of injury associated with agricultural work

In this study risks to subjects are classified as "greater than minimal", primarily since agricultural work is considered a high risk occupation where the likelihood of harm or discomfort is greater than what is encountered in ordinary daily life. In particular, this study involves the operation of tractors and airblast sprayers which present risks of accidents and physical injury, as well as the use of chemicals (pesticides, fertilizers, additives, etc.) which presents a risk of adverse health effects. In addition, AHETF believes the risk of heat-related illness (resulting from wearing an extra layer of clothing to trap chemical) will be increased due to study participation. AHETF has adopted an extensive program to minimize these risks. All of the risk minimization procedures, as described in AHETF SOPs, will be followed during the conduct of the study.

2.3.1 Risk of Heat-Related Illness

This study involves the application of liquid sprays to citrus crops using airblast equipment and tractors with a closed cab. All airblast applications will be made outdoors and some locations and dates are likely to result in hot and/or humid conditions. AHETF expects most tractors to be air conditioned, thus reducing the potential for heat-

related illness. AHETF will not accept tractors without properly operating air conditioners. Researchers will inquire of the participants whether or not the air conditioner units function in their tractors. All participants in the study will be wearing an extra layer of clothing (i.e., long underwear under their WPS-required clothing) that they would not normally wear under such conditions. For these reasons, the study will likely involve an increased risk of heat-related illness due to study participation. AHETF researchers will therefore be vigilant in following the extensive educational and monitoring procedures designed to minimize the risk of heat-related illness that are detailed in SOP AHETF-11.G.

Since heat-related illness may occur during the conduct of the study, Study Directors shall have first aid training that includes recognition of signs and symptoms of heat-related illness. A copy of the certificate of completion of this training will be included in the Study Director's personnel file, maintained by the AHETF.

The following procedures will be followed by researchers to minimize the risk of heat-related illness in study participants:

- Ensure plenty of water and sports drinks are available for the workers.
- During worker orientation immediately before participation in the study, remind the workers of the risk of heat stress, suggest they drink some water before they start work, and let them know how/where they can get water during the monitoring period.
- Urge workers to drink water during the monitoring period and remind them that thirst does not give a good indication of how much water a person needs to drink.
- Observe workers during the monitoring period and be aware of the signs and symptoms of heat-related illness.
- Require workers to take rest breaks when early signs or symptoms of heat illness are present.
- Monitor the heat index (based on air temperature and relative humidity) at least hourly whenever ambient temperature is at or above 70 ºF.
- In cases where the worker has exited the air conditioned cab for a period exceeding 30 minutes, stop the worker activity when the heat index (adjusted for direct sunlight, if applicable) reaches 120^0F and/or move the worker to a cooler environment until monitoring can be resumed
- Have a medical professional on site to observe for signs of heat-related illness
- Know the location of the nearest medical facility

AHETF anticipates that applicators who participate in the study will spend the bulk of their time in the closed cab tractor; driving the tractor and making applications. This is a "sedentary" activity as defined by the North American Free Trade Association (NAFTA) Technical Working Group on pesticides (1998), so physical exertion is low which will reduce the likelihood of heat-related illness. However, each participant will be required to spray at least three loads of pesticide spray, so there will also be some time spent at a mixing/loading site waiting while another (non-study) worker prepares the next load. During these times, the study participant may exit the cab and be exposed to ambient temperatures and humidity which will increase the likelihood of heat-related illness. Applicators may also exit the cab periodically to adjust or repair equipment, if that becomes necessary.

Since workers may exit the cab, AHETF will monitor ambient conditions outside the cab to determine the heat index and base monitoring decisions on the external heat index. A heat index of 120°F is the cutoff, as measured outside the cab. When the worker is inside an air conditioned closed cab the external heat index will not be applicable to that subject and exposure monitoring will not necessarily stop if the heat index cutoff is reached or exceeded. A worker will be allowed to exit the cab for short periods of time even if the heat index cutoff is exceeded; however, if the duration of exiting becomes prolonged (more than 30 minutes), the Study Director or other researcher shall stop the monitoring and/or move the worker to a cooler environment until monitoring can be resumed. For example, a worker who exits an air conditioned cab to adjust the airblast sprayer (e.g., nozzles, deflectors, pressure, etc.) might spend only a few minutes doing so and monitoring would not need to be stopped. On the other hand, if a worker exits to make a repair of the equipment, and it takes more than a half-hour, researchers will stop the monitoring and/or require the worker to move into a cooler environment (e.g., back into the air conditioned cab or into a cooler building).

In addition to the procedures discussed above, it is possible that some monitoring will take place at night or early in the morning to avoid excessively hot and humid conditions. Discussions with orchard airblast applicators in Florida and Georgia (July, 2007) indicate this is often preferred by workers since winds tend to be lower than during the day and temperatures tend to be cooler. AHETF will encourage this practice when daytime conditions are expected to approach the heat index cutoff of 120º F (adjusted for direct sun, if applicable).

2.3.2 Risk of Exposure to Surrogate Chemicals

The short duration of study participation for a subject (generally only one day) limits the risk of toxicity from surrogate chemicals to acute toxic effects (i.e., the potential for chronic effects is negligible). The active ingredients proposed for use in this study have been reviewed to determine the relative acute toxicity risks and status of reregistration at EPA. This study could involve either of two active ingredients: carbaryl or malathion.

The pesticide products containing these active ingredients and potentially used in this study are currently registered for airblast applications to citrus crops. AHETF will only monitor workers making applications in accordance with all label and Worker Protection Standard (WPS) requirements. Margins of Exposure (MOEs) are presented below for the highest amount of active ingredient that will be handled in this scenario (100 lb ai/day). For each of the active ingredients that may be used in this scenario the calculated MOEs greatly exceeded the required MOE for both the individual dermal and inhalation routes of exposure, as well as for the combined exposure, and their use is acceptable for this scenario.

Margins of Exposure for Closed-cab Airblast Application:

	Carbaryl	Malathion
Max. Daily Amount Handled	100 lb ai/day	100 lb ai/A
Dermal MOE	**3,308**	**4,885**
Inhalation MOE	**1,719**	**40,313**
Combined MOE	**1,130**	**4,400**

Level of concern (LOC) dermal = 100
LOC inhalation = 100 (carbaryl) or 1000 (malathion)
LOC combined = 100

The potential surrogates are listed below. All include minimal PPE requirements, especially the need for only a single layer of clothing. A summary of the signs and symptoms of acute overexposure to these products is presented in the following table. Additional detailed information is presented in the Product Risk Statements for these products (attached to the Informed Consent Form).

Product	Signal Word	Acute Toxicity Summary
Sevin® brand 80WSP Carbaryl Insecticide	CAUTION	• Slight eye irritation • Low toxicity for oral, dermal, and inhalation routes • Cholinesterase inhibition
Sevin® brand XLR Plus Carbaryl Insecticide	CAUTION	
Sevin® brand 4F Carbaryl Insecticide	CAUTION	
Fyfanon® 8 lb. Emulsion	CAUTION	• Moderate skin irritation • Moderate eye irritation • Possible allergic skin reactions • Low toxicity for oral, dermal, and inhalation routes • Cholinesterase inhibition
Fyfanon®	CAUTION	
Malathion 8-E	CAUTION	• Moderate eye irritation • Slight skin irritation • Possible allergic skin reaction • Low toxicity for oral, dermal, and inhalation routes • Cholinesterase inhibition
Gowan Malathion 8 Flowable	CAUTION	

AHETF will make an effort to select growers who would normally be using one of these products regardless of their participation in the monitoring study. However, some growers might agree to use one of the listed surrogate products as a substitute for their usual product. In all cases, AHETF will ensure the workers are informed of the risks associated with the specific surrogate product during the informed consent process and prior to participation by reviewing the product label with the worker. In addition, attached to the informed consent form will be a Product Risk Statement that details the signs and symptoms of overexposure for the specific product that each worker will handle. This risk statement must be understood and signed by the subject during the consent process.

The risk of acute toxicity will be minimized by reminding workers of safe handling practices prior to participation in the study, ensuring that worker clothing meets WPS requirements prior to participation, and enforcing the use of label-specified PPE (especially the use of gloves outside the cab if contacting contaminated surfaces) during participation.

For this application study, participants will only be exposed to product that has been diluted in water. The closed cab will likely provide significant protection from both dermal and inhalation exposure. In

addition, dermal exposure potential will be reduced since the long underwear will intercept chemical that might otherwise reach the subject's skin. Therefore, the likelihood of acute overexposure to the test substance during this study is expected to be very low.

2.3.3 Risk Associated with Scripting of Field Activities

AHETF may script certain participant activities to achieve diversity in some factors that might have an impact on exposure potential for a scenario. In particular, for this closed cab airblast application study scripting may be needed to ensure that at least three loads are handled or that certain amounts of active ingredient are handled. However, workers will not be asked to use equipment they do not have recent experience with (i.e., within the past year).

In order to ensure all MUs involve handling at least three loads, AHETF may ask some workers to use a smaller tank size or a higher spray volume than they would normally select. This might lead to a slightly longer work period for those workers which may increase the risks of acute toxicity to the surrogate chemical and of heat-related illness. This type of scripting is only likely for MUs involving the lower amounts of active ingredient handled (AaiH) in the study, such as 5 to 9 or 10 to 17 pounds of AaiH (Section 7.8). If spray volume is increased, the worker's exposure would be to a more dilute spray solution. The increased work period might increase the risk of heat-related illness, but this scripting is likely to result in work periods of only about 4 hours. In summary, scripting to ensure at least three loads are handled involves MUs with relatively low chemical exposure and relatively short work days, so this type of scripting is not likely to result in increased risk.

In order to achieve diversity in AaiH at the high end, AHETF may ask some workers to use larger tank sizes or a lower spray volume per acre than they would normally select. These changes might result in longer work periods and greater chemical exposure than would otherwise occur and this may increase the risks of acute toxicity to the surrogate chemical or heat-related illness. With regard to the increased risk of heat-related illness, this will primarily depend on local environmental conditions. For these MUs, researchers must be extra vigilant in following the guidance discussed above for minimizing the risks of chemical exposure and heat-related illness.

2.3.4 Psychological Risks

Participating in AHETF exposure monitoring studies involves activities that are unusual and might cause subjects psychological

distress. These include:

- Performing an over-the-counter pregnancy test prior to participation (females only)
- Allowing a researcher to assist with removing long underwear

Minimizing the risk of psychological harm related to pregnancy tests involves providing a private place for women to take the test and following procedures outlined in SOP AHETF-11.D to ensure the confidentiality of a positive result. Minimizing the risk of embarrassment during undressing involves providing a private dressing area and ensuring a worker of the same gender will be available to assist in the process.

2.3.4 Risk of Exposure to Detergents During Face/Neck Wipe and Hand Wash Sampling

A very dilute detergent solution (0.01% v/v Aerosol® OT in water) is used as a surfactant for face/neck wipes and hand washes for all MUs. The only variation between MUs is in the duration of exposure since longer work periods or frequent eating breaks can lead to multiple hand washes and/or face/neck wipes. This surfactant is in a very dilute solution and its use represents a very short exposure period, but the undiluted surfactant causes mild to moderate skin and eye irritation in animals. This risk is minimized by making fresh solutions shortly before monitoring, being careful to avoid accidental exposure to the eyes during face/neck wipes, and having an eye rinse station on hand in case of an accidental exposure.

A long history of using this mild detergent solution in pesticide exposure monitoring studies indicates the likelihood of skin or eye irritation is negligible.

2.3.5 Background Risk of Injury Associated with Agricultural Work

Agriculture remains one of the country's most dangerous occupations (i.e., farm occupations, see Bureau of Labor Statistics). It perennially ranks in the top ten occupations measured by fatality rate (on-the-job deaths divided by total number of workers) or injury/illness rate. The most common risks for serious injury to farmers are vehicular accidents (especially tractor rollovers, but also accidents while driving machinery on roads) and entanglement with moving parts of farm machinery. Farm workers are also commonly exposed to a variety of chemical products that present increased risks compared to the general public. These include pesticides, fertilizers, solvents, lubricants, fuels,

etc.

For this closed cab airblast application study, the risk of injury will involve the use of mechanical equipment for all MUs (the tractor as well as the airblast sprayer) and for some MUs will likely involve the use of chemicals in addition to the AHETF surrogate chemical, such as spray adjuvants or other pesticide products. These risks are discussed below.

This study will require workers to utilize two pieces of equipment: a closed cab tractor and an airblast sprayer. AHETF will have very little input on the choice of equipment that workers utilize during exposure monitoring since it is generally dictated by the crop involved and the size of the farm or operation. However, AHETF will require that all participants have experience operating the particular equipment they will utilize in the study. Workers will operate their usual tractor unless researchers determine the closed cab is not intact. If that happens, the worker can use another suitable tractor with which he has experience. Workers will use their usual sprayer unless AHETF requests a different tank size. If that happens, the worker can use a more suitable sprayer with which he has experience, but if no such sprayer is available another worker will be selected who has the necessary experience with that equipment. These practices are designed to ensure the risk of injury from equipment is not increased by asking a worker to use equipment he is not familiar with.

Growers often choose to include chemicals other than the pesticide product in their tank mixes, such as anti-foam agents, spreaders, stickers, other pesticides, or fertilizers. This is likely to be the case during this study, but it is impossible to know in advance, since some decisions are made at the last moment depending on agronomic conditions. AHETF will allow the use of such tank mix "partners" so long as they are legal uses, don't interfere with chemical analysis of the AHETF surrogate pesticide being applied, and do not require the worker to wear any additional PPE. Prior to allowing the use of tank mix partners AHETF researchers will ensure that none of these situations exists. Since AHETF does not require addition of tank mix products, any risks associated with exposure to such products would not result from a worker's participation in this research, and would simply be among the background risks normally experienced as part of the job. Nevertheless, a researcher will review the label precautions for all tank mix products with the worker prior to their handling the products. This discussion will be documented by the researcher and ensures the workers are informed of the risks associated with these tank mix products.

In summary, this study will likely involve a risk of physical injury based on the nature of the agricultural work involved and possibly an increased risk of heat illness. The following practices, designed to minimize these risks and respond to injuries, will be followed during this study:

- Selecting only experienced pesticide handlers
- Requiring experience operating the equipment to be used
- Reminding workers of safe chemical handling practices
- Identifying nearby hospitalization facilities in case of emergency
- Monitoring the heat index and stopping the study if conditions warrant
- Providing transportation to medical treatment and covering the costs of treatment
- Having a medical professional on site to observe the workers and provide urgent care
- Observing study participants throughout the monitoring period
- Ensuring that all tank mix products are used according to approved label (s) and do not require any additional PPE.

2.4 Benefits

The risks and likely benefits of the study described in this protocol will be reviewed with potential participants during the consenting process. There are no personal benefits to the study participants. Growers who allow the study to be conducted using their equipment, crops and facilities will be reimbursed for the pesticides used for the study. While this is beneficial to the grower, it is considered a minor benefit when compared to the costs of running their businesses. The AHETF member companies will likely realize a benefit by addressing regulatory data requirements generically, at lower cost (and using fewer human subjects), than if they conducted similar studies for individual pesticide ingredients.

Data from the AHETF exposure monitoring program has the potential to improve the ability of EPA and other regulatory agencies to accurately assess occupational risks associated with spraying pesticides using airblast equipment and closed-cab tractors. The knowledge likely to be obtained from this study is generalizable and will contribute to assessments of the risks of both new and existing pesticides.

Since there are no existing data suitable for use in a generic database describing the exposure of closed-cab airblast application workers, society will likely benefit from data generated by this study through the improved risk assessments by EPA and other regulatory agencies.

2.5 Risk/Benefit Balance

By monitoring exposure to professional agricultural handlers who follow their normal practices, but wear an additional layer of clothing (as an inner dosimeter which traps chemical that penetrates the work clothing), this study presents a greater than minimal risk to participants. The primary risk comes from their employment as an agricultural worker where accidents and chemicals contribute to injury and illness. In particular, this scenario involves the use of mechanical equipment that could cause physical injury and handling chemicals that could cause adverse health effects. However, workers will be experienced with the equipment they will be using and will follow their usual practices while handling pesticides approved for this use pattern.

Participating in this study increases the risk of heat-related illness, but this risk is mitigated by a medical management program which emphasizes prevention measures and guidelines for stopping participation when warranted based on environmental conditions.

The likely benefit to agricultural workers as a whole and to society in general, in the form of more accurate measurements of potential exposure to pesticides, must be weighed against the risks to participants. Airblast applications are common in both orchard and trellis crops across the country, and a wide variety of experts consulted by AHETF reported that closed cabs are most common now, and are becoming even more common. Exposure data for this scenario meeting contemporary standards of reliability and quality will likely provide a significant benefit to society. Because the margins of exposure (MOEs) calculated for the exposures in this research indicate that subjects are very unlikely to experience acute toxic effects, and because extensive procedures will be in place to minimize these and other risks to participants, the likelihood of serious adverse effects is very small. In sum, AHETF believes the risks to study participants from participating in this study are reasonable in light of the likely benefit to society of the knowledge to be gained.

2.6 Respect for Subjects

2.6.1 Subject Privacy

The AHETF employs many procedures, summarized below, to protect subject privacy during recruitment, consent, study conduct, and maintenance of study records. The consent form also summarizes important confidentiality issues for subjects.

Initial contact with workers during recruitment will be made without the presence of their employer as described in detail in Sections 2.7

and 6.2 of this protocol. If workers are interested in participating, a private meeting with the Study Director or his/her designee will be used to explain the study further, address any questions, and seek the candidate's consent to participate.

Pregnancy tests, required for female participants, must be conducted within 24 hours of the start of the monitoring period. These will be self-administered in a private restroom, but under the supervision of a female researcher. Positive results from pregnancy tests will not be documented or given to a woman's employers or co-workers. If a female volunteer has a positive pregnancy test result, she must withdraw from participation but can do so without stating a reason. Consent forms and all other records associated with the worker will be promptly shredded (SOP AHETF-11.D). Negative results must be confirmed by a female researcher and recorded in the study files.

Certain worker information will be collected during the course of this worker exposure monitoring study. The information collected, such as notes taken by study observers, will not be available to a participant's employer. Most information identifies subjects only by a unique worker identifier. Forms and paperwork that contain personal information (including a worker's name or address) will be kept confidential in a sealed envelope while in the field. After the study is completed, this confidential envelope will be sent to AHETF archives with the other raw data. Unrestricted access to this confidential information is allowed only to the AHETF Administrative Chair (SOP AHETF-6.B).

The information collected in this study may, under certain regulatory circumstances, be given to the U.S. Environmental Protection Agency (EPA) or to state governmental agencies and other countries. Participants in the study will be informed that their names will not be disclosed, but that absolute confidentiality cannot be guaranteed because of the need to give information to these parties.

The results of this research may be presented at meetings or in publications; however, only a unique worker identification number will identify each worker in reports or presentations.

2.6.2 Freedom to Withdraw

The absolute right for subjects to withdraw from the research is the cornerstone of protection of human subjects. Prospective and enrolled subjects will be informed of their right to withdraw without consequence prior to and during the conduct of the research.

Any volunteer expressing a need or desire to withdraw from the

research after exposure monitoring begins will be paid $80 and allowed to return to their normal work duties for their employer. If a participant withdraws while being monitored, the long underwear and air sampling pump will be removed, and the hand and face/neck samples will be collected with the worker's consent. The Study Director will decide whether these samples will be analyzed (SOP AHETF-8.K).

2.7 Informed Consent

The Study Director or designated member of the study team will obtain informed consent from all study volunteers prior to their participation in the study. The consenting process is conducted in a private meeting between the researcher and the volunteer (and possibly other individuals as described below). Depending on the circumstances, consenting may occur several days prior to the study up to the day of the study. The volunteer will be given a copy of the consent form to review at least one day before the consent meeting, and advised of study provisions to accommodate their language preference, the need for readers, witnesses, and their desire to have a confidant or counselor present during an informed consent meeting. For example, the volunteer may feel more comfortable with a confidant or counselor in the consent meeting with him/her.

Study participation will be limited to English or Spanish speakers. When Spanish speakers are involved, a bilingual researcher will conduct the interview. Potential participants that have limited reading ability will have the consent form verbally explained in their preferred language (English or Spanish) with an impartial witness (bilingual as appropriate) present. Witnesses must have no association with AHETF, its member companies, researchers, growers, or workers. Witnesses must have some familiarity with farming and will be recruited from any appropriate source such as a university, grower association, or other organization. The witness cannot serve as the interpreter or an advisor to the volunteer. The witness will sign the consent form to acknowledge that the study participant apparently understood the information presented to him/her.

During the private consent meeting the worker will be provided with a full explanation of the study, its requirements, any potential risks, and its likely benefits. Workers will be informed that the grower or their employer will be reimbursed for the product used in the conduct of the study on their farms. Workers will be advised of their right to withdraw from the study at any time and for any reason without jeopardizing their normal position with their employers. Each volunteer will be provided a copy of the supervisor's signed Employer's Cooperation Statement (in the worker's preferred language) that states they will not suffer any consequence if they decide to participate or not and they will receive their usual pay for the day when the study is conducted.

The volunteer will be informed that he/she will receive the $20 remuneration payment even if he/she decides not to participate.

The volunteer will be provided information about the risk of the particular product he/she will handle, including signs and symptoms of acute overexposure. The product and its risks will be identified in a Product Risk Statement that is an attachment to the consent form. Appropriate sections of the product label and Material Safety Data Sheet will be discussed by the person conducting the consent meeting and made available for review by the volunteer. WPS requirements, especially proper use of clothing, personal protection equipment, and cleaning facilities will be discussed.

The Study Director or designated member of the study team will discuss the germane aspects of the AHETF medical management plan with the prospective participants. Information will be provided about the risk of heat stress, including signs and symptoms, and ways to prevent it.

The IRB-approved consent form will be presented in the preferred language (English or Spanish) of the volunteer. All sections of the consent form including the test substance Product Risk Statement will be discussed in detail.

During the discussions with potential participants, ample time will be provided for questions and any additional information or clarification that is requested will be provided. When the Study Director or designated member of the study team is satisfied that the volunteer understands the requirements and risks of the study, and if the worker still wants to participate, he/she will be asked to sign and date the informed consent form and the Product Risk Statement. The member of the study team conducting the interviews (and witness, if applicable) will also sign the consent form and provide a copy of the signed form (and signed attachments) to the worker. The worker will be informed of the impending date of the study and paid $20 for their participation in the private meeting.

When the pool of available worker volunteers at a site, or a particular citrus grove, exceeds the number of MUs required, a simple random selection of equivalent participants will be made. The names of the volunteers will be written on slips of paper of equal size and placed into a container and mixed thoroughly. The required number of slips will be drawn from the container to fill the MUs. All potential participants will be informed of the possibility of not being selected for this reason. Volunteer workers who decide against participation or who are not selected will be paid $20 for meeting with the study team member and released to resume their normal activities.

In all situations, if the AHETF interviewer is not comfortable that the worker fully understands the discussions and the contents of the consent form, the worker will be excluded from consideration to participate in the study. This

will be ascertained by providing repeated opportunities to ask questions and by asking questions of the potential volunteers that would require a response that indicates understanding of key issues for all sections of the consent form. These responses will be documented and if necessary the person conducting the consent meeting will re-explain topics until the volunteer demonstrates an appropriate understanding.

2.8 Study Procedures

During the consenting process the Study Director or designated researcher will inform each volunteer of the procedures used during the study. Volunteers will be informed if they participate in this study, they will do the following:

1. Provide their name and years of experience making closed cab airblast applications.
2. Confirm whether they have received pesticide safety training or are exempt from pesticide safety training.
3. Allow researchers to measure and record their height and weight.
4. Allow researchers to record their gender, age, and preferred language.
5. Allow the researcher to take notes on the discussions during the informed consent session(s).

Volunteers will also be informed about the procedures to expect on the day of their participation in the study. The Study Director or designated researcher will explain the following procedures to each volunteer during the consenting process. Participants must do the following on the day of the study:

1. Arrive at the study site approximately 1 hour before starting their work.
2. Wash their long-sleeved shirt and long pants before participating in the study to remove any residues of the product we are studying.
3. Bathe or shower the evening or morning before participating in the study to remove any residues of the product we are studying.
4. Wear all personal protection equipment required by the product label (see Product Risk Statement).
5. Work about 4 to 8 hours applying a commercial pesticide according to their normal practices and spray at least 3 loads. Participants will apply the pesticide according to the product label.
6. Wear new long underwear underneath their long-sleeved shirt and long pants. Participants may wear their choice of personal undergarments under the long underwear. The long underwear will be supplied by AHETF and collected at the end of the day. Participants will be asked to dress and undress with the assistance of a researcher of the same sex. A changing area will be provided for privacy. When participants complete their work in the study, they will put on their own clothes and return to their normal work. Participants will be informed there is a risk of becoming overheated and suffering heat illness.

7. Have a tube attached to their shirt collar and connected to a portable air-sampling pump on a belt worn around the waist. Participants will be informed that the pump may be uncomfortable or annoying.
8. Have their face and neck wiped with gauze pads moistened with a mild detergent and water mixture. This will be done before they eat anything, any time they would normally wash their face, and at the end of the workday. Participants will be informed there is a risk of eye or skin irritation from the detergent and water.
9. Have their hands washed in a mild detergent and water mixture. This will be done before they eat anything, any time they would normally wash their hands (such as before using the toilet), and at the end of the day. Participants will be informed there is a risk of skin irritation from the detergent and water.
10. Allow researchers to watch all of their work activities and take notes on what they do.
11. Allow photographs and video recordings to be taken. Participants will not be photographed or video recorded while dressing or undressing. AHETF will own all rights to the photos and videos and may use them for any purpose.

2.9 Post-Exposure Follow-Up

During the consenting process each volunteer will be provided the opportunity to request a summary of their personal results from the study. This will require the worker to provide a name and address (mail or e-mail). The results will include the distribution of chemical exposure among the various body areas measured so the worker can be aware of where most dermal exposure occurs. Results are typically available six to nine months after monitoring occurs. The personal information related to this follow-up will be retained in the confidential envelope described above (SOP AHETF-6.B).

Just prior to the completion of the worker's participation in the study, a researcher will remind the participant he/she should bathe or shower as soon as practical and that they have received a copy of the signed consent form with phone numbers for reporting any health changes they think might be related to participation in the study. Post-study inquiries will be forwarded to the Study Director who will deal with the situation as appropriate and notify AHETF management (SOP AHETF-11.B).

3.0 SITE OF THE FIELD PHASE OF THE STUDY

The site for the field phase of the study will be commercial citrus groves in Polk and Hillsborough counties in Florida. These counties were selected because Polk is highest in orange production and Hillsborough is an adjacent county accessible to major transportation routes. In addition, AEHTF has already expended resources to

discuss airblast applications with the handler community in Florida citrus (Bruce, et. al. 2007) and identified a suitable Local Site Coordinator. These counties are typical of citrus producing areas of Florida that utilize conventional closed cab airblast equipment to maintain the groves. The counties are also adjacent to other citrus producing counties that can be contacted if suitable test conditions cannot be found in these two.

Exposure monitoring will be conducted in at least three citrus groves and require at least three citrus growers within the identified counties.

Researchers will identify eligible growers using a random method as described below.

The primary considerations for site selection will be the availability of citrus crops sprayed with airblast equipment, suitable growers that are willing to use the AHETF surrogate compounds and are willing to participate in the study, and the availability of a Local Site Coordinator with experience conducting similar studies and a familiarity with agricultural practices in the area. Full details of the site selection process and actual sites will be recorded in the study file.

4.0 ELIGIBLE GROWER POOL SELECTION

4.1 Use of Local Resources to Identify Potential Eligible Local Growers

AHETF researchers will contact local resources from each of the following categories in Polk and Hillsborough counties in Florida:

- Local Site Coordinator (LCS)
- Commercial Applicator Firms that service citrus groves
- University Agricultural Researchers / County Extension Agents
- Crop Consultants (e.g., pest control advisors or commercial applicators) that service citrus groves
- Chemical Dealers or Sales Representatives
- Citrus Grower Associations

The researchers will briefly explain the AHETF Exposure Monitoring Program to the local resources who are then asked for a list of growers in Polk and Hillsborough counties who are commercial citrus producers and might utilize airblast equipment in their operations. The list of growers from all of the resources will be compiled and duplicate names eliminated. All local resource contacts shall be documented in a detailed record that shall be maintained in the study file.

4.2 Random Selection of Eligible Growers

The compiled list of growers from local resources shall be placed in random order for further consideration. The randomization process will be

documented and maintained in the study file.

The growers shall be contacted, one at a time, following the random order, to determine whether the grower is 'eligible' to participate in this study. Researchers making the contacts will briefly explain the AHETF Exposure Monitoring Program including the need for the proper equipment, potential worker volunteers, ethical aspects of the study, and reimbursement for the products they supply for the conduct of the study on their farms. Growers are considered eligible who:

- Are willing to cooperate with AHETF, including the ethical aspects of the research,
- Are commercial citrus producers,
- Spray their crop(s) with conventional airblast equipment with closed cabs,
- Have at least one worker with experience making closed cab airblast applications,
- Are willing to allow AHETF to recruit his/her worker(s) for the study
- Have sufficient acreage so the minimum AaiH stratum can reasonably be handled by a worker in one day, and
- Are willing to use at least one of the surrogate active ingredients listed in the study protocol and agree to be reimbursed only for the products utilized in the course of the study on their farm.

Growers who meet the criteria above but indicate they use commercial applicators to make airblast applications to their crop will be asked to identify their preferred commercial applicator(s) and researchers will contact them to screen them for willingness to cooperate by providing suitable equipment and workers to spray that specific grower's crop. This step in the procedure ensures that first the crop acreage is identified and then equipment and workers associated with that acreage are identified. The actual worker involved could be the grower himself, the grower's employee, or an employee of a commercial applicator that services that grower.

Each grower identified as eligible (sometimes with an associated commercial applicator) is placed into a working pool and the following information is assembled to allow construction of an efficient MU selection design:

- Crop(s) available, with acreage that might be treated
- Specific location of crop(s) that might be treated
- Description of equipment available (e.g., number, type, and size)
- Surrogate chemical(s) that might be utilized
- Approximate timing of surrogate applications
- Number of workers available
- AaiH those workers might be able to handle in a day

Screening of the growers (in the order of the random list) continues until the

pool of eligible growers (and/or commercial applicators) contains at least 10 workers who may potentially volunteer for the study, and at least 2 workers are available for each of the AaiH strata. This pool will include more growers and more workers than are ultimately needed for the study.

This process results in a random sample of eligible growers and, by association, a random pool of potential workers associated with eligible growers. All grower contact discussions and decisions made during this eligibility screening will be documented in a detailed study notebook provided by AHETF or kept in files bearing the study number.

5.0 EFFICIENT MU DESIGN

The Study Director and Local Site Coordinator will assemble the information obtained from the pool of eligible growers to construct a plan to efficiently assign all MUs in the study. Details of the potentially available MUs will be used to identify one configuration of MUs (i.e., growers, chemicals, workers, AaiH, timing) that will result in an efficient study. The efficient configuration will be comprised of a group of at least three growers that are near each other, can provide separate workers for all the five strata of AaiH, utilize some diversity in equipment, and plan to make applications within a narrow time frame. The growers and/or commercial applicators in the chosen configuration provide the pool of workers from which study participants will be recruited.

6.0 PARTICIPANT SELECTION

6.1 Site Inspection

The Study Director and/or Local Site Coordinator shall arrange to visit growers from the pool of eligible growers to confirm the suitability of their operation for the study. In accordance with SOP AHETF-11.B the individual growers will be asked to sign a non-coercion statement (Employer Cooperation Statement) affirming to their workers and AHETF that they will not coerce or unduly influence their workers to either participate or not participate in the study. Growers must also certify that alternate work will be provided on study days for workers who choose not to volunteer; and that the employee's decision to participate or not will have no impact on their employment. For grower/owners or grove operators/managers or commercial applicators that do not have a supervisor, but who are eligible handlers themselves, this form is not applicable and will not be used.

6.2 Initial Potential Participants Recruitment

AHETF will follow standard procedures (see SOP AHETF-11.B) to recruit

potential participants for this closed cab airblast application study. Individual workers will be recruited during an initial site inspection or subsequent visit(s) to an eligible grower facility.

The Study Director or designated researcher will seek permission from the eligible grower to approach his/her employees to recruit volunteers for the study. Depending on the number of employees and size of the grower facility the Study Director or researcher may contact employees through the use of an informational recruitment flyer posted in a common work area. Such a flyer will briefly describe the research study and provide contact information for employees who may have an interest in participation in the study. The flyer shall have been previously reviewed and approved by an IRB.

Alternatively, or subsequent to the use of a flyer, the Study Director or researcher will arrange a meeting with the grower's employees who express an interest in participation. Such meetings will always occur without the grower or supervisors being present (SOP AHETF-11.B). The Study Director or researcher shall make a presentation describing the AHETF Exposure Monitoring Program, the goals of the research study, the procedures used in exposure monitoring, and the risks and benefits to participants. Contact information will be provided, and individuals will be encouraged to contact AHETF if they desire additional information about the study or are interested in participating in the study. All presentation materials, such as handouts or visual aids, shall be reviewed and approved by an IRB prior to use in recruiting subjects.

The Study Director or researcher shall continue conducting site inspections and potential participant recruitment as described above until an adequate number of eligible growers and potential participants have been secured for an efficient configuration of all MUs in the study. During this process, the following restrictions will be maintained:

- At least 10 workers who may potentially volunteer for the study
- At least 2 workers available for each of the AaiH strata
- No more than 2 MUs from any one grower (this effectively requires at least 3 different growers since 5 MUs are desired)
- No workers may be used more than once
- No piece of equipment (tractor plus sprayer) may be used more than once

As indicated above, the efficient configuration must include enough eligible growers and potential participants to fill all MUs in the study, even in cases where growers or participants are not available at the last minute for the time interval scheduled for the field phase of the study.

6.3 Participant Selection and Consenting

The Study Director or designated researcher will establish a pool of eligible growers and workers (potential participants) from those in the efficient configuration who shall be contacted prior to initiating the field phase of the study to confirm their availability and interest in being in the study. Individual volunteers will be informed of study provisions to accommodate their language preference, the need for readers, witnesses, and their desire to have a confidant or counselor present during an informed consent meeting.

The Study Director or designated researcher will arrange a place and schedule to conduct consent meetings with individual volunteers from the eligible pool. Prior to such meetings, accommodations will have been made for interpreters, witnesses, and ancillary personnel who must be present for the meeting. Consent meetings shall be conducted as described above in Section 2.7.

7.0 FIELD MATERIALS AND METHODS

7.1 Test System Identification - Workers

The test system for this study is the worker handling pesticides according to label directions. Workers may include farm owners, farm operators, farm employees, contract applicator employees, or employees of agricultural research facilities. Passive dermal dosimetry methods will be used to determine potential exposure of experienced workers handling the test substance. Inclusion/exclusion criteria have been enumerated in Section 2.1 of this protocol. The recruitment and consenting process will follow the procedures presented in Sections 2.7, 6.2, and 6.3 of this protocol. Details are provided in SOP AHETF-11.B. A total of five applicators are anticipated for this study.

7.2 Justification of the Test System and Test Substances

Experienced agricultural workers handling pesticide products using commercial product packaging and typical handling procedures will be monitored. Monitoring these workers provides the best estimate of potential dermal and inhalation exposure for handlers applying pesticides with conventional airblast equipment using closed cab equipment.

The test substances selected for this study are registered and approved for use in a wide variety of agricultural settings, including airblast application to citrus crops. The justification for their possible use in this study is that they have each been deemed suitable by the Sponsor as surrogate compounds for generating exposure data appropriate for a generic database. In addition, the analytical methods have been validated and these products have the requisite degree of stability under field, storage, and transit conditions.

7.3 Mixing/Loading Stations and Application Area

Field maps and/or sketches will be provided in the raw data showing the exact locations where mixing/loading and application occur. Relative distances between mix/load areas and application areas will be recorded. These will include area and local maps or sketches for all sites involved in the study.

7.4 Study Personnel – Field

The study team will be comprised of a sufficient number of people to conduct the following activities:

1. Monitoring the workers and environmental conditions to ensure safe working conditions
2. Assisting with the donning and collection of all dosimeters in a time-efficient manner to minimize the time from completion of the work cycle to sampling (requires a female researcher if there will be female participants)
3. Fortifying field recovery samples
4. Calibrating air sampling pumps and recording beginning and ending flow rates
5. Observing and recording all work practices, recording site details and treatment details
6. Taking a photographic record of representative study-related activities
7. Evaluating the working order and condition of application equipment
8. Monitoring by a Quality Assurance Officer of operations for compliance with the GLP regulations
9. Providing a medical professional on site to observe the workers and provide urgent care

7.5 Test Substances

7.5.1 Approved Test Substances

The test substances approved for use in this study are listed in Section 2.3.2 above and Table 1 below. The most appropriate test substance, based largely on the preference of the grower, will be used at each of the individual locations. A different test substance may be used at each location and by each worker within a location if appropriate.

Selection of the exact test substance is determined as the product selected by an eligible grower for his crop on the day of the study. As previously described, eligible growers are selected from an efficient configuration of MUs who plan to use or are willing to use one of the products approved by the AHETF. As the time approaches to conduct the field phase of the study, the grower will confirm the actual product

he will be using on the day of the study. The researchers will insure a sufficient amount of the test substance product will be available at the grower site. The AHETF will reimburse the grower for the product used in the study at the completion of the study on his farm.

The product name, active ingredient and nominal concentration, EPA registration number, CAS number, lot number, formulation type, package type, and package size will be recorded for each product used by monitored workers.

Table 1. Approved Test Substances for AHE55

Test Substance	Active Ingredient	Type	Activity
Sevin® brand 80WSP	Carbaryl	Powder in water soluble bags	Insecticide
Sevin® brand XLR Plus	Carbaryl	Liquid flowable	Insecticide
Sevin® brand 4F	Carbaryl	Liquid flowable	Insecticide
Fyfanon® 8 Lb Emulsion	Malathion	Emulsifiable concentrate	Insecticide
Fyfanon®	Malathion	Emulsifiable concentrate	Insecticide
Malathion 8-E	Malathion	Emulsifiable concentrate	Insecticide
Gowan Malathion 8 Flowable	Malathion	Liquid flowable	Insecticide

7.5.2 Active Ingredient Stability

The stability of the test substances under recommended storage conditions will be documented before the start of the study. Generally, AHETF will rely on data supplied by the product registrant that were submitted to support the EPA registration of the test substance. Study researchers will record the storage conditions, including temperature, during the days of use of the products at the eligible grower's facility.

7.5.3 Purity Analysis

A sample of each lot of test substance used by each worker in the study at each location will be collected and sent to a designated laboratory for GLP purity analysis (content of active ingredient in the test substance). Purity analysis will be conducted concurrently with analytical phase of the study. Documentation of such analyses will be retained in the study raw data.

7.5.4 Retention Samples

Retained samples from each lot of the test substance(s) used in the study will be sent to the AHETF archive facility.

7.6 Application Parameters

Carrier:	Water
Target application rate:	Products will be applied at a rate specified on the label for the particular crop. Rates depend on target crop and field needs. Actual application rates will be documented in study raw data.
Target application volume:	Application volume will comply with the product label. Volumes depend on target crop and field needs. Actual application volumes will be documented in study raw data.
Route of application:	Applications will be made using available common airblast application equipment.

7.7 Equipment Accuracy Verification

Mixing/Loading equipment accuracy will be verified according to field testing facility SOPs prior to use in this study. This will include equipment used to pump or meter the carrier during the mixing/loading process.

Copies of relevant facility maintenance records (if available) for all mixing/loading and application equipment used for this study will be obtained and retained with the field raw data. The Study Director or designated member of the study team will assure equipment operation is acceptable according to SOP AHETF-10.D.

Workers will only be allowed to handle equipment for which they are familiar and have used recently. This will help ensure the safety of the worker when handling equipment and ensure that the procedures followed by the worker are normal and typical of their usual job function.

7.8 Amount of Material Handled

The amount of test substance that is mixed and loaded for each applicator

worker will be determined and recorded in the raw data. Each worker will handle an amount of active ingredient designed to achieve a within-cluster diversification of AaiH following the standard approach of partitioning the practical AaiH range for the scenario into five strata. These strata are:

(1) 5 to 9 pounds ai handled
(2) 10 to 17 pounds ai handled
(3) 18 to 30 pounds ai handled
(4) 31 to 55 pounds ai handled
(5) 56 to 100 pounds ai handled

A single MU will be conducted in this study from each of the five strata.

Each MU shall consist of a period of at least 4 hours of spraying and at least 3 tank loads of the spray mixture. The application volume, gallons per acre, may be adjusted by ground speed and output volume to achieve a stratum-assigned range of pounds ai handled. The application volume applied shall be in accordance with the product label. The volume of spray mixture applied will be determined and recorded in the field raw data, along with other critical measurements including application area and duration. Upon completion of spraying each load of diluted product, the amount of spray volume remaining in the tank(s) will be determined and recorded in the raw data. Disposal of excess spray mixture will occur in accordance with applicable regulations.

7.9 Rationale for the Route of Administration

The above handling procedures represent typical agricultural practices for each particular location and test substance.

8.0 DERMAL EXPOSURE SAMPLING

Full details of procedures for dermal and inhalation exposure sampling, and sample removal, are specified in the most recent versions of SOPs AHETF-8.A, 8.B, 8.C, and 8.D. At the completion of the monitoring period, exposure samples will be taken in the following order to minimize cross contamination: inhalation samples (discussed in the next section), then hand washes, then face/neck wipes, and finally inner dosimeters as described below and in SOP AHETF-10.E.

Workers will wear the clothing and PPE required by the product label. Depending on the particular product, this may include long pants, long-sleeved shirts, waterproof gloves, chemical resistant gloves, protective eyewear, shoes, and socks. The clothing can be provided by each worker as long as the Study Director agrees they are compliant with the WPS. All items worn must be compliant with the WPS, and the clothing must have been laundered since being worn while handling pesticides, or be new. Any clothing items deemed unacceptable by the Study Director will be replaced by alternate clothing (see SOP AHETF-8.G). Upon approval by the Study Director, Deleted: F

workers may wear a hat or cap.

Workers will wear one layer of work clothing over the inner dosimeters. The inner dosimeter will consist of 100% white cotton long underwear, pre-washed and provided by the AHETF. The inner dosimeter is designed to represent the worker's skin and will act as a collection medium that will be analyzed. It will be worn throughout the period of monitoring and removed at the end of the work period, with the assistance of a member of the monitoring team.

Workers' hands will be washed just prior to the exposure monitoring period as described below. This assures that the worker hands are free of pesticide and provides an opportunity for researchers to ensure the worker understands how to assist with the hand washing procedure. The face and neck area will also be wiped just prior to the exposure monitoring period. All of the pre-monitoring hand wash and face/neck samples will be discarded.

At the end of the monitoring period (and after the inhalation exposure equipment is removed as described below), the worker will first remove his/her PPE (e.g. waterproof gloves) and shoes, then enter a clean, private area for collecting the remaining samples. Once inside the private area, the worker will remove his/her outer clothing and socks. The outer layer of clothing and socks will not be collected or analyzed. To reduce the potential for cross contamination, each set of outer work garments will be used only once. Dermal exposure samples will be collected in the following order: final hand wash sample, final face/neck wipe sample, and the inner dosimeter.

Hand exposure will be measured by having the worker wash their hands in a 0.01% Aerosol OT solution according to a standardized washing procedure described in the most recent version of SOP AHETF-8.B. Interim hand wash samples will be collected whenever a worker would normally wash his/her hands (e.g., before using the toilet, etc.). These interim hand wash samples will be numbered sequentially, as described in SOP AHETF-8.F. After an MU is completed (i.e., at the end of the monitoring period) one final hand wash will be collected from each worker. The post-activity hand wash sample for each MU will be the final hand wash sample for the monitoring period and receive the final sequence number for the MU. This sample will be clearly marked as the post-activity hand wash. All hand washes collected during and at the end of the work period will be treated as separate samples. All hand wash samples will be poured into pre-labeled containers and placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will be maintained in frozen storage until analysis.

Face/neck exposure will be measured by wiping the entire face and neck areas (front and back of neck) with two gauze sponges, sequentially, that have been wetted with 0.01% Aerosol OT as described in the most recent version of SOP AHETF-8.C. Interim face/neck wipe samples (consisting of two gauze sponges) will be collected prior to eating. After each MU is completed, a final face/neck wipe sample will be collected from each worker after the hand wash sample is collected and before

removal of the whole body dosimeters. Face/neck wipe samples will be wrapped in aluminum foil prior to placement in pre-labeled re-sealable plastic bags. All wipes collected during the study for a worker will be combined in the same container, resulting in a single sample for analysis. If more than two samples (4 sponges) are in a sample container, the laboratory must be notified as to the number in the container. All face/neck wipe samples will be placed in pre-labeled containers and placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will be maintained in frozen storage until analysis.

Finally, the inner layer of clothing (inner dosimeter) will be removed with the assistance of a member of the study team and sectioned into two sections for all MUs (upper body and lower body). The sections will be individually wrapped in aluminum foil, placed in pre-labeled containers and placed into temporary frozen storage as soon as possible for transport to the analytical facility. Samples will be maintained in frozen storage until analysis.

9.0 INHALATION EXPOSURE SAMPLING

Full details of the personal air-sampling method, attachment of pumps, monitoring of workers, and pump calibration are given in the most recent versions of SOP AHETF-8.D and 10.G. Suitable low-volume personal air-sampling pumps and OVS tubes with a glass fiber filter and the appropriate sorbent for the test substance being used are required. Valid calibration equipment, specified in SOP AHETF-10.A, and Tygon® (or equivalent) tubing are also required. The pumps and calibration equipment will be uniquely labeled and this information recorded in the raw data records. Deleted: A

Before the work commences, the sampling pump will be attached to a belt around the waist of the worker to be monitored. Tygon® tubing (or equivalent) attached to the inlet valve of the pump will be placed over the shoulder of the worker and attached to the air-sampling tube. A clip will be used to attach the tube to the collar of the worker, thus positioning it in the breathing zone of the worker. The inlet of the air-sampling tube will be facing downward, similar to the nasal passage of a worker.

Each pump will be calibrated, as specified in SOP AHETF-10.G, to a nominal sample flow rate of approximately 2 L/min and will operate for the duration of the exposure monitoring period. Flow rates will be measured before and after each exposure monitoring period and detailed records of flow rates and sampling durations will be maintained in the raw data records. Deleted: A

The pumps will be turned on immediately prior to the start of the monitoring period and will operate continuously until the end of the period. Detailed time logs will be maintained to allow the length of the exposure period to be calculated.

Periodically throughout the monitoring period, the pumps will be inspected to ensure they are still running and the tubing checked to ensure that there are no kinks. Workers will be instructed to inform a study team member if the pump fails to

operate or the tubing becomes kinked.

If a pump stops operating during the work cycle, it will be replaced with a pre-calibrated replacement pump or given fresh batteries as soon as possible. Only the pump or batteries will be changed, the same sampling tube and tubing will continue to be used. At the conclusion of each exposure monitoring period, after the final flow rate has been recorded, the OVS tube will be disconnected from the tubing leading to the pump. The OVS tube will be sealed at both ends, placed in a pre-labeled container, and placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will be maintained in frozen storage until analysis (SOP AHETF-8.D). Deleted: A

10.0 CONTROL OF BIAS

Sampling bias will be controlled by sampling multiple workers over a period representative of a typical work day, and by sampling over the entire body of each worker. Quality control samples in the field and in the laboratory also act as methods for controlling bias.

11.0 FIELD RECOVERY EVALUATION

11.1 Fortification Procedures

Full details regarding field recovery evaluation procedures for all sampling media are given in the most recent version of SOP AHETF-8.E. The SOP instructions for "spiking using vialed spikes" and analytical standard in solvent will be followed.

Sample matrix fortifications designed to assess the stability of the active ingredient during field, storage and transit conditions in or on the sampling materials (inner dosimeters, hand wash solutions, face/neck wipes, and air sampling matrices) will be conducted on a minimum of one day of exposure monitoring at each location, or more days as appropriate for environmental conditions.

Fortification vials with solutions of active ingredient in appropriate solvent will be shipped and stored under frozen conditions until used in the field. The entire contents of the fortification vials will be applied to the sampling media. The OVS tubes will be pre-spiked with the active ingredient (generally in an organic solvent) at the analytical laboratory and kept frozen until their use in the field.

Storage conditions of the individual vials used for fortifications, and of the fortified OVS tubes, will be specified by the analytical laboratory and the actual storage details will be recorded in the study file.

After fortification, the inner dosimeters and OVS tubes will be exposed to ambient conditions (i.e., weathered) for the longest expected exposure monitoring period in a location away from possible contamination (e.g., upwind of mixing/loading and application operations). Inner dosimeter samples will be covered with a single layer of shirt material during weathering. Segments representing any body area may be used for inner dosimeter fortification samples. An air sampling system will be set up in a manner similar to that of the workers, in which a pump will continuously draw air through the pre-fortified filter and OVS tube for the entire duration of the work period.

Hand wash and face/neck wipe samples will be fortified and immediately placed in frozen storage without exposure to ambient conditions. In addition, on each fortification day, duplicate samples of the inner dosimeters fortified in the field at the highest level, and duplicate OVS tubes fortified in the laboratory at the highest fortification level, will be processed for immediate frozen storage and used as travel spikes. These travel spikes will be analyzed only if deemed necessary by the Study Director, for example to help determine the cause of unusually low field fortification recovery results.

Finally, on each fortification day, two untreated control samples of each matrix will be processed similar to the field fortification samples (i.e., some are weathered). Packaging, storage and shipment of the field fortification samples will be the same as for the worker exposure samples.

11.2 Field Fortification Levels

Matrices will be fortified in triplicate at the following levels:

Matrix:	Fortification Levels (µg/sample):
Inner Dosimeters	5, 100, and 2,000
Face/neck Wipes	5, 100, and 2,000
Hand Wash	5, 100, and 2,000
OVS Tubes	0.05, 0.5, and 5.0

12.0 OBSERVATIONS

Observations will be recorded according to SOP AHETF-10.C throughout the monitoring period while the workers perform their tasks. Any specific occurrences that could affect exposure will be noted on the observation forms. Measurements will be made of the amount of test substance handled. A detailed time log will be

maintained for all activities. A photographic record will be taken of representative study-related activities during exposure monitoring.

13.0 ENVIRONMENTAL MONITORING

Exposure monitoring will not be conducted under meteorological conditions inappropriate for the conduct of the activity (e.g., excessive precipitation, excessive wind speed or other adverse condition). Adequate protection from the elements will be provided for handling worker exposure samples and field fortifications in case of inclement weather.

Environmental conditions, including air temperature, relative humidity, wind speed, and wind direction will be recorded by means of an on-site, portable weather station during exposure monitoring. Measuring equipment will be calibrated as per the field contractor's SOP. Additionally, observations concerning pertinent weather conditions, such as amount of cloud cover, degree of sunshine, rainfall, relative humidity, etc. for each day of monitoring will be recorded in the field raw data.

Most importantly, environmental conditions will be monitored regularly by the Study Director or designated members of the study team to evaluate the risk to workers of heat-related illness according to SOP AHETF-11.G and Section 2.3.1 of this protocol. These temperature, relative humidity, and heat index values will be recorded in the field raw data.

14.0 SAMPLE IDENTIFICATION, SHIPPING AND STORAGE

14.1 Sample Identification

The sample identification process is described in the most recent version of SOP AHETF-8.F. Samples will be identified and tracked by unique sample numbers assigned by AHETF. During the analytical phase of the study, the laboratory may assign its own sample numbers as long as the AHETF number is cross-referenced and included in the documentation of the sample.

14.2 Shipping

Samples will be shipped frozen to the analytical laboratory designated for the specific active ingredient used at each location. Full chain of custody record will be available for all samples.

14.3 Storage

All samples will be placed into frozen storage as soon as possible after collection; the analytical laboratory will store samples under frozen conditions until analysis. Freezers will be monitored and the temperatures documented.

15.0 ANALYTICAL PROCEDURES

Experimental exposure and field recovery samples will be analyzed according to the analytical methods for the active ingredient in the specified test substance used in the field. The methodology will have been validated for use in the relevant matrices prior to the initiation of the sample analyses.

15.1 Reference Substance(s)

The reference substance for this study is the analytical standard used by the analytical laboratory to prepare analytical standard solutions.

The Study Director or an authorized representative will obtain analytical standard from the registrant or suitable commercial supplier. Receipt of the standard will be documented, including label identification, date of receipt, person receiving the standard, and the amount received. Preparation of all stock and serially diluted solutions will be documented.

The stability of the analytical standard (reference substance) will be documented before the start of the study. Generally, AHETF will rely on data supplied by the product registrant that were submitted to support the EPA registration of the technical grade active ingredient. An expiration date and recommended storage conditions will be based on the stability data to ensure the analytical standard strength does not change appreciably during conduct of the study. Analytical standards are to be stored under the recommended conditions.

GLP determination of the percent ai analysis (content of ai in the reference substance) will be performed for each lot of reference substance used in the study prior to the use of that substance for sample analyses. Documentation of such analyses will be retained in the study raw data file.

15.2 Analytical Methods

The latest revisions of the following validated analytical methods will be used:

Analytical Method No. ARTF-AM-005 entitled, "Determination of Diazinon and Malathion in Inner Dosimeters."

Analytical Method No. ARTF-AM-006 entitled, "Determination of Diazinon and Malathion in Hand Wash Solutions."

Analytical Method No. ARTF-AM-009 entitled, "Determination of Diazinon and Malathion in OVS Air Sampling Tubes."

Analytical Method No. ARTF-AM-010 entitled, "Determination of Diazinon and Malathion in Facial/Neck Wipes."

ARTF-AM-011, "Determination of Carbaryl in Dermal Dosimeters" by Gary Westberg, Revision 4, September 2003

ARTF -AM-012, "Determination of Carbaryl in Hand Wash Solutions" by Gary Westberg, Revision 2, June 1998

ARTF-AM-013, "Determination of Carbaryl in OVS Air Sampling Tubes" by Gary Westberg, February 1997

ARTF-AM-014, "Determination of Carbaryl in Cotton Facial/Neck Wipes" by Gary Westberg, Revision 2, April 1998

Equivalent instrumentation, apparatus, and reagents may be substituted for those specified in the method. All substitutions must be clearly documented in the raw data.

15.3 Analytical Design

All analytical procedures, techniques and matrices will be provided by the AHETF. Procedures and techniques will be followed as rigidly as possible. No changes are permitted without the prior approval of the AHETF Analytical Monitor and the Study Director.

All data will be measured against a standard curve (five-point minimum) that brackets the levels of the matrix spikes. If necessary, a solvent blank for the standard solutions will be injected prior to the standard solutions for each run.

Analytical data sets for the study will be considered acceptable if the following criteria are met. If these criteria cannot be met, the analytical monitor must be contacted immediately.

1) The limit of determination, r^2, or the regression coefficient, r, must be reported for all curves to demonstrate sufficient linearity of detector response in the range of residues quantified. All r^2 values must be 0.90 or greater or all r values must be 0.94 or greater.

2) Back calculations of the standard to the calculated curve which is based on the standards run in a set of samples will be performed for all analytical sets. The back calculations of the standards to the curve will be around +/-15% for all standards but the lowest concentration standard may back calculate to around +/-20%. No standard will be discarded from a set unless there is a good reason for its being discarded and not without consultation with the analytical monitor.

A minimum of two laboratory spikes must be included in each analytical set. For large analytical sets, include approximately one spike for every ten field samples. The spiking concentrations will bracket the expected levels in the

field samples. The LOQ is defined in each analytical method.

For all samples wrapped in aluminum foil, the inner surface of the foil wrapping will be rinsed with at least 50 mL of extraction solvent, which will be added to the total extract volume. The final volume of solvent used must be documented.

The filter, plus front and rear sorbent sections of the OVS tubes, (along with the retainer ring and sorbent section separators) will be analyzed together as one unit.

15.4 Analytical Statistical Methods

Chromatographic quantification (either GC or HPLC depending on the method) will be achieved using a standard curve obtained from peak heights or areas of injections of several concentrations of standards. The standard curve will be a least squares fit unless otherwise approved by the AHETF Analytical Subcommittee. Means and standard deviations (arithmetic and/or geometric), and coefficients of variation may be calculated on the limited data set generated in this study.

16.0 STUDY RECORDS

16.1 Field Records

Raw data will be obtained to cover all aspects of the study, including but not limited to the following:

1. Test and reference substance lot numbers, receipt and storage location(s) use records
2. Crop description and growth stage, if applicable
3. Mixing/loading equipment details, if applicable
4. Application equipment details, if applicable
5. If available, application equipment maintenance records (retained in the study file)
6. Environmental conditions for the entire monitoring period, including data used for making determinations of potential heat stress indices
7. Approvals from the Institutional Review Board covering the protocol and the Informed Consent document, and all amendments to either document
8. All correspondence with the Institutional Review Board
9. Personal details of workers, including consent forms and documentation of consent process (which will be maintained under confidential conditions as per SOP AHETF-6.D)
10. Trial location maps, including description, dimensions, and exact locations of plots and mixing/loading stations

11. Pounds active ingredient handled, monitoring time, acres treated, and volume of liquid applied
12. Dermal exposure sampling information
13. Inhalation exposure sampling information, including pump identification, calibration, flow rates and times of sampling
14. Field recovery procedure information for all sampling media
15. Test and reference substance, and sample storage temperature records
16. Observations on work practices, including photographs
17. Sample information (including inventory and chain of custody)

Field raw data will be recorded directly into the study notebook provided by AHETF. All data generated during this study will be kept in files bearing the study number. All forms and paperwork that contain personal information (including a worker's name and address) will be kept confidential in a sealed envelope while in the field. After the study is completed, this confidential envelope will be sent to AHETF archives with the other raw data (SOP AHETF-6.B).

16.2 Analytical Records

All study-specific original documents and data generated in the course of this study, including but not limited to the following, will be maintained and turned over to the AHETF when requested, or at the completion of the study.

1. Analytical worksheets, chromatograms, methods, residue calculation sheets and other pertinent analytical data
2. Laboratory notebooks or bench sheets used to record details of the analyses
3. Chromatograms and/or machine-generated analysis reports and data
4. Spreadsheets and other calculated data
5. Chain of custody records

In addition to the above study-specific raw data, the following records must also be kept, and true copies submitted with the raw data:

a. Storage conditions for reference substances and samples
b. Reference substance use log
c. Balance and instrument log book pages
d. Communications logs or records

Following completion of the field or analytical portion of the study, copies of the relevant records will be indexed and sent to the Study Director for preparation of the final report. All original raw data will be transferred directly to the AHETF-designated GLP study archive at Quality Associates, Inc., 8161 Maple Lawn Boulevard, Suite 200, Fulton, MD 20759.

17.0 DATA HANDLING

17.1 Communication of Results

Results will be communicated from Principal Field and Analytical Investigators to the Study Director and the designated AHETF Study Monitor(s) on a regular and timely schedule. Volunteer subjects will have an opportunity to fill out a form to request their personal study results when they are available. Individual results requested by subjects will be communicated in accordance with SOP AHETF-11.B.

AHETF has an adverse effects reporting procedure in place and will submit reports to EPA, IIRB, and appropriate state authorities if potential adverse effects to workers are found (see SOP AHETF-1.F and AHETF-11.F). The Study Director has the primary responsibility for identifying potential adverse effects during study conduct and as exposure results are obtained.

18.0 QUALITY ASSURANCE

AHETF intends that all regulatory studies are conducted in accordance with the FIFRA GLP Standards (40 CFR part 160). Field and analytical aspects of this study will be monitored by the relevant quality assurance unit(s) (QAU) while this study is in progress to ensure compliance with the FIFRA GLP regulation and adherence to this protocol and relevant SOPs. The QAU(s) will submit copies of its/their inspection reports to the Study Director and AHETF Sponsor Representative (40 CFR part 160.35 [4]). The final report will be audited by the QAU specified in Section 1.15 to ensure that the contents of the report accurately describe the conduct and findings of the study.

The final report will contain a Quality Assurance Statement from the QAU of each contributing laboratory conducting QA audits, and from the QAU specified in Section 1.15.

19.0 WORKER SAMPLE RETENTION

All sample extracts, extracted sample matrices, unanalyzed fortification matrices, and analytical standards will be retained until the Study Director and Analytical Monitor determine they are no longer useful. These materials are the property of the AHETF and will be stored or disposed of in a safe and lawful manner by the appropriate authorized personnel with the approval of AHETF and with QA verification at the performing facility.

20.0 PHASE REPORTS

Separate final reports will be prepared for the field and analytical phases of the study.

20.1 Field Report

Upon completion of the field phase at each individual location, the field investigators will submit reports for individual locations to the AHETF and the Study Director in a format specified by the AHETF. Each field report will describe the procedures followed at that location and must contain, but is not limited to, the following:

1. Identification of the locations of the study, and the general environmental conditions during the exposure monitoring periods
2. A field laboratory QAU statement giving dates of inspections and dates that findings were reported to the Study Director and AHETF Management
3. A summary of the worker recruitment and consent process
4. A description of the workers and handling activities
5. A summary of worker observations identifying any specific occurrences that may contribute to unusual worker exposure
6. A detailed summary of the amount of test substance handled by each worker
7. A detailed summary of the length of time each worker was monitored
8. A complete description of the field recovery procedure with a summary of specific handling and weathering of all field samples
9. A complete description of collection, handling, storage, and shipping of field samples

20.2 Analytical Report

At the completion of the analytical phase, each analytical laboratory that analyzed samples for this study will submit a report to the AHETF and the Study Director in a format specified by the AHETF. Each analytical report will describe the procedures followed for analysis of sample matrices and must contain, but is not limited to, the following:

1. Results of analyses
2. An analytical laboratory QAU statement giving dates of inspections and dates that findings were reported to the Study Director and AHETF Management
3. A detailed description of the methods
4. Example calculations
5. A summary of the concurrent lab recovery data
6. Representative chromatograms of control, treated, fortified samples and calibration standards
7. A typical standard curve

21.0 FINAL STUDY SUMMARY REPORT

A final summary report will be prepared according to a standardized format provided by AHETF. The report will contain a description of the conduct of the studies that comprise this scenario as well as a statistical analysis of the exposure data for the scenario. The original signed copy of the summary report will be archived at the AHETF GLP study archive.

22.0 PROTOCOL CHANGES

22.1 Amendments

Amendments to this protocol during the course of the study are permissible and subject to review and approval by the Study Director, the Sponsor representative and the IRB prior to implementation, except where necessary to eliminate apparent immediate hazards to the human subjects (40 CFR 26.1108(a)(4)). Protocol amendments shall to be documented in accordance with SOP AHETF-2.C and reported in the Field Report, Analytical Report and Summary Reports.

22.2 Deviations

GLP deviations are to be documented on the "Statement of GLP Compliance" in the summary report. A description of any changes to the protocol must appear in the Field Report, Analytical Report and Summary Reports. Any deviations to the protocol, lab SOPs or GLPs, or situations that may affect the integrity of the study must be communicated to the Study Director in a timely manner. Any deviations affecting the safety or rights of the subjects must also be reported to the IRB. Protocol deviations are to be documented in accordance with SOP AHETF-2.C.

23.0 REFERENCES

Bruce, E., L. Smith and V. Standart. 2007. Report of workplace meetings with citrus and pecan growers and employees. With attached: AHETF exposure studies: input from the local workplace community. Georgia and Florida, July 2007. Prepared for the Agricultural Handlers Exposure Task Force, 8 August 2007.

Worker Clothing Acceptability Criteria

Chapter 8: MATRIX SAMPLES

AHETF-8.G.2.

Effective Date : September 1, 2003

APPROVAL David Johnson DATE 8-29-03

APPROVAL Cindy Standard DATE 8/1-03

Last Revision Date: May 25, 2003 Previous Version Number: 8.G.1.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the criteria to follow when evaluating individual workers' outer work clothing prior to participation in an Agricultural Handlers Exposure Task Force (AHETF) worker exposure study.

1.2 These criteria were selected based upon the criteria presented in the Worker Protection Standards (WPS) 40 CFR 170, and in the spirit of product stewardship.

1.3 This SOP was revised to allow the workers the choice to wash their own clothing prior to participation on an AHETF study or have their work clothes laundered by AHETF designated personnel as in section 2.1.5. and to add this section as an explanation.

2.0 ACCEPTANCE/REJECTION CRITERIA

2.1 The Study Director will evaluate each worker's outer (work) clothing prior to his or her participation in an AHETF worker exposure study using the following criteria as guidance:

2.1.1 **Condition:** Work clothing should be in relatively good condition. Clothing that does not comply with the spirit of the WPS (*e.g.* clothing with large tears, holes, rips, several missing buttons, or other defects that present a significant exposure to the worker's skin or inner dosimeter) will not be accepted for use during the study. In such

cases, if the Study Director feels appropriate, the AHETF will provide the worker with new outer work clothing.

2.1.2 **Coverage:** Only long sleeves and long pants are acceptable. Sleeves and pant legs may not be rolled-up during the exposure phase of the study. Rolled-up sleeves, T-shirts, and shorts will not be accepted for use during the study.

2.1.3 **Fit:** The outer clothing must completely cover the inner dosimeter. Clothing that is too short, whether during movement or at rest will not be accepted for use during the study.

2.1.4 **Size:** Work clothing must be loose enough to allow for wearing an inner dosimeter under the work clothing, and still completely cover the inner dosimeter. Clothing that is too tight to allow the use of the inner dosimeter garment or does not sufficiently cover the inner dosimeter will not be accepted for use during the study.

2.1.5 **Cleanliness:** Workers' clothing should be reasonably clean prior to participation. Clothing should be free from fresh soiling or chemical exposure. Stains and discolorations might be acceptable, if from a previous event. Any clothing that is freshly or grossly soiled, or has any distinct pesticide odors or stains will not be accepted for use during the study.

2.2 All articles of a worker's outer clothing must be laundered prior to participation in an AHETF exposure study. Workers will be notified in advance of this criterion and should make arrangements to have their work clothes laundered. If necessary, clothing will be collected by the AHETF prior to the start of the study, laundered with detergent by the AHETF, and returned to the worker at the start of their exposure period.

2.3 Should the Study Director deem any article of a worker's clothing unacceptable, that specific article shall be replaced with a clean, new garment provided by the AHETF.

2.4 The Study Director will document each article of clothing replaced and the reasons for the rejection of the original workers' clothing in the raw data.

2.5 For exposure scenarios where low exposure is expected (*e.g.*, closed-system mixing and loading), only AHETF-provided outer garments will be worn.

Personal Air Sampling Pump Calibration

Chapter 10: FIELD OPERATIONS
AHETF-IO.G.O.

Effective Date : October 15, 2003

APPROVAL _____ DATE 09-27-03

APPROVAL _____ DATE 09-26-03

Last Revision Date: N/A Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides the steps to properly calibrate the personal air sampling pumps used to collect air monitoring samples during Agricultural Handlers Exposure Task Force (AHETF) worker exposure studies.

2.0 EQUIPMENT REQUIRED

2.1 The following equipment is needed to calibrate the sampling pumps:

a. Personal low-volume air sampling pump(s) (*e.g.*, SKC, or equivalent)

b. Tygon® tubing or equivalent

c. Appropriate OSHA Versatile Sampler (OVS) Tubes

d. Appropriate calibration device (*e.g.,* Kurz Mass flow meter, Buck Calibrator, bubble meter and stopwatch, or equivalent)

3.0 CALIBRATION PROCEDURE

3.1 Place air sampling pumps on chargers before each use. If the pump is fully charged proceed to 3.2.

3.2 Calibrate air sampling pumps before use in each monitoring replicate. Calibrations will take place on the day prior to or the same day the pumps are to be used.

3.3 Calibrate the pumps under actual use conditions, as the air temperature may affect the airflow (*e.g.*, calibrate outside rather than inside for exposure trials). Calibrate pumps with the appropriate OVS tube/ sampling train attached.

3.4 Follow appropriate contractor SOPs for the individual calibration methods for contractor equipment.

3.5 Adjust the airflow rate to appropriate rate as defined in the study protocol [*e.g.,* 2 liters per min (L/min)] and document the flow rate and pump number in the raw data.

3.6 Turn off the air sampling pump and set aside. Repeat steps 3.4 and 3.5 until all needed sampling pumps (including backups) have been calibrated.

4.0 POST EXPOSURE FLOW RATE CHECK

4.1 Using the same methods to calibrate the air pump, measure the airflow with a new OVS tube. Document the results in the study file.

4.2 Check the post exposure flow rate after the replicate OVS tube has been removed by the field sample collection personnel.

Volume VIII, Part D:

Part D IIRB Review Approvals 3-25-08

INDEPENDENT
INVESTIGATIONAL
REVIEW BOARD INC.
Your Advocate for Clinical Research Participants

DATE: March 25, 2008

TO: Larry D. Smith, PhD
Principal Investigator

FROM: Kim Lerner, Chairman or
Anita McSharry, Vice-Chairman
Independent Investigational Review Board, Inc.

SUBJECT: Revised Protocol;
- English/Certified Spanish Translation Informed Consent Form (Ver. 3/25/2008)
- English/Certified Spanish Translation Fyfanon® 8 lb. Emulsion Product Risk Statement (Ver. 3/25/2008)
- English/Certified Spanish Translation Fyfanon® Product Risk Statement (Ver. 3/25/2008)
- English/Certified Spanish Translation Gowan Malathion 8 Product Risk Statement (Ver. 3/25/2008)
- English/Certified Spanish Translation Malathion 8-E Product Risk Statement (Ver. 3/25/2008)
- English/Certified Spanish Translation Sevin® Brand 4F Product Risk Statement (Ver. 3/25/2008)
- English/Certified Spanish Translation Sevin® Brand 80WSP Product Risk Statement (Ver. 3/25/2008)
- English/Certified Spanish Translation Sevin® Brand XLR Product Risk Statement (Ver. 3/25/2008)
- Protocol Revision dated 3/21/2008 and 3/24/2008
- Agricultural Handlers Exposure Task Force SOPs

PROTOCOL: AHE55

At the meeting held on March 25, 2008 the Independent Investigational Review Board, Inc. had an opportunity to review the above referenced Informed Consent Form, Fyfanon® 8 lb. Emulsion Product Risk Statement, Fyfanon® Product Risk Statement, Gowan Malathion 8 Product Risk Statement, Malathion 8-E Product Risk Statement, Sevin® Brand 4F Product Risk Statement, Sevin® Brand 80WSP Product Risk Statement, Sevin® Brand XLR Product Risk Statement, Protocol Revision and Agricultural Handlers Exposure Task Force SOPs for the above noted research study. The Revised Protocol included changes that were requested as a result of a EPA review. The EPA also requested changes to the Informed Consent Form.

phone 954-327-0778 • fax 954-327-5778 • 6738 West Sunrise Blvd., Suite 102 • Plantation, FL 33313 • info@iirb.com (email) • www.iirb.com

The Informed Consent Form, Fyfanon® 8 lb. Emulsion Product Risk Statement, Fyfanon® Product Risk Statement, Gowan Malathion 8 Product Risk Statement, Malathion 8-E Product Risk Statement, Sevin® Brand 4F Product Risk Statement, Sevin® Brand 80WSP Product Risk Statement, Sevin® Brand XLR Product Risk Statement and Protocol Revision are unanimously approved. The Agricultural Handlers Exposure Task Force SOPs is unanimously accepted. The The Informed Consent Form, Fyfanon® 8 lb. Emulsion Product Risk Statement, Fyfanon® Product Risk Statement, Gowan Malathion 8 Product Risk Statement, Malathion 8-E Product Risk Statement, Sevin® Brand 4F Product Risk Statement, Sevin® Brand 80WSP Product Risk Statement and Sevin® Brand XLR Product Risk Statement have been revised to accommodate the EPA requests. The approved revised English/Certified Spanish Translations of the Informed Consent Form, Fyfanon® 8 lb. Emulsion Product Risk Statement, Fyfanon® Product Risk Statement, Gowan Malathion 8 Product Risk Statement, Malathion 8-E Product Risk Statement, Sevin® Brand 4F Product Risk Statement, Sevin® Brand 80WSP Product Risk Statement, Sevin® Brand XLR Product Risk Statement are identified as Versions 3/25/2008 and are stamped, "Approved 3/25/2008". All current subjects and future volunteers must sign the revised consent forms.

Thank you for your cooperation.

KL/AMS/yc:rr

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Sevin® Brand XLR Plus Carbaryl Insecticide (EPA Registration No. 264-333)

Active Ingredient (AI): Carbaryl (insecticide, CAS No. 63-25-2)

Formulation and Packaging: 4 lb AI/gallon Flowable liquid in 2.5 gallon plastic jugs

You may handle up to: 25 gallons of product

APPROVED BY
Independent IRB
Signature
3/25/08
Date

Initials: _____
Date: _____

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This carbaryl product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye irritation and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 9/21/04
MSDS date: 1/17/08 (Bayer MSDS 102000001927, Version 2.1)

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08; Revised: 3/25/08

Version: 3/25/08
Protocol: AHE55
Sevin® Brand XLR

APPROVED BY
Independent IRB
Signature
3/25/08
Date

Initials: _____
Date: _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
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This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Sevin® Brand 80WSP Carbaryl Insecticide (EPA Registration No. 264-526)

Active Ingredient (AI): Carbaryl (insecticide, CAS No. 63-25-2)

Formulation and Packaging: 80% AI dry powder in a 1.25 lb water soluble pack

You may handle up to: 100 water soluble packs

APPROVED BY
Independent IRB
Signature 3/25/08 Date

Initials: _____
Date: _____

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear waterproof gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This carbaryl product is classified as moderate toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye irritation, minimal skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 9/23/04
MSDS date: 12/26/02 (number 000000001825; Version 1.1)

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08; Revised: 3/25/08

APPROVED BY
Independent IRB
_____ 3/25/08
Signature Date

Initials: _____
Date: _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
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7919 Champaign Dr.
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Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Sevin® Brand 4F Carbaryl Insecticide (EPA Registration No. 264-349)

Active Ingredient (AI): Carbaryl (insecticide, CAS No. 63-25-2)

Formulation and Packaging: 4 lb AI/gallon Flowable liquid in 2.5 gallon plastic jugs

You may handle up to: 25 gallons of product

APPROVED BY
Independent IRB
Signature
3/25/08
Date

Initials: _____
Date: _____

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This carbaryl product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye irritation, minimal skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 9/27/04
MSDS date: 12/18/02 (No. 000000000194, Version 2.1)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08; Revised: 3/25/08

Version: 3/25/08
Protocol: AHE55
Sevin® Brand 4F

APPROVED BY
Independent IRB
Signature 3/25/08 Date

Initials: _____
Date: _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
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7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Gowan Malathion 8 (EPA Registration No. 10163-21)

Active Ingredient: Malathion (insecticide, CAS No. 121-75-5)

Formulation and Packaging: 8 lbs AI/gallon Emulsifiable Concentrate

You may handle up to: 12.5 gallons of product

APPROVED BY
Independent IRB
Signature 3/25/08 Date

Initials: _____
Date: _____

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This malathion product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include slight eye and/or skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label ID: 04-R0699
MSDS date: 2/1/07 (Gowan Malathion 8 Flowable)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08; Revised: 3/25/08

Version: 3/25/08
Protocol: AHE55
Gowan Malathion 8

APPROVED BY
Independent IRB
_____ 3/25/08
Signature Date

Initials: _____
Date: _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Malathion 8-E Insecticide (EPA Registration No. 34704-452)

Active Ingredient (AI): Malathion (insecticide, CAS No. 121-75-5)

Formulation and Packaging: 8 lbs AI/gallon Emulsifiable Concentrate in 1 gallon plastic jugs

APPROVED BY
Independent IRB
Signature
3/25/08
Date

Initials: _____
Date: _____

You may handle up to: 12.5 gallons of product

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This malathion product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include moderate eye irritation, slight skin irritation, possible allergic skin reaction, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: None found
MSDS date: 6/8/06 (Loveland MSDS #000452-06-LPI)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08; Revised: 3/25/08

Version: 3/25/08
Protocol: AHE55
Malathion 8-E

APPROVED BY
Independent IRB
_____ 3/25/08
Signature Date

Initials: _____
Date: _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
_____
_____

Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Fyfanon® (EPA Registration No. 5905-196)

Active Ingredient (AI): Malathion (insecticide, CAS No. 00121-75-5)

Formulation and Packaging: 5 lbs AI/gallon Emulsifiable Concentrate

You may handle up to: 20 gallons of product

APPROVED BY
Independent IRB
_____ 3/25/08
Signature Date

Initials: _____
Date: _____

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves and protective eyewear. The gloves and protective eyewear must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This malathion product is classified as moderate toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include moderate eye irritation, slight skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 2005 MSDS date: 10-5-05

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08; Revised: 3/25/08

APPROVED BY
Independent IRB
_____ 3/25/08
Signature Date

Initials: _____
Date: _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

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7919 Champaign Dr.
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Phone: 440-255-1954
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LOCATION: _____
_____
_____

Introduction
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This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Fyfanon® 8 lb. Emulsion (EPA Registration No. 5905-250-ZA)

Active Ingredient (AI): Malathion (insecticide, CAS No. 00121-75-5)

Formulation and Packaging: 8 lbs AI/gallon Emulsifiable Concentrate in 1 or 2.5 gallon plastic jugs

APPROVED BY
Independent IRB
Signature
3/25/08
Date

Initials: _____
Date: _____

You may handle up to: 12.5 gallons of product

Required Personal Protective Equipment (PPE) for Handling: Applicators must wear long-sleeved shirt and long pants, and shoes plus socks. If you exit the closed cab and might touch contaminated surfaces you must also wear chemical resistant gloves. The gloves must be removed before re-entering the cab and stored in a chemical-resistant container.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

This malathion product is classified as low toxicity for exposure by mouth, by skin, and by breathing. Signs and symptoms of too much short-term exposure include moderate eye irritation, slight skin irritation, and inhibition of cholinesterase (cholinesterase is a chemical in our nervous system that allows the nerves to work correctly; when chemicals prevent it from working correctly, there is a stimulation of the nervous system).

Inhibition of cholinesterase may result in headache, dizziness, nausea, vomiting, cramps, diarrhea, blurred vision, pinpoint pupils, tightness in the chest, difficulty breathing, nervousness, sweating, watering of the eyes, drooling, muscle spasms, and coma.

Label date: 2005
MSDS date: 1-5-05

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08; Revised: 3/25/08

Version: 3/25/08
Protocol: AHE55
Fyfanon® 8 lb. Emulsion

APPROVED BY
Independent IRB
_____ 3/25/08
Signature Date

Initials: _____
Date: _____

RESEARCH INFORMATION AND INFORMED CONSENT FORM

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:

Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
Macon, Missouri 63552

STUDY DIRECTOR:

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

FIELD LOCATIONS: 3 to 5 Orange Orchards in Florida

_____
_____
_____

INTRODUCTION and PURPOSE

The Agricultural Handlers Exposure Task Force (AHETF) was formed by a group of pesticide companies. The purpose of this study is to measure how much pesticide you might get on your skin and breathe in while you spray using closed cab airblast equipment. This will be done by measuring pesticide residues in the samples we collect from you. About 5 people will be monitored in this study. The results of the study will be used to estimate exposure and risks to workers spraying pesticides with closed cab airblast equipment.

For you to participate in this study, you must understand and sign this consent form and a Product Risk Statement that describes the risks from the pesticide. If we have used words or presented information you do not clearly understand, please ask me to explain. You may take home an unsigned copy of this consent form to think about or discuss with family or friends or researchers before making your decision. If you agree to be in this study, you will be given a signed and dated copy of this consent form and the Product Risk Statement.

APPROVED BY
Independent IRB

_____ 3/25/08
Signature Date

Initials: _____
Date: _____

ELIGIBILITY
To be eligible to participate in this study you must:

1. Have made airblast applications using a closed cab tractor within the last year.
2. Provide proof you are at least 18 years old (government-issued photo ID).
3. Confirm you do not work for a pesticide company or a contractor of AHETF, except an employee of the Local Site Coordinator for this study.
4. Consider your general health status to be "good enough to do the work". Tell us if you have any medical conditions that affect your ability to participate in the study.
5. Not be pregnant or nursing. If you are female, you must take an over-the-counter urine pregnancy test before the study. This test will be supervised by a female researcher. You do not have to tell anyone if you have a positive test. Results of a negative test must be confirmed by the female researcher or you cannot participate.
6. Confirm that you do not normally wear personal protective equipment in excess of the label requirements for closed cab airblast applications. Confirm that you will follow label directions.
7. Have a private meeting with a researcher to go over this consent form. The purpose is to make sure you understand what you are agreeing to and to have all your questions answered. You may have a friend, family member or advisor with you during the meeting. If you are an employee, this person may not be from the operation's management.
8. Understand English or Spanish.
9. Understand and sign this consent form and Product Risk Statement.

STUDY DURATION
The duration of your participation in this study is approximately 4-8 hours of one of your normal workdays.

PROCEDURES BEFORE THE DAY OF THE STUDY
If you participate in this study, you will do the following:

1. Tell us your name and how many years you have been making closed cab airblast applications.
2. Allow researchers to measure and record your height and weight.
3. Allow researchers to record your gender, age, and preferred language.
4. Confirm whether you have received pesticide safety training or are exempt from pesticide safety training.
5. Allow us to take notes on the discussions during the informed consent session(s).

APPROVED BY
Independent IRB
Signature 3/25/08 Date

Initials: _____
Date: _____

If you read only Spanish, a Spanish version of the documents will be provided, along with a translator during our meeting. If you have trouble reading these documents in your language of choice (English or Spanish), it will be read to you.

PROCEDURES ON THE DAY OF THE STUDY

1. Bathe or shower the evening or morning before you come to work.
2. Wear a freshly laundered long-sleeved shirt and long pants.
3. Put on new long underwear (which we will provide) under your long-sleeved shirt and long pants. Wear your choice of personal undergarments under the long underwear. The long underwear will be collected at the end of the day. You will be asked to dress and undress with the assistance of a researcher of the same sex. A changing area will be provided for privacy. When you complete your participation, you will put on your own clothes and return to your normal work.
4. Wear a tube attached to your shirt collar and connected to a portable air-sampling pump on a belt worn around your waist. The pump is small and light about the size of a portable radio. This may be uncomfortable or annoying.
5. Wear all personal protection equipment required by the product label (see Product Risk Statement).
6. Work about 4 to 8 hours applying a commercial pesticide according to your normal practices and spray at least 3 loads.
7. Have your face and neck wiped with gauze pads moistened with a mild detergent and water mixture. This will be done before you eat anything, any time you would normally wash your face, and at the end of the day.
8. Have your hands washed in a mild detergent and water mixture. This will be done before you eat anything, any time you would normally wash your hands (such as when you use the toilet), and at the end of the day.
9. Allow researchers to watch all of your work activities and take notes on what you do.
10. Allow photographs and video recordings to be taken. You will not be photographed or video recorded while dressing or undressing. AHETF will own all rights to the photos and videos and may use them for any purpose. **If you do not want to be photographed or recorded you should not participate in this study.**

PRODUCTS HANDLED

You will be asked to apply a pesticide product that is registered by the US Environmental Protection Agency (EPA) and approved for spraying citrus with airblast equipment. The active ingredient will be carbaryl or malathion and farm management will select the product. However, you will know which product you will handle before you are asked to sign this consent form.

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In addition to the pesticide you will spray, farm management may require tank-mixes with other registered or approved products according to label directions. You will be told before your participation which materials will be in the tank mix.

RISKS AND DISCOMFORTS

In this study you will have the usual risks of using the spray equipment. You will only use equipment you have experience operating.

You will be asked to sign another document, the Product Risk Statement, that identifies the product you will spray, indicates how much of that product you might handle, and specifies the risks of handling that product. It also describes what personal protection equipment you must wear.

You will review the product label with the research staff to identify the airblast use directions and precautions. From the label, and Product Risk Statement, you will learn of any possible side-effects (such as skin irritation) and the signs and symptoms of overexposure. If you feel any of the signs or symptoms during or after the workday, or do not feel well for any reason, notify a researcher immediately. A copy of the product Material Safety Data Sheet (MSDS), is available for your review and discussion any time you desire.

Because you will wear long underwear underneath your normal work clothing, you have a risk of becoming sick from being too hot. This is known as heat stress or heat illness and can be serious or life threatening. Early signs and symptoms include feeling overheated, tired, dizzy, irritable, and having decreased concentration. If you feel any of these signs or symptoms during or after the workday notify a researcher immediately. If you don't feel well for any reason, notify a researcher immediately. You will be observed by a researcher watching for these symptoms. AHETF will stop your work if the weather gets too hot.

As a precaution, AHETF will have a paramedic, physician's assistant, nurse, or emergency medical technician on site during the study. If needed, this professional will also observe you for signs of illness and will provide medical attention.

You may have other risks or discomforts, including:

- Eye or skin irritation from the detergent and water mixture used to rinse your hands, face and neck
- Discomfort from wearing a portable air sampling pump around your waist
- Being embarrassed during dressing and undressing
- Being concerned about taking an over-the-counter pregnancy test
- Working longer than normal because of the extra time it takes to collect samples for analysis

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There may be other risks that are unknown at this time. You will be told in a timely manner both verbally and in writing of any new information that might change your decision to be in the study.

INJURY TO PARTICIPANTS

If you are injured or get sick during or after the day of the study, medical treatment will be available at your workplace and at a nearby health care facility. If necessary, AHETF will arrange transportation for you to receive medical attention. You may refuse medical treatment unless you get sick from too much pesticide exposure or from getting too hot, or if we believe you are too sick to make a rational decision about receiving medical treatment. AHETF will cover the cost of reasonable and appropriate medical attention that is not covered by your own insurance or insurance provided through your employer. Treatment records will not become part of the research records for this study. However, AHETF will make note of the event and this will be reported in the study report. For further information about this, you may call the AHETF Manager (David Johnson) at 660-349-4601.

You will not give up any of your legal rights by signing this form.

CONFIDENTIALITY

Your name will appear on the consent form, the Product Risk Statement, and an optional form for you to request your personal study results. All other study information will identify you only by a unique code. Records with your name will be stored in a secure, limited access archive.

Information about your participation in this study will not be given to your employer.

A study report will be written by AHETF and will be available to member companies. It will be sent to the US Environmental Protection Agency (EPA). It may also be sent to state government agencies and to governments of other countries. Your name will not be included in any study report.

We cannot promise you absolute confidentiality because of the need to give information to some organizations or to parties in legal actions, as required by law. All study information, including records which identify you, may be looked at or copied by the sponsor and any consultants working with the sponsor, by EPA or other government agencies, and by the Independent Investigational Review Board, Inc. (IIRB). IIRB is a group of people who review and monitor research to make sure the people who participate in it are protected.

You may ask the Study Director for a copy of your personal results from this study. You will need to provide your name and a mail or e-mail address.

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COSTS
There will be no costs to you for participation in this study.

BENEFITS
You will not directly benefit from your participation in the study. The farm owner may benefit from the product used in the study since AHETF will reimburse the owner for that product. Information from this study will be used to improve the quality of pesticide safety assessments for workers using closed cab airblast equipment.

PAYMENT FOR PARTICIPATION
You will be paid $20 if you meet privately with a researcher to review this informed consent. You will receive the money whether you decide to participate or not. You will receive the money in cash right after the meeting.

You will be paid an additional $80 for the day you participate in sampling. You will be paid $80 for completing the sampling day and allowing us to collect your samples. If you decide to withdraw during the sampling, you will still be paid the $80. If we remove you from the study, you will still receive the $80. Payment will be in cash at the end of the sampling day.

You will also receive your normal pay from your employer.

If more people volunteer than we need, we will decide which volunteers participate by drawing names from a container. You may or may not be selected to participate; if not selected, you will not receive the $80.

VOLUNTARY PARTICIPATION / WITHDRAWAL
Your employer has agreed to let us do the research and has confirmed that he/she does not care whether you to participate in this study. Your decision to be in this study is voluntary and entirely up to you. If you decide to participate, you may change your mind later and drop out of the study at any time and for any reason. A decision not to participate, or to withdraw from the study after it begins, will have no effect on your job or pay or include any penalty or any loss of benefits to which you may be entitled.

If you withdraw, the long underwear and air sampling pump will be removed, and the hand and face/neck samples may be collected with your consent.

Your participation in this study may be stopped at any time by the researchers or the sponsor. The long underwear and air sampling pump will be removed, and the hand and face/neck samples may be collected with your consent.

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If you withdraw or are removed from the study, or if the study does not last an entire workday, you will be released to resume your usual activities.

ALTERNATIVES
No one can require you to participate in this study. Participation is entirely voluntary. If you choose not to participate in this study, then on the day of the study you will perform your ordinary activities. You alternative is to not participate.

QUESTIONS
If you have questions about this study or if at any time you think you have a research-related injury or illness, contact a researcher or call:

Larry D. Smith (Study Director) at 440-255-1954 (collect)
Or 440-554-2812 (24 hours)
Or
David Johnson, Ph.D. (sponsor contact) at 660-349-4601 ext #1.

If you have any questions regarding your rights as a research volunteer, please contact Kim Lerner, Chairman of the Independent Investigational Review Board, Inc. at toll free (877) 888-iirb (4472) during regular working hours. The Independent Investigational Review Board is a committee established for the purpose of protecting the rights of volunteers in a research study.

IIRB is a group of people who perform independent review of research.

Do not sign this consent form unless you were able to ask questions and received satisfactory answers.

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CONSENT

I have read the information in this consent form and in the Product Risk Statement (or it has been read to me) in a language I understand well. All my questions about the study and about being in it have been answered. I freely consent to be in this study.

I authorize the release of my research records, including photographs and video recordings, to the sponsor, to the researchers, to government agencies in other states and/or countries, to EPA, to IIRB, and to other parties as required by law.

By signing this consent form, I have not given up any of my legal rights.

_____ _____
Date Subject's Name (print)

_____
Subject's Signature

_____
Subject's Unique Worker Code

I conducted the private consent meeting with the worker named above and confirm that consent was given voluntarily after being fully informed of the benefits, risks, and procedures. In addition, this worker has reviewed and signed the Product Risk Statement which I will store along with this signed consent form in a secure location:

_____ _____
Date Name of Person Conducting Informed Consent Discussion (print)

_____
Signature of Person Conducting Informed Consent Discussion

_____
Title and Affiliation of Person Conducting Informed Consent Discussion

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_____ 3/25/08
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Date: _____

---------- Use the following only if applicable ----------

If this consent form is read to the worker because the worker is unable to read the form, an impartial witness (who is not associated with the researchers or who is not part of the management of the grower where the study is being conducted) must be present to witness this worker's consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and understood by, this worker. This worker freely consented to participate in the research study.

_____ _____
Date Impartial Witness' Name (print)

_____
Impartial Witness' Signature

_____
Title and Affiliation of Impartial Witness

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not read English.

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08, Revised: 3/25/08

APPROVED BY
Independent IRB
_____ 3/25/08
Signature Date

Initials: _____
Date: _____

FORMULARIO DE INFORMACIÓN SOBRE LA INVESTIGACIÓN Y CONSENTIMIENTO INFORMADO

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, PhD
P.O. Box 509
Macon, Missouri 63552

DIRECTOR DEL ESTUDIO: Larry D. Smith, PhD
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Teléfono: 440-255-1954
Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIONES DE CAMPO: De 3 a 5 huertos de naranjas en la Florida.

_____
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INTRODUCCIÓN y PROPÓSITO

La Agricultural Handlers Exposure Task Force (AHETF) fue formada por un grupo de compañías de pesticidas. El propósito de este estudio es medir cuánto pesticida podría recibir usted en su piel y respirar, mientras que usted esté usando equipo de pulverización neumática de cabina cerrada. Se hará esto mediante la medición de residuos de pesticida en las muestras que nosotros recojamos de usted. Se monitoreará a unas 5 personas en este estudio. Los resultados del estudio se usarán para estimar la exposición y los riesgos a los trabajadores que estén fumigando pesticidas con equipo de pulverización neumática [*airblast*] de cabina cerrada.

Para que usted pueda participar en este estudio, usted debe entender y firmar este formulario de consentimiento y una Declaración de Riesgo del Producto que describe los riesgos provenientes del pesticida. Si hemos usado palabras o presentado información que usted no entienda con claridad, por favor pídame que le explique. Usted puede llevarse a su casa una copia, sin firmar, de este formulario de consentimiento, para pensarlo o para hablar sobre esto con sus familiares o amigos, o investigadores, antes de tomar su decisión. Si usted se pone de acuerdo para estar en

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este estudio, le darán una copia firmada y fechada de este formulario de consentimiento y de la Declaración de Riesgo del Producto.

ELEGIBILIDAD

Para poder participar en el estudio, usted debe:

1. Haber hecho aplicaciones de pulverización neumática [*airblast*] usando un tractor de cabina cerrada dentro del lapso de tiempo del último año.
2. Proporcionar prueba de que tiene por lo menos 18 años de edad (identificación con foto, emitida por un ente gubernamental).
3. Confirmar que no trabaja para una compañía de pesticidas ni para un contratista de AHETF exceptuando un empleado del Coordinador local del Sitio para este estudio.
4. Considera que su estado general de salud es «lo suficientemente bueno como para hacer el trabajo». Díganos si tiene alguna afección [dolencia] médica que afecte a su capacidad para participar en el estudio.
5. No estar embarazada ni lactando [dándole el pecho a un niño]. Si usted es mujer, usted debe hacerse una prueba de embarazo, de las de venta libre, antes del estudio. Esta prueba será supervisada por una investigadora. Usted no tiene que decirle a nadie si es que tiene una prueba positiva. Los resultados de una prueba negativa deben ser confirmados por la investigadora o usted no puede participar.
6. Confirmar que usted no usa, normalmente, equipo de protección personal que exceda los requisitos de la etiqueta para las aplicaciones de pulverización neumática [*airblast*] de cabina cerrada. Confirmar que usted seguirá las instrucciones de la etiqueta.
7. Tener una reunión privada con un investigador para repasar este formulario de consentimiento. El propósito es cerciorarse de que usted entienda con qué se está poniendo de acuerdo y que le respondan a todas sus preguntas. Usted puede tener a un amigo, a un miembro de su familia o a un asesor, con usted, durante la reunión. Si usted es un empleado, esta persona no puede ser de la gerencia de operaciones.
8. Entender inglés ó castellano [español].
9. Entender y firmar este formulario de consentimiento y Declaración de Riesgo del Producto.

LA DURACIÓN DEL ESTUDIO

La duración de su participación en este estudio es de aproximadamente 4-8 horas de uno de sus días normales de trabajo.

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LOS PROCEDIMIENTOS ANTERIORES AL DÍA DEL ESTUDIO
Si participa en este estudio, usted hará lo siguiente:

1. Díganos su nombre y cuántos años ha estado haciendo aplicaciones de pulverización neumática [*airblast*] de cabina cerrada.
2. Permitirles a los investigadores que midan y registren su estatura [altura] y peso.
3. Permitirles a los investigadores que midan y registren su género, edad, e idioma preferido.
4. Confirmar si usted ha recibido entrenamiento de seguridad en pesticidas o si está exento del entrenamiento de seguridad en pesticidas.
5. Permitirnos tomar notas sobre los debates, durante la sesión(es) del consentimiento informado.

Si usted lee solamente español, le proporcionarán una versión de los documentos en español, junto con un intérprete [traductor] durante nuestra reunión. Si usted tuviese problemas para leer estos documentos en el idioma que usted haya elegido (inglés ó español), entonces se los leerán a usted.

LOS PROCEDIMIENTOS EN EL DÍA DEL ESTUDIO

1. Báñese o dúchese en la noche o en la mañana, antes de venir al trabajo.
2. Use una camisa de manga larga y pantalones largos, recién lavados.
3. Póngase ropa interior larga nueva (la cual se la proporcionaremos) debajo de su camisa de manga larga y pantalones largos. Use la ropa interior que usted desee, debajo de la ropa interior larga. La ropa interior larga se recogerá al final del día. Le pedirán que se vista y se desvista con la asistencia de un investigador del mismo sexo. Le proporcionarán un área para cambiarse, por razones de privacidad. Cuando usted complete su participación, usted se pondrá sus propias ropas y regresará a su trabajo normal.
4. Usted usará un tubo adherido al cuello de su camisa y éste estará conectado a una bomba portátil de muestreo de aire, en un cinturón que usted usará alrededor de la cintura. La bomba es pequeña y liviana, alrededor del tamaño de una radio portátil. Esto puede ser incómodo y molesto.
5. Use todo el equipo de protección personal requerido por la etiqueta del producto (vea la Declaración de Riesgo del Producto).
6. Trabaje alrededor de 4 u 8 horas aplicando un pesticida comercial, de acuerdo con sus prácticas normales y fumigue por lo menos 3 cargas.
7. Limpiarse la cara y cuello con almohadillas de gasa humedecidas con una mezcla de detergente suave y agua. Esto se llevará a cabo antes de que usted coma nada, en cualquier momento en el que usted normalmente se lavaría la cara y, al final del día.
8. Lavarse las manos con una mezcla de detergente suave y agua. Esto se llevará a cabo antes de que usted coma nada, en cualquier momento en el que usted normalmente se lavaría las manos (tal como cuando usa el cuarto de baño) y, al final del día.

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9. Permitirles a los investigadores que observen todas sus actividades laborales [de trabajo] y que tomen notas acerca de lo que hace usted.
10. Permitirles que saquen fotografías y grabaciones en vídeo. No lo fotografiarán ni lo grabarán en vídeo, mientras que se esté vistiendo o desvistiendo. AHETF será la propietaria exclusiva [con todos los derechos] de las fotografías y vídeos y puede usarlos con cualquier propósito. **Si usted no desea que lo fotografíen ni que lo graben en vídeo, usted no debería participar en este estudio**.

PRODUCTOS MANIPULADOS

Le pedirán que aplique un producto pesticida que está registrado por la Agencia Estadounidense de Protección Medioambiental (EPA) y aprobado para fumigar cítricos con equipo de pulverización neumática [*airblast*]. El ingrediente activo será carbarilo [carbaryl] ó malatión [malathion] y la gerencia de la granja seleccionará el producto. No obstante, usted sabrá cuál producto va a manipular, antes de que le pidan que firme este formulario de consentimiento.

Además del pesticida que usted fumigará, la administración de la granja pudiera requerir las mezclas de tanques con otros productos registrados o aprobados, de acuerdo con las instrucciones de la etiqueta. Antes de su participación, le dirán cuáles materiales habrá en la mezcla del tanque.

RIESGOS Y MOLESTIAS

En este estudio, usted correrá los riesgos usuales del uso de equipos de fumigación. Usted usará solamente equipos en los que tenga experiencia en operarlos.

Le pedirán que firme otro documento, Declaración de Riesgo del Producto, que identifica al producto que usted fumigará, que indica cuánto de ese producto usted podría manipular y, que especifica los riesgos del manipuleo de ese producto. También describe qué equipo de protección personal debe usar usted.

Usted revisará la etiqueta del producto junto con el personal de la investigación científica, para identificar las instrucciones y precauciones del uso de la pulverización neumática [*airblast*]. De la etiqueta y de la Declaración de Riesgo del Producto, usted se informará acerca de cualquier efecto(s) secundario(s) posible (tal como irritación en la piel) y las señales y síntomas de la sobre-exposición. Si usted sintiese cualquiera de las señales ó síntomas durante ó después del día de trabajo, ó si no se sintiese bien por cualquier razón, notifíqueselo inmediatamente a un investigador. Hay a su disposición, en cualquier momento en el que usted lo desee, una copia de la Hoja de Datos de Seguridad del Material (MSDN) del producto.

Debido a que usted usará ropa interior larga debajo de sus ropas normales de trabajo, usted corre un riesgo de enfermarse debido a que sienta mucho calor. A esto se le conoce como golpe de calor [*heat stress* ó *heat illness* en inglés] y puede ser grave o puede constituir una amenaza a la vida. Las señales y los síntomas tempranos

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incluyen la sensación de exceso de calor, cansancio, mareos, estar irritable y, la disminución de concentración. Si usted sintiese cualquiera de estas señales ó síntomas, durante ó después de un día de trabajo, notifíqueselo inmediatamente a un investigador. Si usted no se sintiese bien por cualquier razón, notifíqueselo inmediatamente a un investigador. Un investigador que esté tratando de detectar estos síntomas, va a estar observándolo a usted. AHETF detendrá su trabajo si el tiempo se pusiese muy cálido.

Como medida de precaución, AHETF tendrá un paramédico, asistente de médico, enfermera, ó un técnico en emergencias médicas, en el sitio durante el estudio. Si fuere necesario, este profesional también lo observará a usted para detectar señales de enfermedad y le proporcionará atención médica.

Usted pudiera tener otros riesgos o molestias, incluyendo:

- Irritación en los ojos o en la piel, proveniente de la mezcla de detergente y agua que use para enjuagarse las manos, cara y cuello.
- Molestia debida al uso de una bomba portátil de muestreo de aire, alrededor de su cintura.
- Sentirse con vergüenza mientras que se esté vistiendo o desvistiendo.
- Estar preocupada acerca de tener que hacerse una prueba de embarazo de venta libre.
- El trabajar más tiempo de lo normal, debido al tiempo extra que lleva recolectar muestras para los análisis.

Pudiera haber otros riesgos que se desconozcan en estos momentos. Le dirán de manera puntual, tanto verbalmente como por escrito, acerca de cualquier información nueva que podría cambiar su decisión de estar en el estudio.

LESIÓN AL PARTICIPANTE

Si usted se lesionase o se enfermase durante o después del día del estudio, habrá a su disposición tratamiento médico en su lugar de trabajo y en una instalación cercana de atención médica. Si fuere necesario, AHETF arreglará para que lo transporten para que reciba atención médica. Usted puede rehusar el tratamiento médico, al menos que usted se enferme debido a la demasiada exposición al pesticida o debido al excesivo calor, o si nosotros creyésemos que usted está demasiado enfermo como para tomar una decisión racional acerca de recibir tratamiento médico. AHETF cubrirá el costo de la atención médica razonable y apropiada, que no esté cubierta por su propio seguro o por el seguro que le proporcione su empleador. Los expedientes del tratamiento no se convertirán en parte de los expedientes de la investigación científica para este estudio. No obstante, AHETF tomará nota del evento y esto estará reportado en el informe del estudio. Para más información acerca de esto, usted puede llamar al Administrador de AHETF (David Jonson) al 660-349-4601.

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Usted no renunciará a ninguno de sus derechos legales por firmar este formulario.

CONFIDENCIALIDAD

Su nombre aparecerá en el formulario de consentimiento, en la Declaración de Riesgo del Producto y, en un formulario optativo para que usted solicite sus resultados personales del estudio. Toda la otra información proveniente del estudio, lo identificará a usted solamente por medio de un código único. Los expedientes que contengan su nombre se almacenarán en un archivo seguro, de acceso limitado.

La información acerca de su participación en este estudio no se le dará a su empleador.

AHETF escribirá un informe del estudio y estará a disposición de compañías miembro. Se le enviará a la Agencia Estadounidense de Protección Medioambiental (EPA). También pudiera ser enviada a agencias gubernamentales estatales y a gobiernos de otros países. Su nombre no estará incluido en ningún informe del estudio.

Nosotros no podemos prometerle a usted una confidencialidad absoluta debido a la necesidad de darles información a algunas organizaciones o a partes [a terceros] en acciones legales, según lo requiera la ley. Toda la información proveniente del estudio, incluyendo los expedientes que lo identifiquen a usted, pueden ser mirados o copiados por el patrocinador y por cualquier consultor(es) que esté trabajando con el patrocinador, por la EPA o por otras agencias gubernamentales y, por el Independent Investigational Review Board, Inc. (IIRB). El IIRB es un grupo de personas quienes revisan y monitorean la investigación científica para cerciorarse de que las personas quienes participen en ella, estén protegidas.

Usted puede pedirle, al Director del Estudio, una copia de sus resultados personales provenientes de este estudio. Usted va a necesitar proporcionar su nombre y una dirección postal o de correo electrónico [*e-mail*].

COSTOS

No habrá costos para usted por la participación en este estudio.

BENEFICIOS

Usted no se beneficiará, directamente, de la participación en el estudio. El propietario de la granja pudiera beneficiarse del producto usado en el estudio, dado que AHETF lo reembolsará al propietario por ese producto. La información proveniente de este estudio se usará para mejorar la calidad de las evaluaciones de seguridad en los pesticidas, para los trabajadores que estén usando equipo de pulverización neumática [*airblast*] de cabina cerrada.

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EL PAGO POR LA PARTICIPACIÓN

Le pagarán $20 si usted se reúne en privado con un investigador para repasar este consentimiento informado. Usted recibirá el dinero si usted decide participar o no. Usted recibirá el dinero en efectivo enseguida de la reunión.

Le pagarán $80 adicionales por el día que usted participe en el muestreo. Le pagarán $80 por completar el día de muestreo y por permitirnos recoger sus muestras. Si usted decide retirarse durante el muestreo, aún le pagarán los $80. Si nosotros lo hiciésemos retirarse del estudio, usted aún recibirá los $80. El pago se efectuará en efectivo al final del día de muestreo.

Usted también recibirá su pago normal de su empleador.

Si hubiese más voluntarios de los que necesitamos, nosotros decidiremos cuáles voluntarios participarán, sacando nombres de un recipiente. Usted pudiera, o no, ser seleccionado para participar, si no fuese seleccionado, usted no recibirá los $80.

LA PARTICIPACIÓN / EL RETIRO VOLUNTARIOS

Su empleador se ha puesto de acuerdo en permitirnos llevar a cabo la investigación científica y ha confirmado que él/ella no le importa si usted participa en este estudio. Su decisión de estar en este estudio es voluntaria y queda librada enteramente a usted. Si usted decide participar, usted pudiera, más adelante, cambiar de manera de pensar y abandonar el estudio en cualquier momento y por cualquier razón. Una decisión de no participar, o de retirarse del estudio después de que éste haya empezado, no tendrá efecto sobre su trabajo ni sobre su pago, ni incluirá ninguna multa ni pérdida de beneficios a los cuales usted pueda tener derecho.

Si usted se retirase, la ropa interior larga y la bomba de muestreo de aire se los removerán, y las muestras de las manos y cara/cuello pudieran recogerse con su consentimiento.

Su participación en este estudio pudiera ser detenida en cualquier momento por los investigadores o por el patrocinador. La ropa interior larga y la bomba de muestreo de aire se los removerán, y las muestras de las manos y cara/cuello pudieran recogerse con su consentimiento.

Si usted se retirase del estudio, o si lo quitasen del estudio, o si el estudio no durase un día entero de trabajo, a usted lo dejarán que reanude sus actividades usuales.

ALTERNATIVAS

Nadie puede requerirle a usted que participe en este estudio. La participación es enteramente voluntaria. Si usted opta por no participar en este estudio, entonces en el día del estudio usted desempeñará sus actividades normales y corrientes. Su alternativa es la de no participar.

APROBADO POR
Independent IRB
Firma
25/marzo/08
Fecha

Iniciales: _____
Fecha: _____

PREGUNTAS

Si tiene preguntas acerca de este estudio o si en cualquier momento usted tuviese una lesión o enfermedad relacionada con el estudio, póngase en contacto con un investigador o llame a:

Larry D. Smith (Director del Estudio) al 440-255-1954 (llamada a cobrar; *collect*)
Ó 440-554-2812 (las 24 horas)
Ó
David Johnson, PhD (contacto del patrocinador) al 660-349-4601 ext. № 1.

Si usted tiene cualquier pregunta(s) en lo concerniente a sus derechos en calidad de voluntario de una investigación científica, por favor póngase en contacto con la señora Kim Lerner, Presidenta del Independent Investigational Review Board, Inc. llamando al número gratuito (877) 888-iirb (4472) durante horas regulares de trabajo. El Independent Investigational Review Board es un comité que se ha establecido con el propósito de proteger los derechos de los voluntarios en un estudio de investigación científica.

El IIRB es un grupo de personas quienes desempeñan la revisión independiente de la investigación científica.

No firme este formulario al menos que usted haya podido hacer preguntas y que haya recibido respuestas satisfactorias.

APROBADO POR
Independent IRB
Firma
25/marzo/08
Fecha

Iniciales: _____
Fecha: _____

CONSENTIMIENTO

Yo he leído la información existente en este formulario de consentimiento y en la Declaración de Riesgo del Producto (ó me la han leído) en un idioma que entiendo bien. Todas mis preguntas acerca del estudio y acerca del hecho de estar en él, me las han respondido. Yo consiento libremente a estar en este estudio.

Yo autorizo la divulgación de mis expedientes de la investigación científica, incluyendo fotografías y grabaciones de vídeo, al patrocinador, a los investigadores, a agencias gubernamentales en otros estados y/ó países, a la EPA, al IIRB, y a otras partes, según lo requiera la ley.

Al firmar este formulario de consentimiento, yo no he renunciado a ninguno de mis derechos legales.

Fecha _____ Nombre del Sujeto (en letra de molde; de imprenta) _____

Firma del Sujeto _____

Código Único de Trabajador, del Sujeto _____

Yo dirigí la reunión privada del consentimiento, con el trabajador mencionado anteriormente y confirmo que el consentimiento fue dado voluntariamente después de haber sido informado acerca de los beneficios, riesgos y procedimientos. Además, este trabajador ha revisado y firmado la Declaración de Riesgo del Producto, la cual yo almaceno junto con este formulario de consentimiento firmado, en un lugar seguro:

Fecha _____ Nombre de la Persona que está Dirigiendo la Discusión del Consentimiento Informado (en letra de molde; de imprenta) _____

Firma de la Persona que está Dirigiendo la Discusión del Consentimiento Informado _____

Título y Afiliación de la Persona que está Dirigiendo la Discusión del Consentimiento Informado. _____

APROBADO POR
Independent IRB
Firma
25/marzo/08
Fecha

---------- Use lo siguiente solamente si fuere pertinente ----------

Si este formulario de consentimiento se le lee al trabajador debido a que el trabajador no puede leer el formulario, debe estar presente un testigo imparcial (quien no esté asociado con los investigadores ó quien no forme parte de la administración del cultivador donde el estudio se esté llevando a cabo) para atestiguar el consentimiento de este trabajador y firmar la siguiente declaración:

Yo confirmo que la información existente en este formulario de consentimiento y cualquier otra información escrita, le fue explicada con precisión a este trabajador y éste la entendió. Este trabajador consintió libremente a participar en el estudio de investigación científica.

Fecha	Nombre del Testigo Imparcial (en letra de molde; de imprenta)
	Firma del Testigo Imparcial
	Título y Afiliación del Testigo Imparcial

Nota: Este bloque de firmas no puede usarse para las traducciones a otro idioma. Se necesita un formulario de consentimiento, traducido, para inscribir a sujetos quienes no lean inglés.

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08; Revisado: 25/marzo/08

APROBADO POR
Independent IRB
Firma
25/marzo/08
Fecha

Iniciales: _____
Fecha: _____

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 26, 2008

To Whom It May Concern:
A Quién Corresponda:

This is to certify that the attached document from English into Spanish is an accurate representation of the informed consent form received by this office. This document is designated as:

(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/25/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 25/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Américo Gómez, who translated this document, is fluent in Spanish and standard North American English and qualified to translate. He attests to the following:

Américo Gómez, quien tradujo dicho documento, tiene dominio de los idiomas inglés norteamericano y español, y está capacitado para traducir. Él declara lo siguiente:

"To the best of my knowledge, the accompanying text is a true, full and accurate translation of the specified document".
«Según mi leal saber y entender, el texto que sigue a continuación es una traducción fiel y correcta del documento que se adjunta».

Signature of Américo Gómez/*Firma de Américo Gómez*

Declaración de Riesgo del Producto
Riesgo de Toxicidad del Producto Pesticida Manipulado
(Debe adjuntarse al Formulario de Consentimiento Informado)

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, PhD
P.O. Box 509
Macon, Missouri 63552

DIRECTOR DEL ESTUDIO: Larry D. Smith, PhD
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Teléfono: 440-255-1954
Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIÓN: _____
_____
_____

Introducción
Usted se ha puesto de acuerdo para participar en el estudio de referencia. El formulario de consentimiento informado que usted firmó, enunciaba que se le informaría verbalmente y por escrito, acerca de cualquier riesgo(s) que podría influir sobre su disposición para participar en el estudio.

Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Fyfanon® (Registro de EPA № 5905-196)

Ingrediente Activo (AI): Malathion (insecticida, CAS № 00121-75-5)

Formulación y Embalaje: 5 lbs. AI/galón Concentrado Emulsionante.

Usted puede manipular hasta: 20 galones del producto

APROBADO POR
Independent IRB
Firma
25/marzo/08
Fecha

Iniciales: _____
Fecha: _____

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes a las substancias químicas y anteojos protectores para los ojos. Debe quitarse los guantes y los anteojos protectores para los ojos, antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto malatión [malathion] está clasificado como de toxicidad moderada para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación moderada de los ojos, irritación ligera de la piel, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Fecha de la etiqueta: 2005 Fecha de la MSDS: octubre-5-05

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma del Testigo Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08; Revisado: 25/marzo/08

Versión: 25/marzo/08
Protocolo: AHE55
Fyfanon®

APROBADO POR
Independent IRB
Firma 25/marzo/08 Fecha

Iniciales: _____
Fecha: _____

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 26, 2008

To Whom It May Concern:
A Quién Corresponda:

This is to certify that the attached document from English into Spanish is an accurate representation of the informed consent form received by this office. This document is designated as:

Fyfanon®
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/25/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

Fyfanon®
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 25/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

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«Según mi leal saber y entender, el texto que sigue a continuación es una traducción fiel y correcta del documento que se adjunta».

Signature of Américo Gómez/*Firma de Américo Gómez*

Declaración de Riesgo del Producto
Riesgo de Toxicidad del Producto Pesticida Manipulado
(Debe adjuntarse al Formulario de Consentimiento Informado)

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, PhD
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Mentor, Ohio 44060
Teléfono: 440-255-1954
Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIÓN: _____
_____
_____

Introducción
Usted se ha puesto de acuerdo para participar en el estudio de referencia. El formulario de consentimiento informado que usted firmó, enunciaba que se le informaría verbalmente y por escrito, acerca de cualquier riesgo(s) que podría influir sobre su disposición para participar en el estudio.

Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Fyfanon® 8 lb. Emulsión (Registro de EPA № 5905-250-ZA)

Ingrediente Activo (AI): Malathion (insecticida, CAS № 00121-75-5)

Formulación y Embalaje: 8 lbs. AI/galón Concentrado Emulsionante en jarras de plástico de 1 ó 2,5 galones.

APROBADO POR
Independent IRB
Firma
25/marzo/08
Fecha

Iniciales: _____
Fecha: _____

Usted puede manipular hasta: 12,5 galones del producto

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes a las substancias químicas. Debe quitarse los guantes antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto malatión [malathion] está clasificado como de baja toxicidad para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación moderada de los ojos, irritación ligera de la piel, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Fecha de la etiqueta: **2005**
Fecha de la MSDS: **enero-5-05**

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma del Testigo Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08; Revisado: 25/marzo/08

Versión: 25/marzo/08
Protocolo: AHE55
Fyfanon® 8 lb. Emulsión

APROBADO POR
Independent IRB
Firma 25/marzo/08 Fecha

Iniciales: _____
Fecha: _____

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
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March 26, 2008

To Whom It May Concern:
A Quién Corresponda:

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Fyfanon® 8 lb. Emulsion
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/25/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

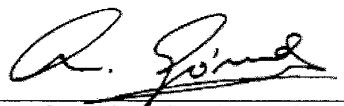
Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

Fyfanon® Emulsión de 8 libras
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 25/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Américo Gómez, who translated this document, is fluent in Spanish and standard North American English and qualified to translate. He attests to the following:

Américo Gómez, quien tradujo dicho documento, tiene dominio de los idiomas inglés norteamericano y español, y está capacitado para traducir. Él declara lo siguiente:

"To the best of my knowledge, the accompanying text is a true, full and accurate translation of the specified document".
«Según mi leal saber y entender, el texto que sigue a continuación es una traducción fiel y correcta del documento que se adjunta».



Signature of Américo Gómez/*Firma de Américo Gómez*

Declaración de Riesgo del Producto
Riesgo de Toxicidad del Producto Pesticida Manipulado
(Debe adjuntarse al Formulario de Consentimiento Informado)

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
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Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIÓN: _____
_____
_____

Introducción
Usted se ha puesto de acuerdo para participar en el estudio de referencia. El formulario de consentimiento informado que usted firmó, enunciaba que se le informaría verbalmente y por escrito, acerca de cualquier riesgo(s) que podría influir sobre su disposición para participar en el estudio.

Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Insecticida Servin® Brand 80 WSP Carbaryl (Registro de EPA № 264-526)

Ingrediente Activo (AI): Carbaryl (insecticida, CAS № 63-25-2)

Formulación y Embalaje: 80% AI polvo seco en un paquete soluble en agua de 1,25 libras.

Usted puede manipular hasta: 100 paquetes solubles en agua

APROBADO POR
Independent IRB
Firma
25/marzo/08
Fecha

Iniciales: _____
Fecha: _____

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes al agua. Debe quitarse los guantes antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto carbarilo [carbaryl] está clasificado como de toxicidad moderada para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación ligera de los ojos, irritación mínima de la piel, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Fecha de la etiqueta: septiembre-23-04
Fecha de la MSDS: diciembre-26-02 (Número 000000001825; Versión 1.1)

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma de la Persona que está dirigiendo la discusión del Formulario de Consentimiento Informado Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08; Revisado: 25/marzo/08

APROBADO POR
Independent IRB
Firma 25/marzo/08 Fecha

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Independent Translator
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March 26, 2008

To Whom It May Concern:
A Quién Corresponda:

This is to certify that the attached document from English into Spanish is an accurate representation of the informed consent form received by this office. This document is designated as:

SevinBrand® 80 WSP
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/25/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

SevinBrand® 80 WSP
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 25/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Américo Gómez, who translated this document, is fluent in Spanish and standard North American English and qualified to translate. He attests to the following:

Américo Gómez, quien tradujo dicho documento, tiene dominio de los idiomas inglés norteamericano y español, y está capacitado para traducir. Él declara lo siguiente:

"To the best of my knowledge, the accompanying text is a true, full and accurate translation of the specified document".
«Según mi leal saber y entender, el texto que sigue a continuación es una traducción fiel y correcta del documento que se adjunta».

Signature of Américo Gómez/*Firma de Américo Gómez*

Declaración de Riesgo del Producto
Riesgo de Toxicidad del Producto Pesticida Manipulado
(Debe adjuntarse al Formulario de Consentimiento Informado)

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, PhD
P.O. Box 509
Macon, Missouri 63552

DIRECTOR DEL ESTUDIO: Larry D. Smith, PhD
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Teléfono: 440-255-1954
Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIÓN: _____
_____
_____

Introducción
Usted se ha puesto de acuerdo para participar en el estudio de referencia. El formulario de consentimiento informado que usted firmó, enunciaba que se le informaría verbalmente y por escrito, acerca de cualquier riesgo(s) que podría influir sobre su disposición para participar en el estudio.

Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Insecticida Servin® Brand 4F Carbaryl (Registro de EPA № 264-349)

Ingrediente Activo (AI): Carbaryl (insecticida, CAS № 63-25-2)

Formulación y Embalaje: 4 lbs. AI/galón líquido fluyente en jarras de plástico de 2,5 galones.

Usted puede manipular hasta: 25 galones del producto

APROBADO POR
Independent IRB
Firma
25/marzo/08
Fecha

Iniciales: _____
Fecha: _____

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes a las substancias químicas. Debe quitarse los guantes antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto carbarilo [carbaryl] está clasificado como de baja toxicidad para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación ligera de los ojos, irritación mínima de la piel, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Fecha de la etiqueta: septiembre-27-04
Fecha de la MSDS: diciembre-18-02 (№ 000000000194, Versión 2.1)

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma del Testigo Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08; Revisado: 25/marzo/08

APROBADO POR
Independent IRB
Firma 25/marzo/08 Fecha

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 26, 2008

To Whom It May Concern:
A Quién Corresponda:

This is to certify that the attached document from English into Spanish is an accurate representation of the informed consent form received by this office. This document is designated as:

SevinBrand® 4 F
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/25/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

SevinBrand® 4 F
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 25/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

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«Según mi leal saber y entender, el texto que sigue a continuación es una traducción fiel y correcta del documento que se adjunta».

Signature of Américo Gómez/*Firma de Américo Gómez*

Declaración de Riesgo del Producto
Riesgo de Toxicidad del Producto Pesticida Manipulado
(Debe adjuntarse al Formulario de Consentimiento Informado)

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, PhD
P.O. Box 509
Macon, Missouri 63552

DIRECTOR DEL ESTUDIO: Larry D. Smith, PhD
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Teléfono: 440-255-1954
Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIÓN: _____
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Introducción
Usted se ha puesto de acuerdo para participar en el estudio de referencia. El formulario de consentimiento informado que usted firmó, enunciaba que se le informaría verbalmente y por escrito, acerca de cualquier riesgo(s) que podría influir sobre su disposición para participar en el estudio.

Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Gowan Malathion 8 (Registro de EPA № 10163-21)

Ingrediente Activo: Malathion (insecticida, CAS № 121-75-5)

Formulación y Embalaje: 8 lbs. AI/galón Concentrado Emulsionante.

Usted puede manipular hasta: 12,5 galones del producto

APROBADO POR
Independent IRB
Firma
25/marzo/08
Fecha

Iniciales: _____
Fecha: _____

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes a las substancias químicas. Debe quitarse los guantes antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto malatión [malathion] está clasificado como de baja toxicidad para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación ligera de los ojos y/ó piel, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Identificación de la etiqueta: 04-R0699
Fecha de la MSDS: febrero-1-07 (Gowan Malathion 8 que fluye)

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma del Testigo Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08; Revisado: 25/marzo/08

Versión: 25/marzo/08
Protocolo: AHE55
Gowan Malathion 8

APROBADO POR
Independent IRB
Firma 25/marzo/08 Fecha

Iniciales: _____
Fecha: _____

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 26, 2008

To Whom It May Concern:
A Quién Corresponda:

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Malathion® 8
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/25/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

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Malathion® 8
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 25/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
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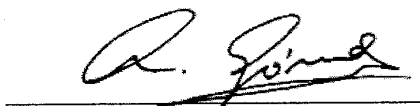

Signature of Américo Gómez/*Firma de Américo Gómez*

Declaración de Riesgo del Producto
Riesgo de Toxicidad del Producto Pesticida Manipulado
(Debe adjuntarse al Formulario de Consentimiento Informado)

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
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Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Insecticida Malathion 8-E (Registro de EPA № 34704-452)

Ingrediente Activo (AI): Malathion (insecticida, CAS № 121-75-5)

Formulación y Embalaje: 8 lbs. AI/galón Concentrado Emulsionante en jarras de plástico de 1 galón.

Usted puede manipular hasta: 12,5 galones del producto

APROBADO POR
Independent IRB
Firma
25/marzo/08
Fecha

Iniciales: _____
Fecha: _____

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes a las substancias químicas. Debe quitarse los guantes antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto malatión [malathion] está clasificado como de baja toxicidad para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación moderada de los ojos, irritación ligera de la piel, posible reacción alérgica en la piel, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Fecha de la etiqueta: no se ha encontrado
Fecha de la MSDS: junio-8-06 (Loveland MSDS № 000452-06-LPI)

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma del Testigo Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08; Revisado: 25/marzo/08

APROBADO POR
Independent IRB
Firma 25/marzo/08 Fecha

Iniciales: _____
Fecha: _____

Américo Gómez
Independent Translator
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Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 26, 2008

To Whom It May Concern:
A Quién Corresponda:

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Malathion® 8 E
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/25/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

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Malathion® 8 E
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 25/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
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Signature of Américo Gómez/*Firma de Américo Gómez*

Declaración de Riesgo del Producto
Riesgo de Toxicidad del Producto Pesticida Manipulado
(Debe adjuntarse al Formulario de Consentimiento Informado)

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
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UBICACIÓN: _____
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Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Insecticida Servin® Brand XLR Plus Carbaryl (Registro de EPA № 264-333)

Ingrediente Activo (AI): Carbaryl (insecticida, CAS № 63-25-2)

Formulación y Embalaje: 4 lbs. AI/galón de líquido fluyente en jarras plásticas de 2,5 galones.

Usted puede manipular hasta: 25 galones del producto

APROBADO POR
Independent IRB
Firma
25/marzo/08
Fecha

Iniciales: _____
Fecha: _____

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes a substancias químicas. Debe quitarse los guantes antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto carbarilo [carbaryl] está clasificado como de baja toxicidad para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación ligera de los ojos, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

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Fecha de la etiqueta: septiembre-21-04
Fecha de la MSDS: enero-17-08 (Bayer MSDS 102000001927; Versión 2.1)

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma de la Persona que está dirigiendo la discusión del Formulario de Consentimiento Informado Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08; Revisado: 25/marzo/08

APROBADO POR
Independent IRB
Firma 25/marzo/08 Fecha

Iniciales: _____
Fecha: _____

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March 26, 2008

To Whom It May Concern:
A Quién Corresponda:

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SevinBrand® XLR Plus
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/25/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

SevinBrand® XLR Plus
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 25/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Américo Gómez, who translated this document, is fluent in Spanish and standard North American English and qualified to translate. He attests to the following:

Américo Gómez, quien tradujo dicho documento, tiene dominio de los idiomas inglés norteamericano y español, y está capacitado para traducir. Él declara lo siguiente:

"To the best of my knowledge, the accompanying text is a true, full and accurate translation of the specified document".
«Según mi leal saber y entender, el texto que sigue a continuación es una traducción fiel y correcta del documento que se adjunta».

Signature of Américo Gómez/*Firma de Américo Gómez*

LS Consulting

From: Robert Roogow [rroogow@iirb.com]
Sent: Wednesday, April 02, 2008 9:42 AM
To: lsconsulting@oh.rr.com
Subject: Minutes from 3/25/2008
Attachments: 3-25-2008 (AHE55&AHE56).doc

Dear Larry,

I have attached the portion of the minutes From 3/25/2008 that pertain to your protocols, AHE55 and AHE56. Please let me know if you should need anything else.

Regards,

Robert Roogow, MS, CIM
Director of Operations
Independent Investigational Review Board, Inc.
Ph: 954-327-0778
Fax: 954-327-5778
rroogow@iirb.com

Tuesday, March 25, 2008
MINUTES

ATTENDANCE:

PRESENT	ALSO PRESENT
David Wells, MD	Glenn Moran, MD
Anita McSharry, RN	Marcos Rejtman, DO
Shari Somerstein, RPh	
Edward Wiederhorn	BOARD/STAFF LIASON
Robert Lettman, Esq	Katy Kysela
Rabbi Akiva Mann	
Kim Lerner	NOT PRESENT
	George Garbarino

I. CALL TO ORDER

The meeting was called to order at 10:00 AM, by Chairman, Kim Lerner. The meeting was held at 6738 West Sunrise Blvd., Suite 102, Plantation, FL 33313. Quorum was determined to be present and all attendees affirmed that no significant financial or non-financial conflicts of interest existed with review of any of the items listed on the agenda.

II. APPROVAL OF THE 3/18/2008 MINUTES

The minutes of the meeting held 3/18/2008 were reviewed and unanimously approved as reviewed.

IV. OTHER BUSINESS

H Revised Protocol; AHE55; Larry D. Smith, PhD;

- Informed Consent Form version 3/25/2008
- Fyfanon® 8 lb. Emulsion Product Risk Statement version 3/25/2008
- Fyfanon® Product Risk Statement version 3/25/2008
- Gowan Malathion 8 Product Risk Statement version 3/25/2008
- Malathion 8-E Product Risk Statement version 3/25/2008
- Sevin® Brand 4F Product Risk Statement version 3/25/2008
- Sevin® Brand 80WSP Product Risk Statement version 3/25/2008
- Sevin® Brand XLR Product Risk Statement version 3/25/2008
- Protocol Revision dated 3/21/2008 and 3/24/2008
- Agricultural Handlers Exposure Task Force SOPs

The Independent Investigational Review Board, Inc. had an opportunity to review the above referenced Informed Consent Form, Fyfanon® 8 lb. Emulsion Product Risk Statement, Fyfanon® Product Risk Statement, Gowan Malathion 8 Product Risk Statement, Malathion 8-E Product Risk Statement, Sevin® Brand 4F Product Risk Statement, Sevin® Brand 80WSP Product Risk Statement, Sevin® Brand XLR Product

Risk Statement, Protocol Revision and Agricultural Handlers Exposure Task Force SOPs for the above noted research study. The Revised Protocol included changes that were requested as a result of a EPA review. The EPA also requested changes to the Informed Consent Form.

ACTION: The Informed Consent Form, Fyfanon® 8 lb. Emulsion Product Risk Statement, Fyfanon® Product Risk Statement, Gowan Malathion 8 Product Risk Statement, Malathion 8-E Product Risk Statement, Sevin® Brand 4F Product Risk Statement, Sevin® Brand 80WSP Product Risk Statement, Sevin® Brand XLR Product Risk Statement and Protocol Revision are approved. The Agricultural Handlers Exposure Task Force SOPs is accepted. The Informed Consent Form has been revised to accommodate the Revised Protocol and EPA requested change. The approved revised Informed Consent Form is identified as Version 3/25/2008 and stamped, "Approved 3/25/2008". The Fyfanon® 8 lb. Emulsion Product Risk Statement has been revised to accommodate the Revised Protocol. The approved revised Fyfanon® 8 lb. Emulsion Product Risk Statement is identified as Version 3/25/2008 and stamped, "Approved 3/25/2008". The Fyfanon® Product Risk Statement has been revised to accommodate the Revised Protocol. The approved revised ation Fyfanon® Product Risk Statement is identified as Version 3/25/2008 and stamped, "Approved 3/25/2008". The Gowan Malathion 8 Product Risk Statement has been revised to accommodate the Revised Protocol. The approved revised Gowan Malathion 8 Product Risk Statement is identified as Version 3/25/2008 and stamped, "Approved 3/25/2008". The Malathion 8-E Product Risk Statement has been revised to accommodate the Revised Protocol. The approved revised Malathion 8-E Product Risk Statement is identified as Version 3/25/2008 and stamped, "Approved 3/25/2008". The Sevin® Brand 4F Product Risk Statement has been revised to accommodate the Revised Protocol. The approved revised Sevin® Brand 4F Product Risk Statement is identified as Version 3/25/2008 and stamped, "Approved 3/25/2008". The Sevin® Brand 80WSP Product Risk Statement has been revised to accommodate the Revised Protocol. The approved revised Sevin® Brand 80WSP Product Risk Statement is identified as Version 3/25/2008 and stamped, "Approved 3/25/2008". The Sevin® Brand XLR Product Risk Statement has been revised to accommodate the Revised Protocol. The approved revised Sevin® Brand XLR Product Risk Statement is identified as Version 3/25/2008 and stamped, "Approved 3/25/2008". All current subjects and future volunteers must sign the revised consent form and appropriate Product Risk Statement.

I Revised Protocol; AHE56; Larry D. Smith, PhD;

- Informed Consent Form version 3/25/2008 dated 3/25/2008
- Fyfanon® 8 lb. Emulsion Product Risk Statement version 3/25/2008
- Fyfanon® Product Risk Statement version 3/25/2008

- Gowan Malathion 8 Product Risk Statement version 3/25/2008
- Malathion 8-E Product Risk Statement version 3/25/2008
- Sevin® Brand 4F Product Risk Statement version 3/25/2008
- Sevin® Brand 80WSP Product Risk Statement version 3/25/2008
- Sevin® Brand XLR Product Risk Statement version 3/25/2008
- Protocol Revision dated 3/21/2008 and 3/24/2008
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The Independent Investigational Review Board, Inc. had an opportunity to review the above referenced Informed Consent Form, Fyfanon® 8 lb. Emulsion Product Risk Statement, Fyfanon® Product Risk Statement, Gowan Malathion 8 Product Risk Statement, Malathion 8-E Product Risk Statement, Sevin® Brand 4F Product Risk Statement, Sevin® Brand 80WSP Product Risk Statement, Sevin® Brand XLR Product Risk Statement, Protocol Revision and Agricultural Handlers Exposure Task Force SOPs for the above noted research study. The Revised Protocol included changes that were requested as a result of a EPA review. The EPA also requested changes to the Informed Consent Form.

ACTION: The Informed Consent Form, Fyfanon® 8 lb. Emulsion Product Risk Statement , Fyfanon® Product Risk Statement, Gowan Malathion 8 Product Risk Statement , Malathion 8-E Product Risk Statement, Sevin® Brand 4F Product Risk Statement, Sevin® Brand 80WSP Product Risk Statement, Sevin® Brand XLR Product Risk Statement and Protocol Revision are approved. The Agricultural Handlers Exposure Task Force SOPs is accepted. The Informed Consent Form has been revised to accommodate the Revised Protocol and EPA requested change. The approved revised Informed Consent Form is identified as Version 3/25/2008 and stamped, “Approved 3/25/2008”. The Fyfanon® 8 lb. Emulsion Product Risk Statement has been revised to accommodate the Revised Protocol. The approved revised Fyfanon® 8 lb. Emulsion Product Risk Statement is identified as Version 3/25/2008 and stamped, “Approved 3/25/2008”. The Fyfanon® Product Risk Statement has been revised to accommodate the Revised Protocol. The approved revised Fyfanon® Product Risk Statement is identified as Version 3/25/2008 and stamped, “Approved 3/25/2008”. The Gowan Malathion 8 Product Risk Statement has been revised to accommodate the Revised Protocol. The approved revised Gowan Malathion 8 Product Risk Statement is identified as Version 3/25/2008 and stamped, “Approved 3/25/2008”. The Malathion 8-E Product Risk Statement has been revised to accommodate the Revised Protocol. The approved revised Malathion 8-E Product Risk Statement is identified as Version 3/25/2008 and stamped, “Approved 3/25/2008”. The Sevin® Brand 4F Product Risk Statement has been revised to accommodate the Revised Protocol. The approved revised Sevin® Brand 4F Product Risk Statement is identified as Version 3/25/2008 and stamped, “Approved 3/25/2008”. The Sevin® Brand 80WSP Product Risk Statement

has been revised to accommodate the Revised Protocol. The approved revised Sevin® Brand 80WSP Product Risk Statement is identified as Version 3/25/2008 and stamped, "Approved 3/25/2008". The Sevin® Brand XLR Product Risk Statement has been revised to accommodate the Revised Protocol. The approved revised Sevin® Brand XLR Product Risk Statement is identified as Version 3/25/2008 and stamped, "Approved 3/25/2008". All current subjects and future volunteers must sign the revised consent form and appropriate Product Risk Statement.

Volume VIII, Part E:

Transmittal Additional AHETF SOPs 4-2-08

LS Consulting

From: LS Consulting [lsconsulting@oh.rr.com]
Sent: Wednesday, April 02, 2008 4:04 PM
To: 'rroogow@iirb.com'
Subject: Additional AHETF SOPs Cited in AHE55 and AHE56 Documentation
Attachments: AHETF-11B1 - Recruitment of Study Volunteers IC QA'd.pdf; AHETF-1B2 - Personnel Responsibilities QA'd.pdf; AHETF-10G1 - Pers Air Sampling Pump Calibration.pdf

Robert,

I have attached three additional SOPs cited in the documentation for AHE55 and AHE56. These are the most recent versions of these SOPs and approved by the AHETF Quality Assurance Officer and task force management.

AHETF-1B2 Personnel Responsibilities
AHETF- 10G1 Personal Air Sampling Pump Calibration
AHETF- 11B1 Recruitment of Study Volunteers

I believe I have these protocols ready for submission to the EPA and HSRB. Thanks for your assistance.

Larry D. Smith, Ph.D.
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, OH 44060
440/255-1954

Personnel Responsibilities

Chapter 1: Administration
AHETF-1.B.2.

Effective Date : April 4, 2008

APPROVAL David Johnson	DATE 04-02-08
APPROVAL	DATE 02 APR 2008
Last Revision Date: March 3, 2008	Previous Version Number: 1.B.1

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines the roles and responsibilities of personnel participating in studies conducted for the Agricultural Handlers Exposure Task Force (AHETF). This may include contracted personnel who directly oversee the conduct of a study, or phase of a study.

1.2 This SOP was revised to modify section 6.0 to define Principal Field Investigator and Principal Analytical Investigator, and to add section 7.0 to describe the required ethics training for AHETF personnel.

2.0 RESPONSIBILITIES

2.1 The Task Force member companies and contracted companies will provide the appropriate personnel to manage, conduct, and monitor all regulated studies and other projects.

2.2 The AHETF is both the study Sponsor and testing facility. Independent companies that are members of the Task Force are sponsor representatives. They will assure compliance with the following requirements. Please refer to SOP AHETF-1.A.

3.0 TESTING FACILITY (AHETF) MANAGEMENT

3.1 The testing facility management for the AHETF consists of member company representatives serving on various committees and subcommittees, with various levels of responsibility and in various capacities.

3.2 There will be chosen representatives who will be the primary management contacts for the AHETF. These positions will be the Technical Committee Chair, the Technical Committee Vice-Chair, the Task Force Manager, and the Subcommittee Chairs.

3.3 As required by the EPA GLPs, § 160.31, the testing facility management shall:

a. designate the Study Director.

b. Replace the Study Director promptly, when necessary during the conduct of the study.

c. Assure that there is a QAU.

d. Assure that the test, control, and reference substance(s) or mixture(s) have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable.

e. Assure that personnel, resources, facilities, equipment, materials, and methodologies are available as scheduled.

f. Assure personnel clearly understand the functions they are to perform via the study protocol, SOPs, and memoranda.

g. Assure that corrective actions are taken, as necessary, for all GLP regulation deviations reported by the QAU, and documented.

4.0 AHETF TASK FORCE MANAGER

4.1 A designated individual will serve as the Task Force Manager for the AHETF. This person may be consulted regarding study conduct by the participants listed above, and may serve as an arbiter to settle issues involving AHETF studies.

4.2 The Task Force Manager, as well as the Study Director, has the authority to terminate an AHETF study that no longer has interest to the AHETF, or has been compromised (scientifically or through regulatory misconduct) by the contractor(s).

4.3 One individual will be assigned by AHETF management as the Task Force Manager, who will authorize study protocols, approve SOPs, oversee the contracting of third-party companies for studies and other projects, and provide overall study coordination until study completion and archiving. The Task Force Manager is a representative of AHETF management.

5.0 STUDY DIRECTOR

5.1 Good Laboratory Practice Standards require that a single person assume responsibility for the conduct of a study. Responsibilities, as defined in the GLPs, §160.33, apply to the scope of the AHETF Study Director's involvement in assigned studies. The Study Director shall assure that:

a. The protocol, including any change, is approved - in writing by the Study Director and sponsor's representative - and followed.

b. All experimental data are recorded and verified.

c. Unforeseen circumstances that may affect the integrity of the study are noted as they occur, and corrective action is taken and documented.

d. Test systems are as specified in the protocol.

e. All applicable good laboratory practice regulations are followed.

f. All raw data, documentation, protocols, specimens and final reports are transferred to the archives during or at the close of the study.

g. Specific responsibilities are assigned to AHETF personnel, contracted Principal Investigators, or other designees, as necessary.

h. The progress of the field and analytical portions of AHETF studies, including the preparation of each final report, are monitored and the AHETF Management is informed of progress $^{and}/_{or}$ problems.

5.2 The AHETF Study Director will be contracted to oversee the field and analytical phases of each AHETF study. Please refer to SOP AHETF-1.C.

6.0 PRINCIPAL INVESTIGATORS

6.1 For each field and laboratory study, contractor facility management may assign a person to fulfill the role of principal investigator (PFI: Principal Field Investigator; PAI: Principal Analytical Investigator), as necessary. The PFI's and PAI's responsibility involves direct communication with the AHETF Study Director. The PFI/PAI may have direct and immediate responsibility over an AHETF study in the absence of the Study Director or designated AHETF member.

6.2 In situations where several contractors are participating on an AHETF study, each contractor will designate its own PFI/PAI who will coordinate with the Study Director.

7.0 ETHICS TRAINING FOR RESEARCHERS

7.1 Researchers that participate in the study and interact with study participants must undergo ethics training. The only exception to this rule is that an interpreter, if used, does not need to have ethics training as long as they are accompanied by a researcher who does have ethics training.

7.2 The training shall include successful completion of the course from the National Institutes of Health (NIH; Human Participant Protections Education for Research Teams) and/or the Basic Collaborative IRB Training Initiative Course (CITI; The Protection of Human Research Subjects). There are links to both of these on-line training courses at www.wirb.com (start with link at bottom of home page called Training Requirements).

7.3 Copies of the certificates of completion for the ethics courses will be included in the raw data and in the respective personnel files.

Personal Air Sampling Pump Calibration

Chapter 10: FIELD OPERATIONS

AHETF-10.G.1.

Effective Date : June 30, 2007

APPROVAL David Johnson DATE 04-02-08

APPROVAL [signature] DATE 02 APR 2008

Last Revision Date: October 15, 2003 Previous Version Number: 10.G.0

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides the steps to properly calibrate the personal air sampling pumps used to collect air monitoring samples during Agricultural Handlers Exposure Task Force (AHETF) worker exposure studies.

1.2 This SOP has been revised to change the term "replicate" to monitoring period or worker.

2.0 EQUIPMENT REQUIRED

2.1 The following equipment is needed to calibrate the sampling pumps:

a. Personal low-volume air sampling pump(s) (*e.g.*, SKC, or equivalent)

b. Tygon® tubing or equivalent

c. Appropriate OSHA Versatile Sampler (OVS) Tubes

d. Appropriate calibration device (*e.g.*, Kurz Mass flow meter, Buck Calibrator, bubble meter and stopwatch, or equivalent)

3.0 CALIBRATION PROCEDURE

3.1 Place air sampling pumps on chargers before each use. If the pump is fully charged proceed to 3.2.

3.2 Calibrate air sampling pumps before use in each monitoring period. Calibrations will take place on the day prior to or the same day the pumps are to be used.

3.3 Calibrate the pumps under actual use conditions, as the air temperature may affect the airflow (*e.g.*, calibrate outside rather than inside for exposure trials). Calibrate pumps with the appropriate OVS tube/ sampling train attached.

3.4 Follow appropriate contractor SOPs for the individual calibration methods for contractor equipment.

3.5 Adjust the airflow rate to appropriate rate as defined in the study protocol [*e.g.,* 2 liters per min (L/min)] and document the flow rate and pump number in the raw data.

3.6 Turn off the air sampling pump and set aside. Repeat steps 3.4 and 3.5 until all needed sampling pumps (including backups) have been calibrated.

4.0 POST EXPOSURE FLOW RATE CHECK

4.1 Using the same methods to calibrate the air pump, measure the airflow with a new OVS tube. Document the results in the study file.

4.2 Check the post exposure flow rate after the worker's OVS tube has been removed by the field sample collection personnel.

Recruiting, Informing and Seeking Consent from Study Volunteers

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-11.B.1.

Effective Date : April 4, 2008

APPROVAL David Johnson DATE 04-02-08

APPROVAL DE DATE 02 Apr 2008

Last Revision Date: March 3, 2008 Previous Version Number: 11.B.0

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines general procedures for recruiting, informing, and seeking informed consent from workers in field studies being conducted by the Agricultural Handlers Exposure Task Force (AHETF). A more detailed study-specific recruitment plan will be developed for each field study and will be included in the study-specific protocol.

2.0 ETHICS TRAINING FOR RESEARCHERS

2.1 The Study Directors (SD), Principal Field Investigators (PFI), Task Force Field Study Monitors, Local Site Coordinators (LSC), worker observers, and others working on behalf of the Task Force who interact with study participants, will have completed one or more ethics training courses. The only exception to this rule is that an interpreter, if used, does not need to have ethics training as long as they are accompanied by a researcher who has had ethics training. Certificates of completion for the course(s) will be available prior to their participation in the field phase of the study on behalf of the AHETF. Details on the courses are defined in SOP AHETF-1.B.

3.0 PROTOCOL APPROVAL

3.1 Growers and workers will not be recruited for participation in any field study until after the following items have been completed:

a. IRB approval has been obtained for the study protocol, consent forms and documentation required by 40 CFR 26

b. Approval of the proposed study by the California Department of Pesticide Regulation when a study is to be conducted in California

c. Review of the proposed study by EPA and the Human Studies Review Board, and

d. IRB approval of any changes in the protocol or any supporting document required as a result of the reviews by EPA, the HSRB, and/or CDPR

4.0 RECRUITMENT OF WORKERS

Recruitment of workers typically occurs in two phases. A study-specific recruitment plan will be specified in each study protocol.

4.1 The first phase typically involves contacting and selecting growers and/or commercial application companies that can provide the necessary crop/site, equipment, workers, and need for pesticide. This will often be done in a random manner, such as by calling from a randomized list of growers for a local area. During this first phase, employers are asked for permission to recruit their workers at a later date. Written assurance will be obtained from the employer that the workers will not suffer any consequence if they decide either to participate or not to participate in the study and that there will be no coercion of the workers (see Attachment 11-B-1).

4.2 The second phase typically involves recruiting workers from a pool of eligible growers and/or commercial applicators identified in the first phase. These workers may be the growers, their employees, or employees of commercial applicators. The process is as follows:

a. Growers and/or commercial applicator companies will have been selected who are willing to cooperate with AHETF in the monitoring study and the SD will have determined they are acceptable. The grower or other responsible personnel will have given permission for the SD to contact their employees to determine employee interest in study participation.

b. The SD (or designee) then initiates contact with the employees, sometimes by distributing an IRB-approved flyer which generally describes what participation in the study entails and providing a contact number for the SD. Note that growers themselves (if they are qualified handlers) may also be contacted at this time. The SD (or designee) organizes a meeting with only the interested workers present. This may be done one-on-one or with a group of interested workers.

4.3 The meeting with interested workers will consist of the following:

a. Growers, commercial application company managers, or other personnel to whom employees might report will not attend.

b. The SD (or designee) will explain the nature of the study and the general content of the protocol and Consent Form. Any materials used during this recruitment meeting will be approved by the IRB before use.

c. Eligibility criteria will be reviewed with the potential volunteers and all questions will be answered.

d. Informed Consent Forms will be available for review by potential volunteers. Workers will be urged to take a copy home for review.

e. Potential volunteers will be shown the written assurance obtained from the employer that they will not suffer any consequence if they decide not to participate in the study and that there will be no coercion of, or undue influence on, the workers.

f. At the conclusion of the meeting, interested workers may either contact the SD (or designee) at a later time to express their intent to participate or may go through the individual private consent process at that time (described below in Section 7.0).

5.0 INCLUSION AND EXCLUSION CRITERIA

5.1 Potential participants may be farm owners, farm operators, farm employees, contract applicator employees, or commercial applicators, etc.

5.2 Participants in this study must meet the following inclusion criteria:

a. Be freely willing to participate

b. Handle pesticides as part of their job

c. Be trained in safe pesticide handling procedures in accordance with the Worker Protection Standard (WPS) or equivalent Canadian regulations, or must be exempt from such training

d. Have experience within the past year with the work activity being monitored in the study (including the particular to be used during mixing/loading or application)

e. Be at least 18 years old with a government-issued ID to verify age

f. Consider themselves to be in good general health with no medical conditions that could impact their ability to participate in the study

g. Be willing to follow all label and WPS requirements

h. Understand English or Spanish (*see below for further discussion of this topic*)

5.3 Potential subjects who meet the following exclusion criteria will not be allowed to participate in the study:

a. Are pregnant females

b. Are nursing mothers

c. Normally wear personal protective equipment (PPE) than is not required by the label, such as chemical-resistant clothing

d. Are employed by a pesticide manufacturers or a contractor to the AHETF

e. Do not understand English or Spanish

6.0 LANGUAGE REQUIREMENTS

6.1 Study participation will be limited to subjects who understand English or Spanish since study information, including benefits and risks of participation, will be verbally described to the subject. Potential subjects will choose whether these discussions are conducted in English or Spanish. Potential subjects will also receive the Consent Form in the language of their choice for reading during the consent process (if they are readers) and will sign their preferred version of the form. For workers whose preferred reading language is Spanish, AHETF obtains an IRB-approved translation of the Consent Form.

6.2 While AHETF does not intentionally recruit workers with limited literacy, pesticide handlers occasionally do fall into this category and will therefore not be excluded from participation. Special precautions are used with such workers. Reading ability will be self-reported by the worker. Each potential subject will decide for himself/herself whether or not they are comfortable reading the consent form. If not, an impartial witness will be used to read the form to them as described below.

6.3 When the need for a witness arises*, i.e.* if a worker has limited reading ability, an impartial witness will be used to verify that the worker has apparently understood the materials read to and discussed with them. Witnesses will have no association with researchers in this study nor will they be a part of the management of the grower where the research is being conducted. In addition, an impartial witness must have a general understanding of agriculture. The witness will also sign the Consent Form.

6.4 When study volunteers choose to have recruitment and consent discussions be done in Spanish, a bilingual researcher will be utilized. However, if all reasonable efforts to obtain a bilingual researcher have been exhausted, it is acceptable to instead utilize an interpreter. In this case, the SD (or designee) will conduct the discussions in English and the interpreter will translate the discussions into Spanish. The interpreter will also translate any questions from the volunteers into English so the SD

(or designee) can respond appropriately. If an interpreter is used, the SD (or designee) will ensure the interpreter knows enough about the research design and the content of the Consent Form to provide an accurate translation. If necessary, this will involve tutorial discussions from the SD (or designee). To test the understanding by the interpreter, the SD will ask him/her to explain some portions of the Spanish Consent Form, in English. Interpreters are not considered part of the research team and will not sign the Consent Form. An interpreter who assists in consent form communication between the SD (or designee) and the worker will not be permitted to serve as an impartial witness for that worker.

6.5 The following procedures will be followed with each individual wanting to participate in an AHETF study. The SD (or designee) will go through the entire consent process with the worker (see Section 7.0 below). The following paragraphs describe how workers with varying reading and language skills will be guided through the consent process. Attachment 11-B-2 provides a summary of the procedures described below.

a. Workers who understand English and are comfortable reading English will be provided a copy of the Consent Form in English, will be asked to read the Consent Form in its entirety and encouraged to ask questions of the SD or research staff pertaining to their participation in the study. A copy of the signed Consent Form will be provided to the worker.

b. Workers who understand English, but are not comfortable reading English will have the Consent Form read to them and will be encouraged to ask questions of the SD or research staff pertaining to their participation in the study. An impartial witness will verify that the worker has apparently understood the materials read to and discussed with them. The witness may assess the worker's understanding by their answers to the questions asked of the worker by the SD (or designee) [see Section 7.0 below]. A copy of the signed Consent Form will be provided to the worker.

c. Workers who understand Spanish and are comfortable reading Spanish will be provided a copy of the Consent Form in Spanish, will be to read the Consent Form in its entirety and encouraged to ask questions of the SD or research staff pertaining to their participation in the study. Interpreters for

Spanish speakers will be provided only if all reasonable efforts to obtain a bilingual researcher have been exhausted. A copy of the signed Consent Form will be provided to the worker.

d. Workers who understand Spanish, but are not comfortable reading Spanish will have the Consent Form read to them and they will be encouraged to ask any questions to the SD or research staff pertaining to their participation in the study. Interpreters for Spanish speakers will be provided only if all reasonable efforts to obtain a bilingual researcher have been exhausted. A bilingual impartial witness will verify that the worker has apparently understood the materials read to and discussed with them. The witness may assess the worker's understanding by their answers to the questions asked of the worker by the SD (or designee) and relayed by the interpreter, if used; (see Section 7.0 below). A copy of the signed Consent Form will be provided to the worker.

7.0 INFORMED CONSENT PROCESS

7.1 Although Consent Forms are unique to individual studies, each Consent Form will contain the elements required by 40 CFR 26.1116.

7.2 The SD (or a researcher designated by the SD) will be responsible for obtaining informed consent from all study workers prior to their participation in the study. Any materials used during the consent meeting will be approved by the IRB before use.

7.3 Informed consent discussions will be conducted by the SD (or designee) in private with each worker and others that the worker may want to have present. Interpreters and witnesses may also be present as described above in Section 6.0. When a bilingual researcher is obtaining consent from a Spanish-speaking worker, the Study Director may also be present during the private meeting.

7.4 The SD (or designee) will inform the worker that he/she will receive $20, or the amount specified in the protocol, even if he/she decides not to participate following the discussion.

7.5 During the private meeting the SD (or designee) will provide each worker with a full explanation of the study, its requirements, any potential risks, its benefits, alternatives to participation, *etc*. Workers will be advised of their right to withdraw from the study at any time and for any reason without jeopardizing their normal position with their employers or their daily wages. Workers will receive an additional $80, or the amount specified in the protocol, if they decide to participate (don the dosimeters) but withdraw before the end of the monitoring period. Each worker will be provided a copy of the supervisor's signed form (described above) that states they will not suffer any consequence if they decide not to participate.

7.6 The SD (or designee) will provide information about the risk of the surrogate chemical in the study, including signs and symptoms of acute overexposure. This information will be presented as an attachment to the Consent Form and must be signed by the worker (and impartial witness, if present). The product label and Material Safety Data Sheet also will be explained. WPS requirements, especially proper use of clothing, personal protection equipment, etc., will be discussed. Refer to SOP AHETF-11.E for details.

7.7 The SD (or designee) will discuss the medical management plan with the prospective participants. Information will be provided about the risk of heat stress, including signs and symptoms, and ways to prevent it. Details on heat stress and its presentation are outlined in SOP AHETF-11.G, while details on emergency medical procedures are outlined in SOP AHETF-11.H.

7.8 During the discussions between potential participants and the SD (or designee), ample time will be provided for questions and the SD will provide any additional information or clarification that is requested.

7.9 The IRB-approved Consent Form will be presented in the preferred language (English or Spanish) of the worker. All sections of the Consent Form will be explained in detail. When the SD (or designee) is satisfied that the worker understands the requirements and risks of the study, and if the worker still wants to participate, he/she will be asked to sign and date the Consent Form and the SD (or designee) will provide a copy of the signed form to the worker.

7.10 An additional document, "Product Risk Statements", will be attached to the Consent Form. If the study is conducted in California, the "Experimental Subject's Bill of Rights" will also be attached. These documents will be reviewed, signed and dated by the worker, and copies will be provided.

a. In all situations, the SD (or designee) will not sign the Consent Form unless he/she believes the candidate fully understands the information presented. This will be ascertained by providing repeated opportunities to ask questions and by asking questions of the potential workers that would require a response that indicates understanding of key issues. (See Attachment 11-B-3)

7.11 The SD (or designee) will not sign the Consent Form unless he/she believes they have done everything possible to ensure that the process has been free of any element of coercion or undue influence, and that the worker understands the material in the Consent Form.

8.0 FOLLOW-UP PROCEDURES

8.1 Each study participant will be provided an opportunity to request a copy of the exposure data resulting from their activities in the study. A summary of their personal study data will be mailed to the address provided by the participant(s) desiring it (the SD or designee will complete the form in Attachment 11-B-4). This form (and all forms that contain the worker's name and address) will be maintained in a confidential file with the study records as outlined in SOPs AHETF-6.B and -6.D.

8.2 When the monitoring period is completed, or at the time a participant withdraws from the study, the SD (or designee) will remind the worker that he/she has received a copy of the signed Consent Form that has phone numbers for reporting any health changes the worker thinks may be related to his/her participation in the study. Worker inquiries of this nature will be forwarded to AHETF management to be resolved on a case-by-case basis.

ATTACHMENT 11-B-1

Employer Cooperation Statement

Employer / Supervisor: _____

Study Director: _____

Date of Discussion: _____

Site of Discussion: _____

Employer / Supervisor Cooperation Statement:

I certify that I'm authorized to make the following statements:

- After discussing the nature of the study with the Study Director, I will allow AHETF to recruit any of my employees with applicable training and experience (as determined by the Study Director) in the tasks involved in the study.
- While I acknowledge that there may be benefits to me:
    - I will neither encourage nor discourage my employees to participate in the study.
    - An employee's decision to participate, not to participate, or to withdraw from participation in the study will have no impact on his/her employment status or pay.
    - Employees who decide not to participate, who withdraw from participation, or who complete participation in less than a typical work shift will be offered alternative work at their usual pay to complete their usual work shift.
    - Employees will receive their normal pay for days they participate in the study.

Signature: _____ Date: _____

Title and Affiliation: _____

ATTACHMENT 11-B-2

Language Procedures

	Worker Understands English (and maybe Spanish, too)	Worker Understands Spanish (but not English)
Worker is Comfortable Reading This Language	SD (or designee) Discussions in English Consent Form in English read by worker No Witness needed	Bilingual researcher Discussions in Spanish* Consent Form in Spanish read by worker No Witness needed
Worker is not Comfortable Reading This Language	SD (or designee) Discussions in English SD (or designee) reads English Consent Form to worker Witness needed (English)	Bilingual researcher Discussions in Spanish* Bilingual researcher reads Spanish Consent Form to worker Witness needed (bilingual)

* If all reasonable efforts to obtain a bilingual researcher have been exhausted, an interpreter may be used as described in Section 6.

ATTACHMENT 11-B-3

Consent Form Understandability – Worker Feedback Form

Questions	Answered correctly?		Revisited material with apparent understanding?	
	Yes	No	Yes	No
INTRODUCTION				
Can you take an unsigned copy of this consent form home to think about? Yes				
Purpose				
What is the purpose of this study? To measure how much pesticide I might breathe or get on my skin.				
What job will you be performing in this study? Response will be site-specific				
Procedures				
What type of clothing will you wear underneath your normal work clothing? Long underwear				
When will you have your hands washed? At the end of the day, before eating and anytime I normally wash my hands (toilet)				
Products Handled				
Is the product you will be handling approved for use in the activity you will be performing in this study? Yes				
Risks & Discomforts				
Name two risks that you might have by participating in this study. Equipment, heat, product, embarrassment, eye/skin irritation, etc.				

Consent Form Understandability – Worker Feedback Form (Con't)

What are some early signs of heat stress? **Dizziness, being tired, irritability, lack of concentration**				
If you feel sick from too much heat, what do you do? **Tell a study investigator**				
Injury to Participant				
Where can you get medical treatment if you are injured or get sick during the study? **Either on-site or at a nearby health care facility**				
Who will pay for your medical treatment? **Either my own insurance, my employer's, or AHETF**				
Confidentiality				
Will your name be given in any written report of this study? **No**				
Will information about your participation in this study be given to your employer? **No**				
How do you obtain a copy of your personal results from this study? **Ask Study Director for a copy**				
Benefits				
Will you benefit directly from participating in this study? **No**				
How will your employer benefit? **Free product**				
Section 7: Payment for Participation				
When will you receive $80? **At the end of monitoring; after I withdraw; after AHETF removes me from the study**				
Will you receive your normal pay from your employer if you participate in this study? **Yes**				

Consent Form Understandability – Worker Feedback Form (Con't)

Voluntary Participation / Withdrawal				
Can you employer help you decide whether or not you want to participate in this study? No				
When can you withdraw from the study? Anytime I want				
If you drop out of this study after it has already started, do you have to give a reason? No				
Will you normal pay be affected if you drop out? No				
What happens if you drop out of the study? I will go back to your usual activities.				
Alternatives				
What will you do on the day of the study if you decide that you do not want to participate in the study? Perform my normal work				
Questions				
Who do you call if you have questions about the study or think you have a study-related illness or injury? Study Director or AHETF				
Consent				
If you sign the CF, name one thing that you are agreeing to? I have read the CF; all my questions have been answered; I freely consent; I authorize release of records to 3rd parties; I have not given up any legal rights				
Product Risk Statement				
What product will you be using today? Response will be site-specific				
What symptom or symptoms might result from being overexposed to this product – for example, if there is a spill Response will be product-specific				

ATTACHMENT 11-B-4

REQUEST FOR PERSONAL STUDY RESULTS - AHETF Study (AHExx)

This worker wishes to receive a copy of his/her personal study results.

Name: _____

Address: _____

City: _____

State: _____

Zip Code: _____

Study Worker ID: _____

Description of Data Sent:_____

_____

_____

Sent By: _____

Date Sent: _____