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Water Soluble Packet Mixer/Loader
Scenario Submission

from the
Agricultural Handler Exposure Task Force
(AHETF)

Submitted to Environmental Protection Agency on
January 16, 2009

Statement of No Data Confidentiality Claims

No claims of confidentiality are made for any information contained in this study on the basis of its falling within the scope of FIFRA 10(d)(1)(A), (B) or (C).

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Submitter
Administrative Committee Chair
Agricultural Handler Exposure Task Force

01/16/09
Date

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Statement of Compliance with Good Laboratory Practice Standards

Agricultural Handler Exposure Task Force (AHETF) Study AHE120 "Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Pesticide Products in Water Soluble Packets in the United States " will be conducted according to the Good Laboratory Practice Standards (GLPS), 40 CFR Part 160 and the regulations for the protection of human subjects of research at 40 CFR Part 26.

Richard H. Collier 01/16/09

Richard H. Collier, Ph.D. Date
Sponsor/Submitter
Administrative Committee Chair
Agricultural Handler Exposure Task Force

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AHETF Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Pesticide Products in Water Soluble Packets in the United States
January 16, 2009

Any person or institution who intends to conduct or sponsor human research covered by §26.1101(a) shall, after receiving approval from all appropriate IRBs, submit to EPA prior to initiating such research all information relevant to the proposed research specified by §26.1115(a), and the following additional information, to the extent not already included:

Requirement	Y/N	Comments/ Page References
(1) Copies of		
• all research proposals reviewed by the IRB,	Y	Page 180
• scientific evaluations, if any, that accompanied the proposals reviewed by the IRB,	n/a	none
• approved sample consent documents,	Y	Pages 127, 149
• progress reports submitted by investigators, and reports of injuries	n/a	none
(2) Minutes of IRB meetings . . . in sufficient detail to show • attendance at the meetings; • actions taken by the IRB; • the vote on these actions including the number of members voting for, against, and abstaining; • the basis for requiring changes in or disapproving research; • a written summary of the discussion of controverted issues and their resolution.	Y	Page 550
(3) Records of continuing review activities.	n/a	none
(4) Copies of all correspondence between the IRB and the investigators.	Y	Pages 82-84, 180, 182-183, 541, 543, 545, 548
(5) • A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations;	Y	IIRB roster and credentials on file with EPA.
• any employment or other relationship between each member and the institution, for example, full-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.	Y	
(6) Written procedures for the IRB in the same detail as described in §26.1108(a) and §26.1108(b).	Y	Separately submitted to EPA under confidentiality claim
(7) Statements of significant new findings provided to subjects, as required by §26.11 16(b)(5).	n/a	none

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		(1) The potential risks to human subjects	Y	Page 93
		(2) The measures proposed to minimize risks to the human subjects;	Y	Page 93
		(3) The nature and magnitude of all expected benefits of such research, and to whom they would accrue	Y	Page 100
		(4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and	Y	Page 16, and AHETF Governing Document (reviewed June 2008 HSRB Mtg)
		(5) The balance of risks and benefits of the proposed research.	Y	Page 100
	§1125(b): All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.		Y	Original: Pages 243, 254, 259 Approved: Pages 127, 138, 147, 149, 162, 165
	§1125(c): Information about how subjects will be recruited, including any advertisements proposed to be used.		Y	Pages 34, 92, 105-111, 145,175
	§1125(d): A description of the circumstances and methods proposed for presenting information to potential human subjects for the purpose of obtaining their informed consent.		Y	Pages 100-103
	§1125(e): All correspondence between the IRB and the investigators or sponsors.		Y	Pages 82-84, 180, 182-183, 541, 543, 545, 548
	§1125(f): Official notification to the sponsor or investigator . . . that research involving human subjects has been reviewed and approved by an IRB.		Y	Page 82

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Part A: WSP Mixer/Loader Monitoring Unit Selection Plan

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AGRICULTURAL HANDLER EXPOSURE TASK FORCE (AHETF)

Monitoring Unit Selection and Construction Plan for Scenario:

MIXING/LOADING OF WATER SOLUBLE PACKETS

Final version December 4, 2008

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1 INTRODUCTION AND OVERVIEW

This document describes the plan and rationale for selecting and constructing monitoring units (MUs) to represent future exposures to an arbitrary active ingredient (AI) for the mixing/loading of water soluble packets scenario. It provides a characterization of the scenario, the basis for the number of monitoring sites (i.e., clusters of MUs) and MUs per site, and methodology for diversification of important study conditions. No study data were purchased, nor conducted by, AHETF for this scenario. Therefore, this plan will constitute the entire exposure data set for AHED® (Agricultural Handler Exposure Database) for this scenario.

For this scenario, AHETF discussed plans to monitor mixer/loaders of pesticide products packaged in water soluble packets with agricultural experts in all 12 of the EPA growing regions in the contiguous U.S. These discussions were used to help the worker exposure experts from AHETF member companies define the scenario and guide the selection of geographic locations and equipment types for this scenario. A companion submission that accompanies this scenario plan includes a report that identifies the 17 agricultural experts consulted and presents the information they provided (Honeycutt, 2008). (Nineteen experts were consulted, but one provided information for wettable powders not in water soluble packets and one provided information about the structural pest control industry that was not pertinent to this agricultural scenario.) Throughout this MU selection plan, expert input is briefly summarized to provide a rationale for various decisions related to the plan. The agricultural experts consulted for this scenario included:

- University professors and/or agricultural extension agents; experts were consulted in EPA Regions II, III, V, VI, VIII, IX, and XI
- Agricultural experts from agricultural chemical companies; EPA Regions II, V, VI, VII, and X.
- Commercial pesticide applicators and/or agricultural researchers; EPA Regions I, III, X, XII

This scenario includes the mixing/loading of water soluble packets into various types of farm equipment and dilution with water for future application as liquid sprays. This is accomplished by mixing/loading the packets directly into the tank to be used for the application or into a pre-mix tank where the contents will later be transferred to the spray tank used for the actual application.

Water Soluble Packet M/L MU Selection Plan

This scenario contains no existing data deemed suitable for a generic database. Statistical simulations indicate that a scenario design involving a first-stage selection of five monitoring sites (clusters) followed by a second-stage selection of five MUs at each site should be sufficient to satisfy the benchmark objectives for a complete scenario. This results in a total of 25 MUs to represent this scenario. The basis for these evaluations is described in Appendix C of the Governing Document (AHETF, 2008).

As discussed in the Governing Document, both stages of selection will formally induce diversity of conditions expected to influence exposure. At the first stage this is done by defining predominant surrogate-using states with geographic strata (i.e., agronomic regions of the US) from which the monitoring sites will ultimately be selected. At the second stage of selection, diversity among MUs is based on the amount of active ingredient handled (AaiH) and the use of different workers for each MU. Many other incidental factors that might influence exposure will be indirectly diversified within the scenario because of the diversity selection of equipment, locations, AaiH, and workers. Table 1 summarizes the major steps in this two-stage diversity selection process.

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Table 1. Summary of the Selection and Construction Plan for Water Soluble Packet Mixing/Loading Monitoring Units

Selection Stage	Steps Involved	Program Level
Select Monitoring Site	Identify those geographic area(s) where the use of water soluble packets is possible	Scenario
	Stratify the water soluble packet use 'area' by EPA Growing Region	
	Identify states (or portions of states) in the EPA Growing Regions where the predominant use of AHETF surrogate active ingredients occurs	
	Select five of the predominant surrogate-usage states (or portions of states) so that no two states are in the same EPA Growing Region	
	Within each of the selected states, select one local area (i.e., site) likely to support an efficient site (i.e., ample supply of mixer/loaders, limited in area and test duration) with timing of monitoring determined by when surrogate active ingredients in water soluble packets might be used in the local area	Site
Select and Construct Monitoring Units at each Site	Stratify the practical range of amount of active ingredient handled (AaiH) into 5 logarithmically-spaced strata	Scenario
	Group the possible scenario-related equipment types into 3 general categories	
	Construct a list of growers based on information from a variety of local resources	Site
	In random order, screen the growers for eligibility, willingness to participate, availability of workers and equipment type. Terminate screening when an adequate pool of growers is obtained.	
	Recruit workers from the randomly selected eligible grower pool that will cost-effectively provide the necessary mixing/loading conditions for the cluster of MUs.	
	Construct a cluster of 5 MUs by assigning one worker to each of the AaiH strata with the ability to provide at least 1 MU for each of the 3 general equipment types If multiple workers are available for a given combination, then they may be randomly selected.	

Experts have indicated that water soluble packets are used throughout the U.S. (at least the contiguous 48 states) and that the spectrum of equipment in which they're used is likely available in all 12 EPA regions. However, the predominant use of the two

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surrogate active ingredients (i.e., acephate and carbaryl) is limited to only 12 states spanning 11 EPA regions. Considering all factors, the following states are proposed for this scenario to provide monitoring sites with the desired diversity in geography and likely use of one or more surrogates:

- New York
- Louisiana
- Michigan
- California (the southern portion in EPA Region X)
- Washington (the eastern portion in EPA Region XI)

Workers will perform their tasks in their normal manner, that is, they will not be instructed to conduct their work in a specified manner. However, workers will be required to mix/load at least three loads and work for at least four hours. Within the appropriate equipment type stratum, typical equipment used for mixing/loading water soluble packets will be utilized. The equipment types will also indirectly affect, or be affected by, the crops to be treated, grower's preferences, etc.

2 SCENARIO DEFINITION

This is a mixing/loading scenario defined by the formulation and packaging type, i.e., solid pesticide products packaged in water soluble packets (also called water soluble bags). These packets are added to various types of farm equipment and are diluted with water for future application as liquid sprays. This is accomplished by mixing/loading the water soluble packets directly into the tank to be used for the application or into a pre-mix tank where the contents will later be transferred to the tank used for the actual application.

Some soluble or wettable powder products are packaged in water-soluble packets (considered to be an engineering control) in order to reduce the potential for direct contact with the solid pesticide product. They are used across the U.S. and can be applied to virtually any type of crop in liquid sprays through a wide variety of application equipment. The equipment types that will be used in this scenario are described later in this document.

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3 JUSTIFICATION FOR ADDITIONAL DATA

AHETF has identified the WSP mixing/loading scenario as being within the scope of the task force goals and one for which data are lacking. A number of AHETF member products are labeled for this use pattern. This mixing/loading scenario is applicable to a wide variety of commercially important crops (e.g., orchards, row crops, grains, field crops, trellis crops, greenhouse and nursery plants, forestry, etc.). Therefore, it is necessary to have data in AHED for the mixing/loading technique described by this scenario.

As discussed in detail in the Governing Document, most current pesticide handler exposure assessments are based on the Pesticide Handler Exposure Database (PHED), but that database has several technical limitations since the studies included in PHED were not designed to meet the needs of a generic database. In addition, the data are now somewhat dated and many agricultural practices have changed. In January of 2007, the EPA [in conjunction with the California Department of Pesticide Regulation (CDPR) and the Canadian Pest Management Regulatory Agency (PMRA)] presented a summary of current pesticide handler exposure assessment procedures and existing data available for such assessments to a scientific advisory panel (SAP). The written summary of that SAP meeting concluded the PHED database has serious limitations and agreed with the regulatory agencies that new and improved exposure data are needed to meet regulatory requirements (SAP, 2007). However, each handler scenario needs to be examined individually to determine the extent that new data might be warranted. This conclusion was also reached by the Human Studies Review Board (HSRB) in response to their review of the 2007 draft of the AHETF Governing Document (Brimijoin, 2007).

Multiple sources of studies must be reviewed to determine whether data exist that might be useful for inclusion in this scenario. These sources include studies conducted by AHETF member companies, individual studies in PHED that may have utility for a generic database, and studies that have been submitted to the EPA that do not fit into the first two groups.

AHETF (in conjunction with EPA, PMRA, and CDPR, collectively the Joint Regulatory Committee (JRC)) reviewed handler exposure measurements in existing studies (mostly not included in PHED) to identify those that satisfy current acceptability criteria and qualify for inclusion in a generic database. For this particular scenario, the JRC reviewed three studies (AH508, AH520, and AH608) involving mixing/loading only with water soluble packets; however, none of these studies were deemed appropriate for a generic database.

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AHETF also conducted a detailed review of the data in PHED (EPA, 1998a) for this scenario to determine if any of the data were suitable for a modern generic database. Data for mixing/loading of water soluble packets comprise PHED Scenario 5 – Wettable Powder, Water Soluble Bags (MLOD). Data within that scenario were graded by EPA as "Low Confidence" for the "No Clothes" and "Single Layer, No Gloves" and "Single Layer, Gloves" clothing scenarios. The inhalation exposure data were also graded as "Low Confidence". The low confidence ratings were primarily due to low numbers of measurements.

In the AHETF detailed review of the PHED data, no MUs were found that met the acceptance criteria established by AHETF (Exponent, 2007). Thus, there are no data currently in PHED for this scenario that are useful for a modern generic database.

Finally, EPA examined data from existing water soluble packet mixing/loading exposure studies or exposure assessments that were not available to the AHETF and concluded that none of the exposure data should be included in the AHETF database (meeting, November 3, 2008).

This MU selection plan therefore proposes to collect a full set of new data for this mixing/loading of water soluble packet scenario to meet the scientific objectives outlined in the Governing Document.

4 DESIGN OBJECTIVES AND SAMPLE SIZE DETERMINATION

The water soluble packet mixing/loading scenario program will monitor instances of worker exposure resulting from the mixing/loading the packets of pesticide. Each instance is termed a monitoring unit (MU). Each MU consists of a set of mixing/loading conditions (including the particular worker) that are intended to represent the scenario activities for a single workday. In many cases monitoring units will be selected from 'naturally occurring' water soluble packet mixer/loader-days. However, the selected mixing/loading conditions are sometimes modified or scripted slightly to ensure that the sample of MUs reflects the expected diversity in the entire population of future water soluble packet mixer/loader-days. It is important to emphasize that MU conditions are not necessarily associated with the particular active ingredient used. The key assumption underlying the AHETF monitoring program is that exposures are generic: they do not depend upon the particular active ingredient although they may depend upon the way in which that ingredient is handled. As a result, some MUs could be selected for conditions that are less typical for the active ingredient being monitored providing these conditions are expected for other active ingredients. Thus, MUs are technically not 'sampled' from a population. More

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correctly, they should be viewed as synthetic water soluble packet mixing/loading-days derived from both selected and constructed conditions.

4.1 Two-Stage Selection of New Monitoring Units

Mixing/loading of water soluble packets can occur over a wide geographic area and at different times. Locating a potential worker and handling-day condition from which to construct an MU is a complicated process. No convenient national list of upcoming water soluble packet mixing/loading locations and dates is available. As a result, potential mixing/loading conditions have to be selected in stages.

This selection process can be envisioned as occurring in two successive stages. The first stage consists of selecting specific geographic locations and a range of possible dates for monitoring at each location. Each such local area and range of potential monitoring dates is termed a 'site'. For example, a site might consist of one or more counties in California and a particular one-week period in August. The second stage of this process consists of selecting one or more mixer/loaders and mixing/loading conditions within each site to form monitoring units.

N sites are selected at the first stage and M_c monitoring units will be obtained within site c at the second stage ($c=1,2,\cdots,N$). Most commonly, the planned number of new MUs for each site will be the same. However, M_c could differ from site to site. The set of MUs at the same site is termed a 'cluster'. In general, MUs in the same cluster are expected to be more similar than those in different clusters. This correlation usually means that the smallest total sample sizes (i.e., number of MUs) are attainable when there is only a single MU per site. On the other hand, there are often substantial overhead costs per site that make multi-MU sites more efficient.

4.2 Diversity Selection

For this scenario the objective is not a representative sample of sites or a representative selection of handler-days within sites. Rather it is to obtain, as much as is practical for small sample sizes, a diversity of conditions that are expected to influence exposure, either directly or indirectly. Representative selection attempts to have the sample reproduce the actual frequencies of conditions in the population. In contrast, diversity selection attempts to create a sample that contains as many of the different conditions as possible that exist in the population. If the diversifying conditions are associated with exposure,

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then a diversity sample will tend to be more variable with respect to exposure than would a same-sized representative sample. As a result, a diversity selection sample will tend to have more extreme exposures (both higher and lower) and fewer exposures 'in the middle'. Thus, a diversity selection sample will tend to estimate central tendencies of the exposure distribution better than it will either upper or lower percentiles. To the extent that the diversifying conditions are associated with exposure, diversity selection will tend to under-predict lower percentiles and over-predict upper percentiles. This effect is illustrated by envisioning a normal, or even lognormal, distribution compared with its most extreme 'diversity selection' counterpart, a uniform distribution covering the same range.

In small samples it is more difficult to ensure that the population conditions occur in the correct frequencies than it would be to capture as many different conditions as possible. For regulatory purposes the important aspects of the distribution of exposures are the central tendencies and the upper percentiles. In addition, overestimation of these characteristics is less of a problem than underestimation since it is protective of workers. Therefore, a diversity selection goal is seen as more useful than one for representative selection.

Selection for diversity can be based on either random or purposive choices of conditions. For MUs in the water soluble mixing/loading scenario both types of selection are used and both utilize stratification as the diversifying mechanism. At each stage of selection, potential sampling units are partitioned into groups, called strata. The strata are non-overlapping and, when taken together, comprise all the available sampling units. In diversity sampling, no more than a single unit is selected from each stratum. This contrasts with proportional stratified sampling, a form of representative sampling in which units are selected from larger strata more often than from smaller strata.

Random diversity selection means that a unit is chosen from each stratum randomly. Purposive diversity selection means than units are selected intentionally, usually for practical reasons. When the number of strata exceeds the desired sample size, then the strata used can either be selected randomly or purposively. When this occurs, a purposive (diversity) selection of strata can usually yield a more diverse sample than a purely random set of strata.

Random diversity selection avoids the appearance of intentional bias that can result when researchers choose some conditions and exclude others. When choices are equivalent and easily listed, this is a natural approach. On the other hand, purposive selection can be more efficient and cost effective

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whenever the possible choices are non-equivalent. However, neither form of sampling provides justification for the use of statistical sampling theory. For this to be the case, all stages in the sampling would need to be random, representative, and conform to a rigorous statistical sampling protocol. In addition, all MUs would need to be completely observational. That is, MUs with synthetic (e.g., scripted) components could never be considered an element of an existing handler-day population.

Diversity selection as it applies generally to the entire AHETF Monitoring Program is described more fully in the AHETF Governing Document (Section 9 and Appendix B). Details of the MU diversity selection and construction procedures for the MUs for this water soluble packet mixing/loading scenario are described in Section 5 below.

4.3 Reference Distribution

As noted above, sample sizes can only be determined using statistical theory alone when either

1. There is assumed random, representative sampling from a population and the goal is to estimate some characteristic of that population (including relationships among characteristics); or

2. There is assumed randomization of experimental units to treatments and the goal is only to compare or to contrast treatments in some fashion; or

3. It is assumed that all non-random influences can be mathematically 'removed' in some fashion through modeling and any remaining deviations from the model are effectively random (although this 'residual randomness' might take a complicated form)

Only in these general situations can statistical theory predict how increasing sample size decreases estimation error. In other data-collecting situations, sample size must be determined using one of the pure 'random' situations above as a reference model. The random reference model is constructed so that it reflects the actual situation (i.e., a mixture of random and non-random selection) as closely as possible. The sample size that is appropriate for the reference model is then used for the actual study design. In a real sense, then, the reference two-stage random sampling model is used to establish benchmark sample sizes that satisfy benchmark objectives. The use of benchmarks, however, is not a claim that the reference model represents total reality.

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Rather, it is only a claim that the reference model provides reasonable and practical guidelines.

The water soluble packet mixing/loading scenario uses both natural and synthetic MUs that will be used to predict aspects of the target population of future daily exposures. The goal is to use these data to characterize some 'population' aspect of the future exposure when water soluble packets are mixed/loaded into agricultural equipment. Hence, this scenario is more closely aligned with the random sampling situation (1) above.

For this water soluble packet mixing/loading scenario, random nested (or cluster) sampling is used as the reference model for the combination of purposive and random two-stage diversity selection actually used for new MUs. This reference model assumes that:

- Exposure normalized by the amount of active ingredient handled is lognormally distributed with geometric standard deviation GSD. Equivalently, the logarithm of normalized exposure is normally distributed with standard deviation Log(GSD).
- There are N clusters (i.e., sites) and M_c MUs in cluster c, c=1, 2, ⋯, N. The total number of MUs in this scenario is, therefore, $M_T = M_1+M_2+ \cdots + M_N$.
- The intra-cluster correlation (i.e., the correlation between MUs in the same cluster or 'site') of log normalized exposure is equal to ICC (intra-cluster correlation).

4.4 Benchmark Objectives

The primary benchmark objective for this scenario is that a sample from the hypothetical reference sampling distribution above be of adequate size to describe selected measures of the (normalized) exposure distribution with a pre-determined level of accuracy. EPA provides guidance to AHETF on the minimum degree of accuracy needed for regulatory use in particular scenarios. The current consensus is that estimates of the geometric mean, the arithmetic mean, and the 95th percentile generally need to be accurate to within approximately 3-fold of the actual population value. AHETF and the Joint Regulatory Committee (EPA, California Dept. of Pesticide Registration, Pest Management Regulatory Agency [Canada], and the U.S. Department of Agriculture) agreed 3-fold accuracy is an appropriate benchmark for this scenario (meeting with AHETF, November 3, 2008).

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It should always be kept in mind, however, that this objective is specified, by analogy, in terms of the reference random sampling distribution. This reference sampling model does have a two-stage nesting structure analogous to the actual selection approach for new MUs. The lognormal distribution assumption is also reasonable, robust, and consistent with existing data. However, the reference distribution assumes simple random sampling at each stage. It does not, and cannot, incorporate the combination of purposive and random diversity sampling actually used.

As noted above, the consequence of diversity selection of MUs is expected to be a tendency for the sampling variation of normalized exposure to be overestimated. The sample will likely over-represent extremes and under-represent the more common values. Such diversity-oriented data collected for this scenario, but analyzed with respect to the two-stage reference distribution, is expected to have minimal bias for central tendency. In contrast, upper percentiles of exposure are expected to be, on the average, too large. There is no way to determine the actual magnitude of such overestimation. In this case, overestimation of upper percentiles is of minimal concern: for practical exposure assessments, overestimation of exposures is a conservative practice utilized by regulatory agencies. A tendency to both consider and even overestimate upper percentiles is consistent with this practice.

A minor (secondary) benchmark objective of this scenario is that the data, coupled with the reference sampling model, provide adequate power for a limited examination of the relationship between exposure and AaiH, the normalization factor. As shown in Appendix C of the Governing Document, this objective is usually satisfied when the primary objective is met as long as the normalizing factor has adequate variation within each cluster. As described in section 5.2.1 below, within-cluster diversification of AaiH is a formal part of the selection process for all MUs. However, this objective is considered less important than the primary objective and will be accommodated only when it does not negatively impact the primary objective.

4.5 Sample Sizes

Appendix C of the Governing Document describes the methodology to calculate sample sizes when the reference model used is cluster sampling from a lognormal distribution. For the purposes of determining sample sizes, the default variation structure for normalized dermal exposure derived in Appendix C is also assumed applicable to the water soluble packet mixing/loading scenario. AHETF and the Joint Regulatory Committee agreed

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there is no evidence to suggest otherwise and no strong opinion to the contrary (meeting with AHETF, November 3, 2008). It is therefore appropriate to use the default relative variation structure consisting of a geometric standard deviation (GSD) of 4.0 and intra-cluster correlation (ICC) of 0.3.

Appendix C shows that under these conditions (and where no suitable MUs exist) a sample of 5 clusters (N_C=5) with 5 MUs per cluster (N_M=5) is the most cost effective design configuration that meets the 3-fold accuracy requirement. This accuracy is possible with a variable number of MUs/cluster as long as the total number of MUs is at least 25 and no cluster has more than 5 MUs. Each cluster (i.e. monitoring site) will be addressed in the same study protocol.

Appendix C of the Governing Document also shows that when the benchmark accuracy requirement above is met there may also be sufficient power to permit users of the database to perform a limited examination of the relationship between the normalizing factor (e.g., AaiH) and exposure. This is true provided: (1) the practical range of the normalizing factor is at least an order of magnitude and (2) there is adequate within-cluster variation in the normalizing factor. When these conditions occur, the MU sample will be of sufficient size and diversity to provide at least 80% statistical power to distinguish complete proportionality from complete independence between exposure and the normalizing factor used in the primary benchmark. Since these conditions can be satisfied for the reference sampling design, then the purposive diversity design for the water soluble packet scenario should provide adequate power for the minor (i.e., secondary) objective: the ability to conduct limited examinations of the relationship between AaiH and exposure.

5 DIVERSITY SELECTION AND CONSTRUCTION OF WATER SOLUBLE PACKET MIXING/LOADING MONITORING UNITS

As described in Sections 4.1 and 4.2 above, the basic conditions necessary to construct MUs for the water soluble packet mixing/loading scenario are obtained by a two-stage diversity selection process. These two stages are:

1. Selection of a set of five new monitoring sites that are diverse with respect to geography and, perhaps, other site-specific factors expected to influence exposure.
2. Selection and construction of five monitoring units within each new site that exhibit diversity in AaiH without using the same worker repeatedly.

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At both stages, diversity among selection units (i.e., site or MU) is formally induced by first grouping the available units to be selected into combinations called strata. If the number of strata equals the number of units to be selected, then, one unit is selected from each stratum. Otherwise, a subset of the strata is selected first. For practical reasons, selection of units will usually be purposive. However, whenever feasible, random selection of monitoring units will be used to reduce the possibility of intentional or unintentional selection bias.

5.1 First Stage Diversity Selection of Monitoring Sites

A monitoring site is defined as a particular local geographic area and range of dates associated with monitoring. Five sites need to be selected at the first stage. This process requires several steps:

1. Partitioning U.S area(s) associated with water soluble packet mixing/loading into geographic strata using EPA Growing Regions.
2. Identification of states with the geographic strata where usage of the two surrogate active ingredients for this scenario predominates.
3. Selection of five predominant surrogate usage states that span the geographic strata.
4. Selection of a specific monitoring site within each selected state. This selection will be made in the study protocol.

Specific timing of pesticide applications (i.e., dates) is generally chosen by the grower and is dependent on weather conditions, crop stages, as well as disease and insect pressure. Monitoring activities at each site could be conducted at any time that mixing/loading activities are required to support the applications. However efficiency and cost concerns create the desire to collect all MUs for a particular site (i.e., cluster) over a short period, such as within a week or two. This may involve choosing growers who intend to make pesticide applications at approximately the same time. The grower and worker selection process is described in Section 5.2.2 below. It will be documented in detail in the protocol and the raw data.

5.1.1 Geographic Stratification

As discussed above, the use of water soluble packets can be found throughout the United States and can involve a wide variety of crops, including field crops, trellis crops, and orchard crops. Geographic diversity between clusters of monitoring units is expected to provide

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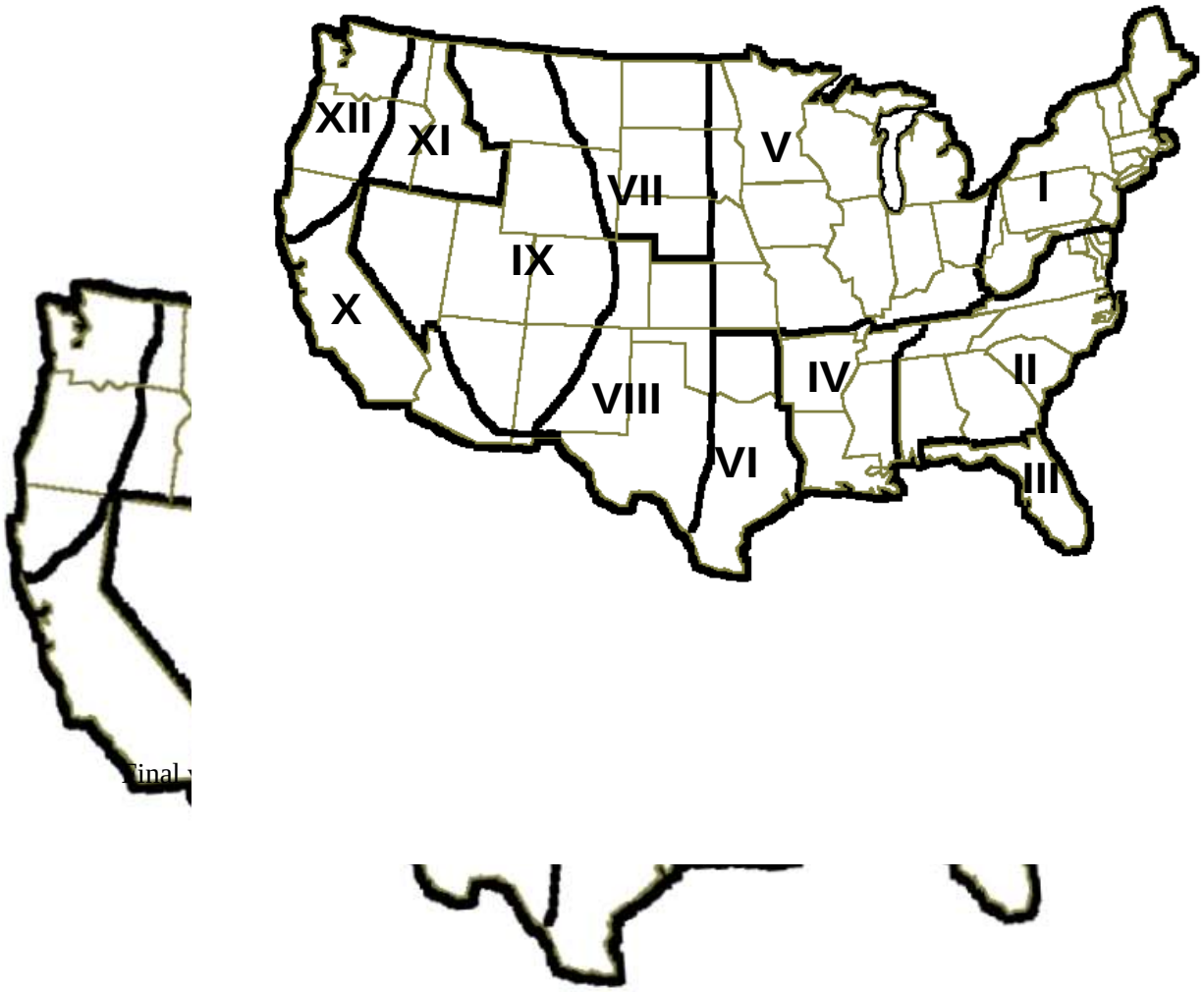
some variability in agronomic conditions and of other factors, such as equipment type, work practices, weather, etc. That is, it is viewed as a meta-factor that is associated with both known and unknown effects usually classified as simply 'study effects'. Some of these factors are discussed in Section 6 below. However, these factors will not be specifically analyzed for their effects on worker exposure. The objective is merely to capture diversity of different conditions across the five new clusters.

EPA has established 13 U.S. Growing Regions. The 12 regions of the continental U.S. are shown below in Figure 1. Growing Region XIII consists of Hawaii and Puerto Rico and is not being considered for this scenario. These Growing Regions provide a convenient basis for geographic stratification. These regions have been used when planning and conducting pesticide residue trials for various crop types. The regions were based on natural geography and climatic boundaries (ACPA, 1992) and are therefore useful for indicating when locations selected for exposure monitoring are geographically diverse.

Figure 1. The 12 EPA Growing Regions Defined for the Continental U.S.



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Since it is likely that water soluble packets are used in all 12 EPA Growing Regions, these regions completely stratify the geographic extent of the water soluble packaging mixing/loading scenario.

5.1.2 Predominant Surrogate Use

Although water soluble packets may be used in all 12 EPA Growing Regions, not all are expected to have wide use of the two AHETF surrogate active ingredients (acephate and carbaryl). Thus, for practical reasons, the distribution of surrogate use will be considered when selecting the five monitoring sites.

Table 2 illustrates this surrogate distribution with chemical usage data obtained from USDA online (NASS 2003 and 2006). The total usage for acephate and carbaryl (in thousands of lbs per year) are shown for the top seven crops for each chemical. For acephate, these seven crops account for more than 99% of acephate usage reported by NASS. For carbaryl, the top seven crops account for 77% of reported usage. For each crop the predominant states in which the surrogates are used are also shown. The sets of predominant states accounts for at least 90% of the total surrogate usage in the listed crop, or are the only states listed in the USDA database for that crop. Clearly, the majority of surrogate active ingredient usage is concentrated in only 19 of the 48 contiguous states.

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Table 2. Predominant Usage of the Surrogate Active Ingredients for this Scenario

Surrogate Active Ingredient	Crop	Total a.i. Usage (lbs/year x 10^3)	Predominant States (% total usage)[1]
Acephate	Cotton, upland	2,537	LA (43), MS (29), TX (7), AR (7), AZ(5)
	Soybean	546	LA (75), MS (5)
	Lettuce, head	66.8	CA (81), AZ (19)
	Pepper, bell	48.5	CA (14), NC (8), NJ (5)
	Snap Bean, proc.	23.4	MI (49), WI (13), PA (6)
	Snap Bean, fresh	19.9	GA (43), FL (34)
Carbaryl	Celery	8	CA (100)
	Apple	245	WA (66), NY (12), MI (11), CA (5), PA (2)
	Soybean	91	None Listed
	Orange	77	CA (57), FL (43)
	Cherry, sweet	73	WA (75), MI (10), CA (7), OR (7)
	Peach	60	SC (48), GA (20), CA (13), MI (5), NJ (5)
	Grape	51	NY(62), MI (20), CA (10), WA (4)
	Asparagus	32.3	MI (68)

[1]These are either all states provided by NASS or those, as a group, that account for at least 90% of the total usage on the crop

Table 3 shows the EPA Growing Regions that contain these 19 predominant surrogate-usage states. These states span 11 of the 12 EPA Growing Regions. In some cases (e.g. OR, WA, TX, and AZ) a state spans two regions and the region(s) with the predominant acreage are listed based on NASS data for crop acres by county (NASS, 2002). There are no predominant surrogate usage states located in EPA Growing Region VII.

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Table 3. The 11 EPA Growing Regions Predominantly Associated with the 2 Surrogates for this Scenario[1]

EPA Growing Region	Predominant Surrogate Use States in Region	Crops Potentially Associated with Surrogates[2]
I	NY, NJ, PA	Apple, grape, peach, snap bean, bell pepper
II	GA, NC, SC	Peach, snap bean, bell pepper
III	FL	Orange, snap bean
IV	AR, LA, MS	Cotton, soybean
V	MI, WI	Apple, asparagus, snap bean, grape, peach, cherry
VI	TX (eastern)	Cotton
VIII	TX (western)	Cotton
IX	AZ (northeastern)	Cotton
X	AZ (southwestern), CA (central, southern)	Lettuce, celery, bell pepper, apple, cherry, peach, orange, grape
XI	OR (eastern), WA (eastern)	Apple, cherry, grape
XII	OR (western)	Cherry

[1] Based on information from Table 2
[2]Crops were not repeated when the state ranked high for both acephate and carbaryl

5.1.3 Selection of a Geographically Diverse Set of Clusters

Five new monitoring sites need to be selected that are geographically diverse. Such a diverse configuration can be obtained by simply locating each site in a different EPA Growing Region. In theory, five growing regions could be selected at random from among the 12 regions that stratify the continental U.S. A state (or portion of a state) could then be randomly or purposively chosen from within the selected Region. The monitoring site is then purposively located within each selected state.

However, such undirected selection of states would be quite inefficient. As discussed above, the use of the surrogate active ingredients is not common in all states in all 12 regions. Locating sites near crop areas

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where the surrogates have wide use over a wide variety of crops increases the likelihood that surrogates will be in use at the particular monitoring site ultimately chosen and also widens the window of opportunity in which to acquire the MUs. In particular, having orchard, trellis, and field crops is desirable for obtaining diversity in mixing/loading equipment (see Section 5.2.2).

Secondarily, it is also preferable to select states that are likely to contain support research personnel (e.g., Contract Research Organizations or Local Site Coordinators). This increases the number of people that can quickly be mobilized to conduct the exposure monitoring, decreases shipping, transportation, and housing costs, and widens the window of opportunity in which to acquire the MUs because of the proximity to these entities.

Using these guidelines and the information contained in Tables 2 and 3, the following states were purposively selected to contain the following five monitoring sites. The geographic diversity resulting from this configuration is illustrated in Figure 2.

1. New York (Region I)

New York involves usage of carbaryl on a variety of crops including orchard, trellis, and field crops. This state reflects a cool climate in the northwestern U.S.

2. Louisiana (Region IV)

Louisiana involves by far the highest usage of acephate, including cotton and soybeans. Louisiana reflects mostly a hot and humid climate in the southern U.S.

3. Michigan (Region V)

Michigan involves usage of acephate and carbaryl and a variety of crops including orchard, trellis, and field crops. This state reflects a cool climate in the upper midwestern U.S.

4. California (the central/southern portion in Region X)

California involves significant usage of acephate and carbaryl and a

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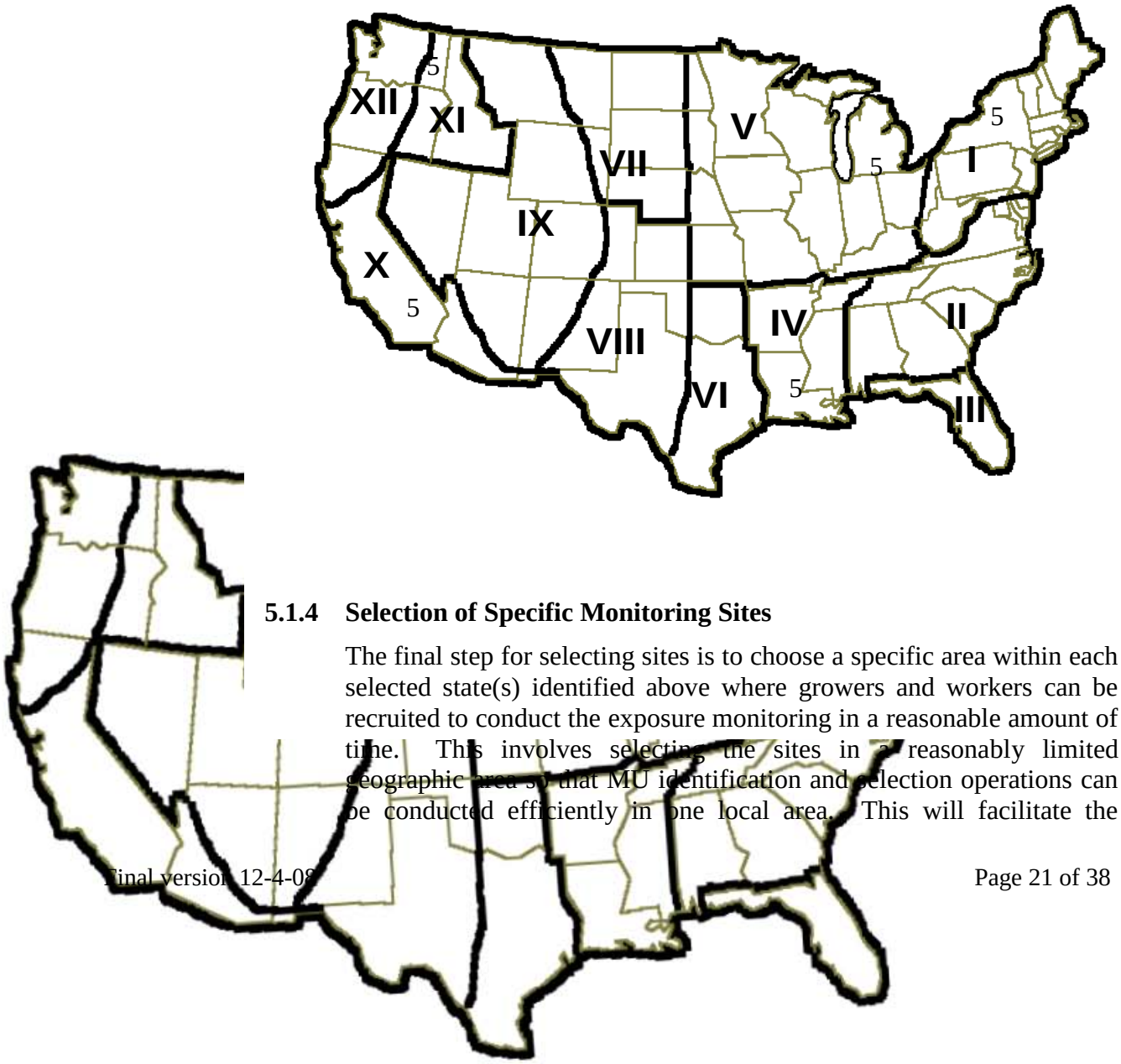
variety of orchard, trellis, and field crops. The central and southern portions of California generally reflect a hot and dry climate in the western U.S.

5. Washington (the eastern portion in Region XI)

Washington involves the highest usage of carbaryl, primarily on apples and cherries, but also some on grapes. Eastern portions of Washington reflect a hot and dry climate in the northwestern U.S.

Figure 2. Proposed Locations for Clusters



5.1.4 Selection of Specific Monitoring Sites

The final step for selecting sites is to choose a specific area within each selected state(s) identified above where growers and workers can be recruited to conduct the exposure monitoring in a reasonable amount of time. This involves selecting the sites in a reasonably limited geographic area so that MU identification and selection operations can be conducted efficiently in one local area. This will facilitate the

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logistics of the field research team and keep the costs of study conduct reasonable so a sufficient number of MUs can be obtained in the AHETF monitoring program.

Choosing a cost-effective configuration of MUs is necessary since costs escalate rapidly when a research team makes multiple visits to a location in order to monitor the desired five MUs. Cost-effectiveness is obviously maximized when all MUs are collected during the same visit so researcher salary, travel, food, lodging, and field fortification expenses are minimized.

Therefore, for each cluster, a particular area of each target state will be selected and identified in the study protocol. The actual site location within this general growing region will be determined by discussions with local resources to indicate counties that are most likely to apply the surrogate product and have sufficient growers, equipment, and workers to allow an efficient design.

5.2 Second Stage Diversity Selection and Construction of Monitoring Units

Once the monitoring sites have been identified, a set of five MUs is constructed based on a second-stage diversity selection of water soluble packet mixing/loading conditions. This selection and construction process consists of several steps for each site:

1. Stratification of amount of active ingredient to be handled based on the practical range for the scenario.
2. Stratification of the equipment associated with mixing/loading of water soluble packets.
3. Constructing joint AaiH and equipment type strata within each cluster.
4. Identification of a sufficient pool of eligible growers and workers willing to participate.
5. Selection and construction of an efficient set of five monitoring units so that each MU has a different combination of AaiH and equipment type.

5.2.1 Stratification of Amount of Active Ingredient Handled (AaiH)

Since the number of pounds of active ingredient handled is the

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normalizing factor and indirectly influences many other handling conditions, efforts will be taken to generate data in as wide a range of AaiH as practical within each cluster of MUs. AaiH is selected as the normalizing factor since AHETF feels it is the most reasonable measure of active ingredient contact potential for this scenario. (See Appendix B of the Governing Document for a discussion of contact potential and normalizing factors.) In addition, EPA currently normalizes water soluble packet mixing/loading exposure by AaiH during pesticide product exposure assessments. No other normalizing factor has been identified as being more appropriate.

In addition to its potential direct relationship to exposure, the amount of active ingredient handled is also viewed as a meta-factor affecting parameters such as tank size, number of loads, etc. Thus, diversification of AaiH induces diversification of such associated factors as well.

AHETF has calculated a practical range in AaiH for this scenario taking into account such factors as the typical use rates of products, types of products available on the market, types of crops on which the products are used, number of acres that can be treated in a day, etc. AHETF has selected a range of 5 to 2,000 lbs active ingredient to be handled per day for this scenario.

AHETF has set the lower practical limit for AaiH per day at 5 pounds of active ingredient. The lower end of the practical range is set to avoid an inordinate number of non-quantifiable residue levels in the exposure matrices while providing a wide overall range of AaiH (a 400-fold range of AaiH) to aid in achieving the secondary statistical benchmark objective for the scenario.

The rationale for setting the upper end of the range was based on a review of 160 AHETF member labels for products that contained a single AI in a solid formulation (e.g., dry flowables, wettable powders, water soluble bags, granular products, etc.). Many dozens of labels for other products that contained multiple AIs were not considered because products with multiple AIs typically decrease the application rate (and therefore the absolute amount) of individual AIs that are applied. In addition, the use of products with multiple AIs increases the potential for analytical interference.

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Several assumptions were required for the calculations determining the upper end of the practical range of AI that can be handled in a day for solid formulations:

- Acres treated per day were assumed to be the maximum acreage values defined by EPA Policy 9.1 (EPA, 2001) for each crop and application type listed on the label
    - Groundboom acres treated per day = 80 except for the high acreage crops (cotton, corn, wheat, alfalfa, rice, soybean) for which 200 A per day was used
    - Aerial acres treated per day = 350 except for the high acreage crops for which 1200 A per day was used
    - Airblast acres treated per day = 40 A
- For each crop on the label it was assumed that the highest application rate for that crop would be used
- For each crop on the label, calculations of pounds applied per day were performed for each of the three application types listed above (groundboom, aerial, and airblast) when appropriate for the pesticide type (e.g., airblast application to orchard crops would not be appropriate for herbicides)

Use of this combination of maximum values resulted in a theoretical maximum amount of AI in a solid formulation that could be applied as a liquid spray in a day (and hence the maximum amount of AI that would have to be mixed/loaded in a day). It must be emphasized that these are only theoretical values since the maximum application rate is not applied to every crop at the maximum acreage for each application type. It is also known that every product is not necessarily extensively used on every crop listed on its label.

Thus, in evaluating all of the approximate 160 product labels for solid formulations, 2,000 lbs AI was selected as the practical upper limit for an amount that could be handled for a solid formulation in a day. In practice, achieving 2,000 lbs AaiH per day has proven to be extremely challenging for another solid formulation type (i.e., dry flowable formulation). The practical limit also is set lower than the maximum AaiH primarily to reduce the burden of workers handling extremely large amounts of product. This also avoids very long monitoring periods that may be unusual for the workers.

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As previously noted, it is important that the AaiH levels be well-diversified within each cluster. This allows the data for this scenario to be used to discriminate a completely proportional relationship from a completely independent relationship between exposure and AaiH (if one of those two relationships were true). Within-cluster diversification of AaiH will be accomplished by following the standard approach of partitioning the practical AaiH range into five logarithmically-spaced strata. These strata are:

- 5 - 17 lbs
- 18 - 55 lbs
- 56 - 182 lbs
- 183 - 603 lbs
- 604 - 2,000 lbs

(All five strata are of equal width on the log AaiH scale.) As discussed below, an attempt will be made within each cluster to obtain a single MU from each of the five AaiH strata. As noted in Section 4.4 above and detailed in Appendix C of the Governing Document, this type of within-cluster diversification of AaiH satisfies the secondary benchmark objective for the scenario. That is, it provides adequate power to distinguish a proportional overall relationship between exposure and AaiH from a purely independent one.

Note, however that there will be a restriction on the maximum amount of acephate that can be handled in order to meet the acceptable margin of exposure calculations. The maximum amount of acephate that can be handled by a mixer/loader in this scenario is 720 lbs. This still allows the use of acephate to fill the top stratum, albeit only at the lower end of the range for that stratum. This is discussed in more detail in Section 7.

5.2.2 Selecting a Grower Pool

As discussed in the Governing Document, AHETF must obtain grower cooperation before it can recruit workers since the grower must be willing to have his crop treated and must also volunteer his equipment for mixing/loading the chemical and allow AHETF to recruit his/her workers. Selecting growers is an important first step toward selecting all MUs.

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AHETF has determined that a method of randomly choosing a working pool of growers is practical for this scenario. This pool of growers will provide the workers and mixing/loading conditions needed to construct MUs for the cluster. Random selection of growers is preferable, when feasible, to reduce the possibility of selection bias that might arise from the LSC (i.e., a local agricultural researcher) purposively choosing specific growers to contact. Therefore, a procedure for generating a list of available growers for each cluster (i.e., associated with each local monitoring site), and randomly selecting a pool of growers from that list, will be established in the protocol. The general procedure to be followed is described in the following steps:

1. Contact local resources such as those listed below to obtain a list of growers that might utilize water soluble packets at the identified site (generally about one to three counties):

    - Farm Market ID
    - Commercial list providers
    - State and local government entities
    - Grower associations
    - Grower Publication subscription lists

2. Assemble a reasonably sized and randomly selected list of growers from all of the resources contacted and eliminate any duplicates.

3. Contact all the growers on the list and determine whether the grower is 'eligible' to participate. Eligibility generally means all of the following are true:

    - The grower is willing to cooperate with AHETF, including the ethical aspects of the research
    - The grower has the necessary mixing/loading equipment
    - The grower has at least one worker with experience in the mixing/loading of water soluble packets
    - The grower is willing to allow AHETF to recruit his/her worker(s)
    - The grower has sufficient acreage that the minimum AaiH can reasonably be handled by a worker in one day
    - The grower is willing to use at least one of the surrogate

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active ingredients listed in the study protocol

Growers who indicate they use commercial pesticide application companies to mix/load their product will also be considered. Those growers will be asked to identify their preferred commercial companies and AHETF will contact them to screen them for willingness to cooperate by providing suitable mixing/loading equipment and workers. The important consideration with this step is that first the appropriate equipment is identified and then workers associated with that equipment are identified. The actual workers involved could be the grower himself, a grower's employee, or an owner or employee of a commercial pesticide application company.

4. Each grower identified as eligible (sometimes along with an associated commercial pesticide application company) is placed into a working pool along with information on:

    - Specific location of mixing/loading sites
    - 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

This process results in a random sample of eligible growers and, by association, a random pool of potential workers associated with eligible growers. The recruitment of growers and/or commercial pesticide application companies from the list will be made by a task force contractor as specified in the study protocol. All discussions and decisions made during this eligibility screening will be documented (e.g., as phone logs) and retained as raw data for the study.

5.2.3 Selection and Construction of MUs

After the randomly-selected pool of eligible growers is assembled, researchers (e.g., LSC and Study Director) will examine the details of potential MUs and identify a configuration of MUs (i.e., growers, chemicals, workers, AaiH, equipment, and timing) that will result in an efficient cluster design. An efficient configuration will generally

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involve a group of growers that: are in the same geographical area, can provide separate workers for all the strata of AaiH, involve the required diversity in equipment, and are expected to make applications within a narrow time frame. This configuration should include more growers and workers than are needed since growers might change their mind about cooperating; workers might not volunteer to participate; the mixing/loading event might not take place due to lack of pest pressure; and various growers have different application timing, etc.

The growers and/or commercial pesticide application companies in the chosen configuration provide the pool of workers from which cluster participants will be recruited. When constructing MUs, three restrictions will be enforced to ensure diversity within the cluster of MUs:

- No worker may be used for more than one MU in the cluster. Worker-related behaviors are also viewed as a meta-factor since individual practices might be associated with exposure potential.
- No piece of equipment may be used more than once and each of the three general equipment types must be used at least once per cluster (see Section 6.1 below)
- No more than one MU may be obtained from any grower or commercial pesticide application company (so a grower with several workers and several pieces of equipment can contribute only one MU)

From the cost-effective configuration chosen, workers will be recruited as described in the Governing Document and the study protocol. In general, this might begin with sending a flyer to growers in the eligible pool, followed by site visits where the LSC and/or Study Director meets the growers and confirms the suitability of their equipment and willingness to cooperate (including discussions about non-coercion of workers). Then the workers associated with the chosen growers and/or commercial pesticide application companies may be contacted directly (e.g., by the Study Director) to begin participant recruitment.

As the scheduling time approaches, growers and/or workers may decide they are no longer interested in participating. If necessary, additional growers and workers can be recruited from workers already characterized in the pool. If there are insufficient workers available in

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the pool to obtain a new efficient configuration, the random working pool can be expanded by contacting additional growers from a new list.

6 EXPECTED DIVERSITY OF OTHER FACTORS IN THE SAMPLE OF MONITORING UNITS

As described above, the diversity in handling conditions in the sample of MUs for this scenario is driven by the formal use of distinct selection units (i.e., distinct sites and distinct workers) and by the additional stratification imposed on these units (i.e., geography, AaiH, and equipment type). Many of the conditions varied should be considered meta-factors with respect to their impacts on exposure. That is, they might not themselves cause differences in exposure but are associated with factors (both known and unknown) that impact exposure. Some of this indirect diversity is described below. With the possible exception of AaiH and the effect of 'cluster', the AHETF does not claim that the resulting data will be sufficient to assess the impact of any of these factors on exposure. Such diversity will usually be treated as 'natural variation' in any analysis (e.g., see Section 8 below). The impact of using diversity selection as a surrogate for random representative sampling is discussed in the Governing Document and in Section 4.2 above.

6.1 Equipment

Exposure experts within the AHETF have identified equipment type as a potentially important parameter that might impact exposure. Factors such as the design of the equipment affect the spatial relationship of the worker to the opening where loading occurs (e.g., a short tank at chest height versus a taller tank where loading may be slightly overhead). Equipment design can also affect the amount of contact the worker has with contaminated surfaces and other factors such as whether or not diluted product is transferred to another tank. Therefore, equipment type will be informally diversified within clusters of MUs.

Experts identified several general types of equipment and procedures used with WSPs that are identified below (Honeycutt, 2008):

- Direct mixing WSPs into tanks that are used directly for application (e.g., groundboom, airblast, chemigation, etc., tanks)
- Mixing WSPs into tanks not directly used for the application but which serve as holding tanks and contain the spray mix solution in the final concentration at which it will be applied (e.g., these tanks go by various

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names such as holding, nurse, pre-mix, etc. tanks)

- Mixing WSPs into tanks not directly used for the application (e.g., slurry tank or bucket) and which contain a concentrated spray mix solution that must be further diluted and transferred to a final tank used for the application

WSPs are most often mixed directly into an application tank such as those used for groundboom or airblast applications in which the spray solution that is mixed is at the final concentration that will be applied to the crop. However, this is not done in all cases as described below.

For logistical reasons it is sometimes easier to mix the WSPs in tanks not directly used for application. For instance, for aerial applications the WSP would almost always be loaded and mixed in a pre-mix tank not attached to the aircraft. The spray solution in this tank would then be transferred to the tank on the aircraft using pumps and hoses, This is so for two reasons: it is not convenient to carry packets onto aircraft in order to mix directly into the spray tanks while aircraft sit on the runway (usually with the engine running) and because pre-mixing makes the loading process much quicker which reduces fuel and pilot costs. Pre-mix tanks are sometimes larger than the application tanks and are sometimes used to fill the application tanks of several different ground or aerial rigs making simultaneous applications. Again, this decreases the mixing/loading time allowing the application equipment to treat more acres per day.

There are also products that recommend making a concentrated solution (i.e., slurry) of the pesticide and then diluting it further when it is transferred to the actual application tanks in order to produce the best possible suspension. When these slurry tanks or buckets are used, they may have their contents transferred to application tanks such as aerial, groundboom, or airblast spray tanks. Typically, during the transfer and/or within the final application tank the concentration of the slurry is decreased to the final application spray concentration.

Consequently, it is proposed that the possible equipment types used for this scenario be grouped into the following 3 general equipment type categories:

1. Mixing of WSPs directly into the tank used for the application

2. Mixing of WSPs into a “pre-mix” tank in which the solution is at the same concentration as that applied to the crop

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3. Mixing of WSPs into a tank (or other container) to make a concentrated solution that must be diluted & transferred to the final application tank

To informally diversify these general equipment types, the only restriction that will be put on their use is that each equipment type must be used at least once in each cluster. This diversity will be induced when assigning workers to AaiH strata for each cluster and may be done randomly or purposively.

6.2 Work Activity and Duration

The workers will be allowed to follow their normal procedures as long as they fit the scenario definition and do not conflict with EPA's Worker Protection Standard (WPS) regulations. The duration of the work activity will be partially determined by the amount of AaiH but will involve the mixing/loading of at least three loads and a minimum duration of four hours.

A parameter that might impact exposure is the number of loads prepared since each mixing/loading event might requires transferring diluted product from tank to tank and potential contact with contaminated surfaces (e.g., water soluble packets, tanks, hoses, etc.). AHETF has a standard practice that each MU will mix/load a minimum of three tank loads. If other functions are also associated with the mixing/loading event (e.g., transferring from a slurry tank to an application tank) then these events are also included as part of the monitoring. This ensures the generic database will contain exposure data generated from complete job functions, from work periods that represent a full day (i.e., generally four hours or more), and from repeated mixing/loading or application cycles that increases the chances of exposure (and therefore won't underestimate exposure potential). Some diversity in the number of loads will naturally occur since AaiH and equipment size will vary.

Duration of monitoring is another parameter that could vary between MUs, especially since the AaiH will be varied by more than two orders of magnitude. Mixer/loaders might spend several hours per day at the staging site but can also spend long intervals performing other tasks (or just sitting around) between actual mix/load events (i.e., while the applicator is making the application). So MUs will be monitored during their entire work day since many other unknown factors might contribute to exposure. All monitoring periods for this scenario must meet the general rule of being at least 4 hours. This is designed to overcome the criticism of early exposure studies where many of the sampling regimes monitored workers for only a few minutes. Avoiding very

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short monitoring intervals will ensure that daily exposure estimates are not biased by unusual conditions during that short interval. If necessary, some minor scripting of worker activities will be done to ensure the lowest levels of AaiH are handled and/or a minimum of four hours are monitored. For example, a worker may be asked to use a smaller tank, or decrease load size, etc., in order to mix 3 loads in four hours.

6.3 Equipment Experience

Study participants will use equipment that is typical for this scenario and that the workers have recently operated (within the last year). Recent experience is required in order to minimize the risk of injury to the workers and to ensure that the activity performed by the worker is one that they typically perform. In addition, any particular piece of equipment cannot be used more than once (e.g., by two different workers from different growers). This will ensure diversity in equipment within each cluster.

6.4 Other Factors

While other factors were considered that might potentially affect exposure potential, they will not be purposively diversified. For example, size of packets or concentration of the product in the packet might possibly impact exposure. However, WSPs are generally packaged in relatively small packets of 1 to 5 pounds of product. Therefore, in this instance, variability in packaging is not considered a parameter for purposive diversification. Other factors such as the crop being treated are not expected to directly affect exposure, but might lead to selection of various equipment set-ups that could impact exposure potential.

7 ACTIVE INGREDIENTS

The AHETF has developed several pesticide active ingredient compounds for use as surrogates. These include herbicides, insecticides, and fungicides with a wide range of label uses. These surrogates were developed specifically because they only require minimal Personal Protective Equipment (PPE), have low toxicity, and are commonly used on a wide variety of crops and areas of the country. Since the AHETF is developing a generic database that will be applicable to nearly all pesticide products and uses, any of the AHETF surrogates can be used for generating exposure data for this scenario. The choice of surrogate at each location will depend largely upon the

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preference of the grower and pest pressure on his crop at that time.

Whenever possible, surrogate products that require minimal PPE are utilized. AHETF has designed the AHED database to allow estimation of exposure to workers who wear additional PPE or clothing. For this scenario, pesticide products are available which allow a single layer of clothing plus chemical-resistant gloves. The desired PPE and clothing situation for this WSP mixing/loading scenario is:

- Long pants and long-sleeved shirt
- Chemical-resistant gloves (new, provided by AHETF)
- Any footwear that are required by the label or that the workers choose to wear (as long as they are consistent with the WPS)

The following active ingredients are available in water soluble packets and will be considered for use in this mixing/loading scenario. The commercial products of these active ingredients that might be used in particular will be listed in the study protocol.

- Acephate
- Carbaryl

These surrogate active ingredients also typically have high use rates for the potential crops of interest that enables measurements at the high end of AaiH per day. Additionally, cooperating growers who will use these products are likely to be available. Finally, these active ingredients have been used as surrogates in other studies and are known to have the required stability under field study conditions.

To quantify the risk to study participants of handling these active ingredients for this scenario, margins of exposure (MOE) for workers wearing two layers of clothing have been calculated for each of them. Data from PHED Scenario 5 – Wettable Powder, Water Soluble Bags (MLOD) (EPA, 1998a) were used in the calculations since they are the best data currently available. Other data such as toxicology study endpoints (e.g., No-Observed-Adverse-Effect-Levels, NOAELs) and the required MOE (or level of concern) for each active ingredient were obtained from Re-registration Eligibility Decisions (REDs) authored by the EPA (Acephate, 2006 and Carbaryl 2007). Table 4 summarizes the data for these MOE calculations. It should be noted that, for carbaryl, the Daily Dermal and Daily Inhalation Exposure calculations are for the highest AaiH that will be used for this scenario and the least amount of PPE required. However, for acephate, the highest amount of active ingredient that can be handled is limited to 720 lbs, in order to meet the required MOE of 100 for the dermal, inhalation, and combined routes of exposure. This calculation also assumes the least amount of PPE that is required for acephate.

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Therefore, for both of the active ingredients that may be used in this scenario, the calculated MOEs meet or exceed the minimum required MOE for the individual dermal and inhalation routes of exposure, as well as for the combined exposure, and their use is acceptable for this scenario given the restriction on AaiH noted for acephate.

Table 4. MOE Calculations for Active Ingredients in the Water Soluble Packet Mixing/Loading Scenario

Parameter	Acephate	Carbaryl
Maximum AI handled/day (lbs) [a]	720	2,000
PHED Unit Exposure - Dermal (mg/lb AI) [b]	0.0098	0.0098
Adjusted PHED Unit Exposure - Dermal (mg/lb AI) [c]	0.0057	0.0057
PHED Unit Exposure - Inhalation (mg/lb AI) [d]	0.00024	0.00024
Daily Dermal Exposure (mg/kg) [e]	0.0583	0.1619
Daily Inhalation Exposure (mg/kg) [f]	0.0025	0.0069
Short-term Dermal NOEL (mg/kg/day) [g]	50	86
Short-term Inhalation NOEL (mg/kg/day) [g]	0.28	1.1
Dermal Margin of Exposure (MOE) [g]	858	531
Inhalation Margin of Exposure (MOE) [g]	113	160
Combined MOE (dermal + inhalation)	100	123
Minimum Required MOE for Dermal Endpoint [g]	100	100
Minimum Required MOE for Inhalation Endpoint [g]	100	100
Minimum Required MOE for Dermal + Inhalation [g]	100	100

[a] Highest AaiH set for this scenario for carbaryl; acephate use is restricted to 720 lbs to achieve the minimum required MOE for dermal, inhalation, and combined routes of exposure

[b] PHED (Scenario 5) data are best available data; for single layer of clothing with gloves

[c] PHED exposure value for "Upper and Lower Arm, Chest, Back, Thigh, and Lower Leg"

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decreased by 50% due to additional layer of clothing (long underwear inner dosimeter) then added back to "Head and Neck" and "Hand" values to derive the Adjusted total dermal exposure

[d] PHED data are best available data

[e] (AI handled x Adjusted PHED Unit Exposure) / 70 kg BW

[f] (AI handled x PHED Unit Exposure) / 70 kg BW

[g] Values from Re-registration Eligibility Decisions (RED)

[h] Short Term Dermal Endpoint / Daily Dermal Exposure; carbaryl dermal endpoint value is a $BMDL_{10}$ (10% benchmark dose level, lower 95% confidence interval), for acephate it is a NOAEL (no-observed-adverse-effect-level).

[i] Short Term Inhalation Endpoint / Daily Inhalation Exposure; carbaryl inhalation endpoint value is a $BMDL_{10}$, for acephate it is a NOAEL.

[j] Combined Dermal and Inhalation MOE = 1/[(1/Dermal MOE) + (1/Inhalation MOE)]. MOE value must be > Minimum Required MOE for that endpoint.

8 DATA ANALYSIS

The goal of conducting a water soluble packet mixing/loading study is to develop a set of generic dermal and inhalation exposure data which regulators and other potential users of the generic database can utilize to characterize a predicted distribution of future exposures, and perform exposure assessments for this scenario. As detailed in the Governing Document, the data collected from the clusters for this scenario will only be statistically evaluated with respect to the benchmark measures of adequacy. These two categories of data adequacy are:

1. The relative accuracy of selected statistics characterizing the distribution of exposure normalized by amount of active ingredient handled (AaiH).

2. How well the data can be expected to describe a relationship between exposure and AaiH, if one existed.

As emphasized both in the Governing Document and in Section 4 above, it is important to keep in mind that, like the sample size determination, both of the above statistical adequacy benchmarks are relevant only within the context of the reference random sampling distribution defined in Section 4.3. In particular, the monitoring data will be treated as if it were collected as a two-stage random sample from an infinite population. Technically, there is no statistical theory that can be applied to non-random samples (or even to random samples for which the probability structure is unspecified). Nearly all monitoring data used for regulatory purposes is of this type. As has always been the case, any statistical conclusions based on such data imply the qualification: "to the extent that the data can be viewed as deriving from a true random sample." As pointed out in Section 4.2 above, diversity selection is expected to yield

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MUs that tend to overestimate the true variation among future exposures. This suggests that the estimates of upper percentiles will tend to be overestimated (and lower percentiles underestimated) in the resulting monitoring data. With the small sample sizes used in this scenario, however, such estimation bias is probably trivial relative to ordinary uncertainties due to sampling, whether random or purposive.

8.1 Relative Accuracy of the Normalized Exposure Distribution

The primary benchmark objective is that selected lognormal-based estimates of normalized dermal exposure distribution be accurate to within 3-fold, at least 95% of the time. The benchmark estimates specified are those for the geometric mean, arithmetic mean, and the 95^{th} percentile.

To evaluate how well the collected data conform to this benchmark, the 95 percent bound on relative accuracy will be calculated from the confidence interval for each of the three parameters given above. Details of these calculations are provided in Appendix C of the Governing Document.

This primary benchmark objective strictly applies to only dermal exposure. However, for uniformity, the 95 percent bounds on the three parameters will also be computed for inhalation exposure.

8.2 Adequacy of the Data for Distinguishing a Proportional from an Independent Relationship between Exposure and AaiH

This secondary benchmark objective applies to the water soluble packet mixing/loading scenario because the practical range in the amount of active ingredient handled (AaiH) exceeds an order of magnitude. In this case it is reasonable to consider the linear regression of log dermal exposure on log AaiH. Such a regression would use a mixed model formulation in order to incorporate random cluster effects. As described in the Governing Document, in such a model the true slope, β, would be equal to one if dermal exposure were directly proportional to AaiH. If exposure were independent of AaiH, then $\beta=0$. This benchmark objective requires that the number of clusters and the allocation of AaiH levels to MUs should be adequate to ensure that the regression analysis has at least 80% power to reject the hypothesis that $\beta=0$ when β is actually equal to one. By symmetry, the mixed model linear regression would also have the same power to reject the hypothesis that $\beta=1$ when $\beta=0$. This is the precise meaning of being able to 'discriminate between proportionality and independence'.
To evaluate this benchmark, a mixed model regression of log dermal exposure

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on log AaiH will be performed and a confidence interval obtained for β. With this information, power analyses are irrelevant. Even a post-hoc power analysis is less informative than the confidence interval itself. Calibration of the confidence interval for β with the pre-data power analysis is relatively simple. If the adequacy benchmark were satisfied, the mean width of a 95% confidence interval for β would be approximately 1.4. Therefore, if the width of the confidence interval obtained from regression on the actual data is 1.4 or less, then the data will be judged adequate with respect to the secondary benchmark. Note that in this case the adequacy of the data depends only on the width of the confidence interval, not on the endpoints of the interval or on the estimated slope, b. Details of this analysis are described in Appendix C of the Governing Document.

As was the case for the primary objective, the secondary object only applies to dermal exposure. However, for uniformity, the same regression analysis and assessment of the confidence interval will be conducted for inhalation exposure.

9 REFERENCES

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Part B: Background Information from Experts

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Summary of Agricultural Expert Information for Water Soluble Packet Mixing/Loading Scenario: 2008

Prepared By: Richard Honeycutt
October 28, 2008

Introduction: A survey of experts around the US was performed with the goal of determining the use pattern and distribution of pesticide products packaged in water soluble packets (also known as Water Soluble Bags/WSB) products throughout the contiguous US (12 EPA regions). Specific information on the mixing/loading and application equipment associated with the use of water soluble packets was sought. The objective was to obtain the opinions of at least 15 agronomic/formulation experts (with no more than half being AHETF member company experts and no more than 2 experts per EPA region). Note that the terms "water soluble packet" or "WSP" in this survey refers only to those solid formulations that **are** in water soluble packets (WSP).

The sources of the expert contacts included: professors of weed science, agronomy, plant pathology, and horticulture, USDA agricultural extension agents, university pesticide information experts, agrichemical company sales professionals as well as company formulation and spray equipment technology experts, one worker who mixes/loads and applies pesticides, contract research professionals associated with the National Alliance of Independent Crop Consultants (NAICC), weed specialists, and agronomic experts from independent contract facilities. The questionnaire used for this survey is attached as Appendix 1.

Procedures for calling experts: A list of experts associated with agricultural/agronomic practices was developed from the following sources:

- USDA CSREES (Cooperative State Research, Education, and Extension Services) website (http://www.csrees.usda.gov/Extension/index.html)
- NAICC website (http://www.naicc.org/Directory/statemap.htm)
- AHETF contacts
- Past known contacts
- Contacts referred by one of the listed experts.

A list of the experts contacted during this survey is presented in Appendix 2.

Calling procedures: A calling telephone log is shown in Appendix 1. This telephone log was used to record when the expert was called and a brief description of the results of the call. Calling codes were used to record if the identified expert was available at the time, if a message was left, or if there was no answer. A brief description of the results of the telephone conversation was also placed in the appropriate spaces provided on the telephone log.

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Questionnaire: Appendix 1 also shows the questionnaire which was used during the phone conversation with the listed expert. When the expert was contacted, the caller provided a brief background of the AHETF and its research objectives. The expert was informed that if he/she did not feel comfortable providing the information on a broad US scale, they had the option of answering the questionnaire on a more local/regional level. There were some respondents who did not feel comfortable answering questions on a national level, but who did provide information for the survey on a more local/regional level.

Some discussion about the way the questions in Appendix 1 were used to gather information on water soluble packets is warranted. The experts were asked most of the questions verbatim as outlined in Appendix 1. Questions 1, 3, 5, 7, and 8 of Appendix 1 were designed to provide information on wettable powder formulations. Questions 2, 4, and 6 were designed to collect information on water soluble packets. Since water soluble packets are basically wettable or soluble powders packaged in a different manner, it seemed efficient to ask the experts questions about water soluble packet formulations while seeking expert information on wettable powder formulations. While question 8 was designed to provide information on wettable powders, some information on existing water soluble packet products was gained from the interview when asking question 8.

While most questions were asked verbatim to the respondent, some of the questions in Appendix 1 were altered during the course of the conversation with the respondent. This was to supplement the information gathered during the interview. For example, question 3 included a request for the respondent to provide their opinion on how the three categories of wettable powder mixing tanks (direct, pre-mix or eductor) might be distributed (across the US or by region) and their use distribution weighted as an approximate percentage of 100%. Question 3 was structured as follows:

3. What types of equipment or procedures do you believe typically are used with the mixing/loading of WPs? For instance:

Percent

____ *Open pouring of the WP directly into tanks that will be used for the application, e.g., groundboom or airblast tanks, and in what range of sizes?*

____ *Mixing/loading of the WP into tanks not directly used for the application, such as slurry tanks, pre-mix tanks, pre-mix buckets, etc.*

____ *Eductor systems*

Question 4 was then used to gather similar information on the distribution of use of water soluble packets with various mixing systems excluding eductor systems which were assumed not to be used with water soluble bags. Question 4 was structured as follows:

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4. What types of equipment or procedures do you believe typically are used with the mixing/loading of WSBs? Would it be essentially the same as for the WPs just discussed, with the possible exception of eductor systems?

For information gathered on water soluble packets, the answer to question 4 was either a yes or no. A yes was interpreted to mean that for water soluble packets, the type of mix tanks and how their use with water soluble packets would be distributed would be qualitatively the same as for wettable powders except for eductor systems which would be assumed to be excluded from the percentages since it is likely that water soluble packets might clog up an eductor system. Therefore the relative percentage answers obtained in question 3 and applied to question 4 are to be viewed as qualitative and not quantitative estimates of the distribution of the types of mix equipment for water soluble packet products. The use of words such as "more", "less", "much more", "much less" are some of the descriptive words used to qualitatively compare the distribution of the use of WSP by direct addition to spray tanks as opposed to by indirect introduction into a spray tank through, for example, a slurry tank.

Question 5 was also altered during the conversation and the respondent was asked to rank the types of application equipment as to the most used and the least used types of spray equipment for application of wettable powders as liquid sprays. Question 6 was then used to gather similar information on the use of water soluble packets with various mixing systems.

Question 8 involved the survey respondents identifying wettable powder products that they were familiar with. During the course of the interview, some experts volunteered information about existing products sold in water soluble packets. The results of the information collected in question 8 are not recorded in this document but are in the raw data of the survey. This information could be used by the AHETF to identify possible surrogates for field research associated with the mixing/loading of water soluble packets.

Results of Survey: A descriptive summary of the information sought on water soluble packets (WSP) from each of 19 experts is summarized below. Table 1 shows a compilation of the responses from each expert and provides an easy reference to each of their most important responses.

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Summary of Agricultural Expert Information for
Water Soluble Packet Mixing/Loading Scenario: 2008

Prepared By: Richard Honeycutt
October 28, 2008

Entries are presented by U.S. Growing Region (EPA).

EPA Region XII

Expert No. 1
Name: **Jim Thayer**
Position: **Mix-Master and Commercial Applicator**
Location: **Wilbur Ellis Company**
12925 Road 4
Quincy WA, 98848
Experience: **12 years**

Completed Phone Survey: Distribution and use pattern of WSP formulations in **Region XII (which includes the Quincy, WA area) and/or across US**-distribution of mixing/loading equipment for WSP formulations. The respondent provided the following information through the use of the survey:

- This respondent believed that the use of WSP products can be found virtually in every region of the US.
- Believed that in the region of WA where he lives and works, WSP products are placed (mixed/loaded) into tanks not directly used for application (such as slurry tanks, pre-mix tanks, and pre-mix buckets) much more than they are placed directly into tanks that will be used for application of liquid sprays (such as tanks associated with groundboom or airblast application equipment). Believed that water soluble packets are not used with eductor systems in this region of WA.
- No other types of mixing/loading equipment used to introduce the WSP products into mix tanks was cited by the respondent for this region of WA.
- Believed that in this region of WA, aerial, groundboom, airblast, backpack, and handspray equipment would be expected to be used to make liquid spray applications from WSP products.
- Groundboom sprayers would be the most used in this region for making liquid spray applications with WSP products while backpack sprayers would be the least used.
- No other type of application equipment used for making liquid spray applications of WSP products was identified by the respondent for this region.

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EPA Region II

Expert No. 2
Name: Steve Gibson
Position: USDA Extension Agent, Agriculture
Location: 130 South Post St
Shelby, NC 28152
Experience: 29 years

Completed Phone Survey: Distribution and use pattern of WSP formulations in **Region II (which includes the Shelby, NC area) and across US**- distribution of mixing/loading equipment for WSP formulations. The respondent provided the following information through the use of the survey:

- This respondent believed that the use of WSP products can be found virtually in every region of the US.
- Believed that in the region of NC where he lives and works as well as across the US, that WSP products are placed (mixed/loaded) into tanks not directly used for application (such as slurry tanks, pre-mix tanks, and pre-mix buckets) much less than they are placed directly into tanks that will be used for application of liquid sprays (such as tanks associated with groundboom or airblast application equipment). Believed that water soluble packets are not used with eductor systems in this region of NC and across the US.
- Believed that in this region of NC and across the US, aerial, groundboom, airblast, backpack, and handspray equipment would be expected to be used to make liquid spray applications from WSP products.
- Groundboom sprayers would be the most used in this NC area and across the US for making liquid spray applications with WSP products, backpack sprayers would have a low use rate, and handsprayers the least used.
- No other type of application equipment used for making liquid applications of WSPs was identified by the respondent for this NC area as well as across the US.

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EPA Region II

Expert No. 3
Name: **Dwight Seal**
Position: **Western District Manager**
Location: **North Carolina Department of Agriculture**
Division of Structural Pest Control and Pesticides
1090 Mail Service Center
Raleigh, NC 27699
Experience: **21 years**

Completed Phone Survey: Distribution and use pattern of WSP formulations in **Region II (which includes the Raleigh area of NC) and across US**-distribution of mixing/loading equipment for WSP formulations. The respondent provided the following information through the use of the survey:

- This respondent believed that the use of WSP products can be found virtually in every region of the US.
- Believed that in the region of NC where he lives and works, that WSP products are placed (mixed/loaded) into tanks not directly used for application (such as slurry tanks, pre-mix tanks, and pre-mix buckets) much less than they are placed directly into tanks that will be used for application of liquid sprays (such as tanks associated with groundboom or airblast application equipment). Believed that water soluble packets are not used with eductor systems in this region of NC.
- No other types of mixing/loading equipment used to introduce the WSP products into mix tanks was cited by the respondent for this NC area/region.
- Believed that, aerial, groundboom, airblast, backpack, and handspray equipment would be expected to be used throughout the US to make liquid spray applications from WSP products.
- Believed that WSP products would be used more with airblast equipment and the least use would be with backpack and handspray equipment.

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EPA Region II

Expert No. 4
Name: JD Fish
Position: Manager of Field Equipment and Application Technology
Location: Bayer CropScience
Two, T.W. Alexander Drive
Research Triangle Park, NC, 27709
Experience: 28 years

Completed Phone Survey: Distribution and use pattern of WSP formulations **across US**-distribution of mixing/loading equipment for WSP formulations. The respondent provided the following information through the use of the survey:

- This respondent believed that the use of WSP products can be found virtually in every region of the US.
- Believed that across the US, WSP products are placed (mixed/loaded) into tanks not directly used for application (such as slurry tanks, pre-mix tanks, and pre-mix buckets) a little less than they are placed directly into tanks that will be used for application of liquid sprays (such as tanks associated with groundboom or airblast application equipment). Believed that water soluble packets are not used with eductor systems across the US.
- No other types of mixing/loading equipment used to introduce the WSP products into mix tanks was cited by the respondent.
- Believed that WSP products would be placed into groundboom and airblast spray tanks that would range in capacity from 50-500 gallons, slurry tanks ranging from 15-30 gallons, and pre-mix tanks ranging from 15-400 gallons.
- Believed that, aerial, groundboom, airblast, backpack, and handspray equipment would be expected to be used throughout the US to make liquid spray applications from WSP products.
- Believed that WSP products would be used more with groundboom (vegetables) and airblast equipment and the least use would be with backpack and handspray equipment.

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EPA Region X

Expert No. 5
Name: Michael Beevers
Position: President
Location: California Agricultural Research
4141 North Vineland
Kerman, CA 93630
Experience: 22 years

Completed Phone Survey: Distribution and use pattern of WSP formulations **across US**-distribution of mixing/loading equipment for WSP formulations. The respondent provided the following information through the use of the survey:

- This respondent believed that the use of WSP products can be found virtually in every region of the US.
- Believed that across the US, WSP products are placed (mixed/loaded) into tanks not directly used for application (such as slurry tanks, pre-mix tanks, and pre-mix buckets) a much less than they are placed directly into tanks that will be used for application of liquid sprays (such as tanks associated with groundboom or airblast application equipment). Believed that water soluble packets are not used with eductor systems across the US.
- This respondent identified a nurse tank as another type of mixing tank that WSP products might be used with.
- Believed that WSP products would be placed into groundboom and airblast spray tanks that would have a capacity of about 500 gallons.
- Believed that, aerial, groundboom, airblast, backpack, and handspray equipment would be expected to be used throughout the US to make liquid spray applications from WSP products.
- Believed that WSP products would be used the most with airblast equipment and the least use would be with backpack equipment.

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EPA Region VI

Expert No. 6
Name: **Julian Sauls**
Position: **Professor and Extension Horticulturalist**
Location: **Texas Agrilife Service**
2401 East Highway 83
Westlaco, TX, 78596
Experience: **35 years**

Completed Phone Survey: Distribution and use pattern of WSP formulations for **EPA Region VI (which includes the area south Texas)**-distribution of mixing/loading equipment for WSP formulations. **This respondent only represented citrus in south Texas.** The respondent provided the following information through the use of the survey:

- This respondent did not respond to questions 1 and 2 on the survey questionnaire.
- Believed that there was no use of WSP technology in citrus in south Texas.

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EPA Region VI

Expert No. 7
Name: **Name asked to be withheld by respondent**
Position: **Sales Representative**
Location: **UAP**
P.O. Box 655
Blessing, TX 77419
Experience: **12 years on farm and 8 years in sales**

Completed Phone Survey: Distribution and use pattern of WSP formulations for **EPA Region VI (which includes the area of southeastern Texas) and across the US -** distribution of mixing/loading equipment for WSP formulations. The respondent provided the following information through the use of the survey:

- This respondent believed that the use of WSP products can be found virtually in every region of the US.
- Believed that across the US, WSP products are placed (mixed/loaded) into tanks not directly used for application (such as slurry tanks, pre-mix tanks, and pre-mix buckets) at about the same frequency as they would be placed directly into tanks that will be used for application of liquid sprays (such as tanks associated with groundboom or airblast application equipment). Believed that water soluble packets are not used with eductor systems across the US.
- Believed that across the US, aerial, groundboom, airblast, backpack, and handspray equipment would be expected to be used to make liquid spray applications from WSP products.
- Believed that for southeast Texas, groundboom sprayers would be the most used for WSP products, aerial would be second, backpack and handspray equipment would be third and airblast would be the least used.
- Boomless sprayers used on rights-of way applications was also identified for making liquid applications of WSP products.

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EPA Region V

Expert No. 8
Name: **Name asked to be withheld by respondent**
Position: **Professor of Plant Pathology and Extension Specialist**
Location: **Ohio Agricultural Research and Development Center (OARDC)**
Department of Plant Pathology
1680 Madison, Ave
Wooster, OH, 44691
Experience: **30 years**

Completed Phone Survey: Distribution and use pattern of WSP formulations for **EPA Region V (which includes the Wooster, Ohio area) and across the US**- distribution of mixing/loading equipment for WSP formulations. The respondent provided the following information through the use of the survey:

- This respondent believed that the use of WSP products can be found virtually in every region of the US.
- Believed that for the region of Ohio in which he lives and works, that WSP technology is used mainly with pre-mix tanks or suspended in buckets prior to being placed in the spray tank of the application equipment.
- No other types of mixing/loading equipment used to introduce the WSP products into mix tanks was cited by the respondent.
- Believed that across the US, aerial, groundboom, airblast, backpack, and handspray equipment would be expected to be used to make liquid spray applications from WSP products.
- Across Ohio and the Midwest, the most used spray equipment for applying liquid sprays of WSP products would be airblast spray equipment (fruits). Groundboom equipment would be second (vegetables) and aerial would be the least used.
- No other type of application equipment used for making liquid applications of WSP products was identified by the respondent.

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EPA Region III

Expert No. 9
Name: **Fred Fishel**
Position: **Director of Pesticide Information Office and Associate Professor of Agronomy**
Location: **Pesticide Information Center**
University of Florida
Gainesville, FL
Experience: **18 years**

Completed Phone Survey: Distribution and use pattern of WSP formulations for **EPA Region III and across the US**- distribution of mixing/loading equipment for WSP formulations. The respondent provided the following information through the use of the survey:

- This respondent believed that the use of WSP products can be found virtually in every region of the US.
- Believed that in the Florida region where he lives and works, WSP products are placed (mixed/loaded) into tanks not directly used for application (such as slurry tanks, pre-mix tanks, and pre-mix buckets) a much less than they are placed directly into tanks that will be used for application of liquid sprays (such as tanks associated with groundboom or airblast application equipment). Believed that water soluble packets are not used with eductor systems in this region of Florida.
- The respondent did not identify any other types of mixing tanks into which WSP products could be placed.
- Believed that across the US, aerial, groundboom, airblast, backpack, and handspray equipment would be expected to be used to make liquid spray applications from WSP products.
- Across US, the most used spray equipment for applying liquid sprays of WSP products would be groundboom spray equipment. Handspray equipment would be the least used.

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EPA Region IV

Expert No. 10
Name: Keith Dubrock
Position: Owner of McKenzie Pest Control Company
Location: P.O. Box 5602
Lake Charles, LA
Experience: 32 years

Completed Phone Survey: Distribution and use pattern of WSP formulations for **EPA Region IV and across the US**- distribution of mixing/loading equipment for WSP formulations. The respondent provided the following information through the use of the survey. **Note that this information applies only to pest control companies.**

- This respondent believed that the use of WSP formulations in structural pest control can be found virtually in every region of the US.
- Believed that power sprayers were the only application equipment used with WSP products throughout the US for structural pest control.

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EPA Region X

Expert No. 11
Name: **Mac Learned**
Position: **Technical Support Manager**
Location: **FMC Corporation**
1126 Old Peachy Canyon Rd
Paso Robles, CA 93446
Experience: **28 years**

Completed Phone Survey: Distribution and use pattern of WSP formulations for **EPA Region X and across the US-** distribution of mixing/loading equipment for WSP formulations. The respondent provided the following information through the use of the survey:

- This respondent believed that the use of WSP products can be found virtually in every region of the US.
- This respondent believed that the FMC product, Brigade is placed (mixed/loaded) into tanks not directly used for application (such as slurry tanks, pre-mix tanks, and pre-mix buckets) much more than placed directly into tanks that will be used for application of liquid sprays (such as tanks associated with groundboom or airblast application equipment). Believed that Brigade was not used with eductor systems.
- Believed that the use of WSP products would be a way to reduce use of wettable powder products.
- Believed that fertilizer and chemigation equipment may be other types of application equipment with tanks into which WSP products are placed.
- Believed that across the US, aerial, groundboom, airblast, backpack, and handspray equipment would be expected to be used to make liquid spray applications from WSP products.
- Across US, the most used spray equipment for applying liquid sprays of WSP products would be airblast and groundboom spray equipment. Handspray PCO equipment would be the least used.

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EPA Regions I & III

Expert No. 12
Name: Dean Remick
Position: Owner of ENTOCON, Inc.
Location 1: 703 Chelsee Way, Lake Placid, FL, 33852 (EPA Region III)
Location 2: 758 Wollenmill Rd; Hughesville, PA, 17737 (EPA Region I)
Experience: 28 years

Completed Phone Survey: Distribution and use pattern of WSP formulations for **EPA Regions I and III and across the US**- distribution of mixing/loading equipment for WSP formulations. The respondent provided the following information through the use of the survey:

- This respondent believed that the use of WSP products can be found virtually in every region of the US.
- Believed that in FL and PA where he lives and works, WSP products are placed (mixed/loaded) into tanks not directly used for application (such as slurry tanks, pre-mix tanks, and pre-mix buckets) much more than they are placed directly into tanks that will be used for application of liquid sprays (such as tanks associated with groundboom or airblast application equipment). Believed that water soluble packets are not used with eductor systems in these regions.
- The respondent identified nurse tanks as another type of mixing tank into which WSP products could be placed.
- Believed that across the US, aerial, groundboom, airblast, backpack, and handspray equipment would be expected to be used to make liquid spray applications from WSP products.
- Across US, the most used spray equipment for applying liquid sprays of WSP products would be airblast sprayers, groundboom sprayers, and aircraft. Handspray equipment would be the least used.

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EPA Region V

Expert No. 13
Name: **William Mahlburg**
Position: **Director of Government Affairs**
Location 1: **Nufarm Americas, Inc.**
150 Harvester Drive, Suite 200
Burr Ridge, IL 60527
Experience: **35 years**

Completed Phone Survey: Distribution and use pattern of WSP formulations for **EPA Region V and across the US-** distribution of mixing/loading equipment for WSP formulations. The respondent provided the following information through the use of the survey:

- This respondent believed that the use of WSP products can be found virtually in every region of the US.
- Believed that across the US, WSP products are placed (mixed/loaded) into tanks not directly used for application (such as slurry tanks, pre-mix tanks, and pre-mix buckets) much less than they are placed directly into tanks that will be used for application of liquid sprays (such as tanks associated with groundboom or airblast application equipment). Believed that water soluble packets are used to a minor extent with eductor systems.
- This respondent identified handheld sprayers as another type of mix tank in which WSP products would be placed.
- Believed that across the US, aerial, groundboom, airblast, backpack, and handspray equipment would be expected to be used to make liquid spray applications from WSP products.
- Across US, the most used spray equipment for applying liquid sprays of WSP products would be airblast sprayers and groundboom sprayers with aircraft second. Handspray and backpack equipment would be the least used.

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EPA Region VIII

Expert No. 14
Name: **Larry Stein**
Position: **Professor-Extension Horticulturalist**
Location: **P.O. Box 1849**
Uvalde, TX 78801-1849
Experience: **25 years**

Completed Phone Survey: Distribution and use pattern of WSP formulations for **EPA Regions VIII and across the US**- distribution of mixing/loading equipment for WSP formulations. The respondent provided the following information through the use of the survey:

- This respondent believed that the use of WSP products can be found virtually in every region of the US.
- Believed that in the southwest Texas region where he lives and works, WSP products are placed (mixed/loaded) into tanks not directly used for application (such as slurry tanks, pre-mix tanks, and pre-mix buckets) a much less than they are placed directly into tanks that will be used for application of liquid sprays (such as tanks associated with groundboom or airblast application equipment). Believed that water soluble packets are not used with eductor systems in this region.
- The respondent did not identify any other types of mixing tanks into which WSP products could be placed.
- Believed that for the region of southwest Texas, the most used spray equipment with WSP products would be airblast followed by groundboom, backpack, handspray, and finally aerial.
- No other type of application equipment used for making liquid spray applications of WSP products was identified by the respondent.

US EPA ARCHIVE DOCUMENT

EPA Region IV

Expert No. 15
Name: **Patrick McMullan**
Position: **Manager of Agronomic Research**
Location: **Agrotechnology Research, Inc.**
7777 Walnut Grove Rd, Suite C30
Memphis, TN 38120
Experience: **20 years**

Completed Phone Survey: Distribution and use pattern of WSP formulations for **EPA Regions IV and across the US**- distribution of mixing/loading equipment for WSP formulations. The respondent provided the following information through the use of the survey:

- This respondent believed that the use of WSP products can be found virtually in every region of the US.
- Believed that across the US, about as much WSP product would be placed directly into tanks that will be used for application of liquid sprays (such as tanks associated with groundboom or airblast application equipment) as would be placed (mixed/loaded) into tanks not directly used for application (such as slurry tanks, pre-mix tanks, and pre-mix buckets). Believed that no WSP products would be used with eductor mixing systems.
- The respondent did not identify any other types of mixing tanks into which WSP products could be placed.
- Believed that the type of equipment used to spray liquid applications of WSP products would depend on the area of the US you are in. Groundboom followed by aerial and then airblast would be the most used spray equipment for WSP products while the use of backpack and handspray equipment with WSP products would be low.
- No other type of application equipment used for making liquid spray applications of WSP products was identified by the respondent.

US EPA ARCHIVE DOCUMENT

EPA Region VII

Expert No. 16
Name: **John Flynn**
Position: **Associate Scientist (Agronomist)**
Location: **Syngenta Seeds**
443 W. County Rd
Sutherland, NE 69165
Experience: **21 years**

Completed Phone Survey: Distribution and use pattern of WSP formulations for **EPA Regions VII and across the US-** distribution of mixing/loading equipment for WSP formulations. The respondent provided the following information through the use of the survey:

- This respondent believed that the use of WSP products can be found virtually in every region of the US.
- Believed that for the region of western Nebraska in which he lives and works, most of the WSP products are placed into tanks not directly used for the application, such as slurry tanks, pre-mix tanks, pre-mix buckets, etc. There is some minor use of direct addition of WSP to tanks that will be used for the application, e.g., groundboom or airblast tanks.
- Believed that for the region of western Nebraska, the most used spray equipment with WSP products would be groundboom while backpack would be the least used spray equipment with WSP products. This information conflicted with information previously mentioned above.
- No other type of application equipment used for making liquid spray applications of WSP products was identified by the respondent.

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EPA Region XI

Expert No. 17
Name: **Don Thill**
Position: **Professor of Weed Science**
Location: **University of Idaho**
P.O. Box 442339
Moscow, ID 83844
Experience: **28 years**

Completed Phone Survey: Distribution and use pattern of WSP formulations for **EPA Regions XI and across the US**- distribution of mixing/loading equipment for WSP formulations. The respondent provided the following information through the use of the survey:

- This respondent did not answer questions 2, 4 and 6 of the questionnaire. Thus, no information was gathered on water soluble packets with this respondent.

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EPA Region IX

Expert No. 18
Name: **Earl Cheek**
Position: **Extension Weed Specialist**
Location: **University of Nevada, Reno**
111 Sheckler Rd
Fallon, NV 89406
Experience: **8 years**

Completed Phone Survey: Distribution and use pattern of WSP formulations for **EPA Regions IX and across the US**- distribution of mixing/loading equipment for WSP formulations. The respondent provided the following information through the use of the survey:

- This respondent did not believe that WSP products could be found in every region of the US.
- This response represents only Nevada; 93% of the crops in Nevada are in Hay. The use of WSP products would be very low.
- Believed that in Nevada, most all WSP products (when used) would be placed directly into tanks that will be used for application of liquid sprays (such as tanks associated with groundboom or airblast application equipment). Believed that water soluble packets are not used with eductor systems in this region.
- This respondent identified backpack sprayers as a common application equipment available in Nevada that might be used with WSP products for treating inaccessible rangeland areas.
- Believed that in the region of Nevada, groundboom (1^{st}) and aerial equipment (2^{nd}) would be most expected to be used to make liquid spray applications from WSP products. Airblast would be the least used. Handspray and backpack equipment would be used to make some treatments.

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EPA Region XI

Expert No. 19
Name: **Don Morishita**
Position: **Professor of Weed Science & Extension Specialist**
Location: **University of Idaho**
P.O. Box 1827
Twin Falls, ID 83303
Experience: **22 years**

Completed Phone Survey: Distribution and use pattern of WSP formulations for **EPA Regions XI and across the US**- distribution of mixing/loading equipment for WSP formulations. The respondent provided the following information through the use of the survey:

- This respondent believed that the use of WSP products can be found virtually in every region of the US.
- Believed that for southern Idaho, WSP products are placed (mixed/loaded) into tanks not directly used for application (such as slurry tanks, pre-mix tanks, and pre-mix buckets) less than they are placed directly into tanks that will be used for application of liquid sprays (such as tanks associated with groundboom or airblast application equipment). Believed that water soluble packets are used to a minor extent with eductor systems in this region.
- The respondent did not identify any other types of mixing tanks into which WSP products could be placed.
- Believed that across the US, aerial, groundboom, airblast, backpack and handspray would be used for making liquid sprays of WSP products.
- Believed that airblast equipment would be most used to make liquid spray applications from WSP products. Handspray, aerial, and groundboom equipment would be the next most used application equipment with WSP products while backpack equipment would be the least used.

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Table 1: Summary of Information from Experts Concerning WSP Information

Expert #	Location (Region / State)	WSPs Used Widely Across US?	Direct Mix vs. Pre-Mix?	Frequency of Spray Equipment Use?
1	XII / WA	Yes	Pre-Mix >> Direct	Groundboom most, Backpack least
2	II / NC	Yes	Direct >> Pre-Mix	Groundboom most, Handheld sprayers least
3	II / NC	Yes	Direct >> Pre-Mix	Airblast most, Backpack / handheld least
4	II / NC	Yes	Direct > Pre-Mix	Groundboom / Airblast most, Backpack / handheld least
5	X / CA	Yes	Direct >> Pre-Mix	Airblast most, Backpack least
6	VI / TX	No, not in TX Citrus	Did not respond since WSP not used his area / crop	
7	VI / TX	Yes	Direct = Pre-Mix	Groundboom > Aerial > Backpack / Handheld > Airblast
8	V / OH	Yes	Pre-Mix >>> Direct	Airblast > Groundboom > Aerial
9	III / FL	Yes	Direct >> Pre-Mix	Groundboom most, Handheld least
10	IV / LA	Structural Pest Control is not applicable to AHETF		
11	X / CA	Yes	Pre-Mix >> Direct	Groundboom / Airblast most, Handheld least
12	I / PA and III / FL	Yes	Pre-Mix >> Direct	Airblast / Groundboom / Aerial most, Handheld least
13	V / IL	Yes	Direct >> Pre-Mix	Airblast / Groundboom > Aerial > Handheld
14	VIII / TX	Yes	Direct >> Pre-Mix	Airblast > Groundboom / Backpack / Handheld > Aerial
15	IV / TN	Yes	Direct = Pre-Mix	Groundboom > Aerial > Airblast >> Backpack / Handheld
16	VII / NE	Yes	Pre-Mix >>> Direct	Groundboom most, Backpack least
17	XI / ID	Did not respond regarding WSP		
18	IX / NV	Yes	Direct >>> Pre-Mix	Groundboom > Aerial > Airblast >> Backpack / Handheld
19	XI / ID	Yes	Direct > Pre-Mix	Airblast > Handheld / Aerial / Groundboom > Backpack

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APPENDIX 1

Phone Documentation for Calling Experts on Equipment and Procedures for Mixing/Loading Wettable Powders and Water Soluble Bags

Telephone Log **H.E.R.A.C. Inc. 08-03HE**

Expert Name: **Phone Number:**

Date:	Time:	Status: B NA LM CB WC	CB Date/Time: WC Date/Time:
Spoke To:		Position:	
Comments________________________________			

Date:	Time:	Status: B NA LM CB WC	CB Date/Time: WC Date/Time:
Spoke To:		Position:	
Comments________________________________			

Date:	Time:	Status: B NA LM CB WC	CB Date/Time: WC Date/Time:
Spoke To:		Position:	
Comments________________________________			

Date:	Time:	Status: B NA LM CB WC	CB Date/Time: WC Date/Time:
Spoke To:		Position:	
Comments________________________________			

Calling Codes: B = Phone busy; NA = No answer; LM = Left message; CB = Call back expert[1] later; WC = Expert[1] will call back.

_______________________________ ____________

Completed by Date

1 The word “grower” appears at these locations in the original raw data forms. This error was corrected and the word “grower” was replaced by the word “expert” in this report for clarification.

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AHETF Survey of Wettable Powder and Water Soluble Bag Mixing/Loading Procedures and Equipment

Caller's Name and Date		
Person Contacted and Date		
Title and Position		
Contact Information		
Years of Experience		
Preference for Citation	☐ **By Name, etc. -** ☐ **Broader description only -**	

Survey Questions and Information

1. Do you believe that the use of WPs can be found in virtually every region of the U.S. (e.g., all 12 EPA regions covering the contiguous 48 states)?

_____Yes _____No

_____
_____

2. Do you also believe that the use of WSBs can also be found in virtually every region of the U.S.?

_____Yes _____No
_____

3. What types of equipment or procedures do you believe typically are used with the mixing/loading of WPs? For instance:

_____ Open pouring of the WP directly into tanks that will be used for the application, e.g., groundboom or airblast tanks, and in what range of sizes?

_____ Mixing/loading of the WP into tanks not directly used for the application, such as slurry tanks, pre-mix tanks, pre-mix buckets, etc.

_____Eductor systems

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What other types of equipment or procedures?

_____
_____

4. What types of equipment or procedures do you believe typically are used with the mixing/loading of WSBs?

Would it be essentially the same as for the WPs just discussed, with the possible exception of eductor systems?

_____Yes _____No

What other types of equipment or procedures for mixing of WSB do you have knowledge of ?

_____
_____

5. What general types of application equipment do you believe are typically used for making liquid spray applications from WP products?

Would aerial, groundboom, airblast, backpack, handspray, etc., be expected to be used for making liquid spray application of WP products?

_____Yes _____No

_____
_____

What other types of application equipment might be used?

_____
_____

Do you believe that this application equipment would typically be available in all areas of the country?

_____Yes _____No

6. What general types of application equipment do you believe are typically used for making liquid spray applications from WSB products?

_____
_____

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Would it be essentially the same as for the WPs just discussed, with the possible exception of backpack sprayers?

_____ Yes _____ No

What other types of application equipment or procedures would be used for application of liquid sprays that you have knowledge of?

_____

_____

7. Do you believe that some crops or use patterns involve the use of WP products more than others? If so, what are they?

_____Yes _____No

_____

_____

8. Do you know of WP products/active ingredients that are widely used?

_____ Yes ____ No

_____

_____

_____ _____

Completed By Date

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APPENDIX 2

List of Experts--WSP Use Throughout US

Michael Beevers, Ph.D.
California Agricultural Research, Inc.
4141 N. Vineland
Kerman, CA 93630
Office: (559) 843-2997
E-mail: calag@kermantel.net

Earl Cheek
Extension Weed Specialist
University of Nevada, Reno
111 Schekler Rd
Fallon, NV 89406
775 423 5121

Keith Dubrock
McKenzie Pest Control
P.O. box 5602
Lake Charles, LA
337 478 7826

Name withheld
Professor of Plant Pathology & Extension Specialist
ORADC
Wooster, Ohio 44691

John Flynn
Syngenta Seeds
Associate Scientist (Agronomist)
443 West County Rd
Sutherland, NE 69165

JD Fish
Bayer CropScience
Two T.W. Alexander Dr.
Research Triangle Park, NC 27709
919 549 2995
E-mail: Jd.fish@bayercropscience.com

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Fred Fishel
Director of pesticide information office
Assoc. Professor of Agronomy
University of FL
352-392-4721

Steve Gibson
Extension Agent, Agriculture
130 South Post Rd
Suite #1
Shelby, NC 28152
704 482 4365

Mac Learned
Technical Support Manager
FMC Corporation
1126 Old Peachy Canyon Rd
Paso Robles, CA 93446
805 440 8445

William M Mahlburg
Director of Government Affairs
Nufarm Americas, Inc
150 Harvester Dr, Suite 200
Burr Ridge IL 60527
Phone 630-455-2015 (Direct)
E-mail: bill.mahlburg@us.nufarm.com

Patrick McMullan, Ph.D.
AgroTechnology Research, Inc.
Box 57, 7777 Walnut Grove Road
Memphis, TN 38120
Office: (901) 757-2730
E-mail: pmcmullan@agrotechnologyresearch.com

Don Morishita
Professor of Weed Science & Extension Specialist
University of Idaho
P.O. Box 1827
Twin Falls, ID 83303
208 736 3616

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Name withheld
Sales representative
UAP
Blessing, TX 77419

Dean Remick
ENTOCON, Inc.
AG Consultant
758 Wollenmill Rd
Hugesville, PA 17737
Or
703 Chelsee Way
Lake Placid, FL 33852
E-mail: Dean.remick@yahoo.com

Julian Sauls
Professor and Extension Horticulturalist for Texas
Texas Agrilife Extension Service
2401 East Highway 83
Westlaco, TX 78596
956 968-5581

Dwight Seal
Western District Manager
North Carolina Department of Agriculture
Division of Structural Pest Control and Pesticides
1090 Mail Service Center
Raleigh, NC 27699
919 280 4494

Larry Stein
Professor and Extension Horticulturalist for Texas
P.O. Box 1849
Uvalde, TX 78802-1849
Phone: (830) 278-9151

Jim Thayer
Mix-Master and Applicator
Wilbur Ellis Company
12925 Road 4
Quincy, WA 98848

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Don Thill
Professor of Weed Science
University of Idaho
P.O. Box 442339
Moscow, ID 83844
208 885 6214

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Part C: IIRB Approval Letter and Supporting Documents

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IIRB Approval Letter dated 12/17/08

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INDEPENDENT
INVESTIGATIONAL
REVIEW BOARD INC.
Your Advocate for Clinical Research Participants

Kim Lerner
Chairman

Anita McSharry, R.N.
President

DATE: December 17, 2008

TO: Eric D. Bruce
Principal Investigator

FROM: Kim Lerner, Chairman or
Anita McSharry, Vice-Chairman
Independent Investigational Review Board, Inc.

SUBJECT: Approval Clinical Research;
- English/Certified Spanish Translation Informed Consent Form (Ver. 12/16/2008)
- English/Certified Spanish Translation Sevin® 80 Solupak Product Risk Statement Informed Consent Form (Ver. 12/11/2008)
- English/Certified Spanish Translation Acephate 90 WSP® Product Risk Statement Informed Consent Form (Ver. 12/11/2008)
- English/Certified Spanish Translation Acephate 75 WSP® Product Risk Statement Informed Consent Form (Ver. 12/11/2008)
- Research Protocol dated 12/11/2008
- Site Questionnaire
- English/Certified Spanish Translation Experimental Subject's Bill of Rights
- Advertisement
- Agricultural Handlers Exposure Task Force SOPs
- Sevin® Brand 80 Solupak MSDS version 2.0 dated 8/3/2006
- Acephate 90 WSP MSDS dated 4/12/2007
- Acephate 75 WSP MSDS dated 4/12/2007
- Acephate 75 WSP Product Risk Label dated 2/7/2008
- Acephate 90 WSP Product Risk Label dated 2/7/2008
- Sevin® 80 Solupak Product Risk Label dated 7/19/2006

PROTOCOL: (AHE120) Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Pesticide Products in Water Soluble Packets in the United States

The Independent Investigational Review Board, Inc. is an institutional review board structured in compliance with the regulations of the Food and Drug Administration contained in the Code of Federal Regulations (2I CFR 50 and 56, 45 CFR 46, and 40 CFR 26) and is in compliance with the International Conference of Harmonization (ICH) and Good Clinical Practice (GCP) guidelines for IRB/IECs.

At the meeting held on December 16, 2008, the Committee reviewed and unanimously approved the Investigators, Informed Consent Form, Sevin® 80 Solupak Product Risk Statement Informed Consent Form, Acephate 90 WSP® Product Risk Statement Informed Consent Form, Acephate 75 WSP® Product Risk Statement Informed Consent Form, Research Protocol, Experimental Subject's Bill of Rights and Print Ad for the above noted research study. The Site Questionnaire, Agricultural Handlers Exposure Task Force SOPs, Sevin® Brand 80 Solupak MSDS, Acephate 90 WSP MSDS, Acephate 75 WSP MSDS, Acephate 75 WSP Product Risk Label, Acephate 90 WSP Product Risk Label and Sevin® 80 Solupak Product Risk Label were reviewed and unanimously accepted.

The Informed Consent Form, Sevin® 80 Solupak Product Risk Statement Informed Consent Form, Acephate 90 WSP® Product Risk Statement Informed Consent Form and Acephate 75 WSP® Product Risk Statement Informed Consent Form are unanimously approved. The approved English/Certified Spanish Translation Informed Consent Form is identified as Version 12/16/2008 and stamped, "Approved 12/16/2008". The Informed Consent Form contains all regulatory required consent elements. The approved English/Certified Spanish Translations Sevin® 80 Solupak Product Risk Statement Informed Consent Form, Acephate 90 WSP® Product Risk Statement Informed Consent Form and Acephate 75 WSP® Product Risk Statement Informed Consent Form are identified as Version 12/11/2008 and stamped, "Approved 12/16/2008". The English/Certified Spanish Translation of the Experimental Subject's Bill of Rights are stamped, "Approved 12/16/2008".

The following advertisement was approved and stamped "Approved" 12/16/2008:
- 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. A final version, if revisions or reformatting is required, must be submitted to the Independent Investigational Review Board, Inc. and acknowledged prior to use.

The study has been approved for a 12 month period. Prior to the end of approval on 12/15/2009, 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, Inc. review and approval.

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It is the responsibility of the Principal Investigator to submit all unanticipated problems and serious or continuing non-compliance in a timely manner to the IIRB, Inc. For more information on reporting requirements visit www.iirb.com and the Investigator's Guidebook. Please provide this reporting to the above-noted address so that appropriate follow-up can be initiated.

Thank you for your cooperation.

KL/AMS/yc:rr

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AGRICULTURAL HANDLERS EXPOSURE TASK FORCE (AHETF)

STUDY No. AHE120

Study Title: Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Pesticide Products in Water Soluble Packets in the United States

PROTOCOL AUTHORIZATION

Read and Approved by:

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

Signature _____

Date _____

Study Director: Eric D. Bruce

Signature _____

Date _____

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1.0 GENERAL INFORMATION

1.1 Study Title

Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading Pesticide Products in Water Soluble Packets in the United States

1.2 Study No. AHE120

1.3 Objective

The objective of this study is to develop data to determine the potential exposure for workers who mix and load solid pesticide products packaged in water soluble packets in five regions of the United States. This activity involves adding water soluble packets (generally a soluble or wettable powder in a plastic film pouch) into a variety of mixing, holding, or application equipment; dilution with water; and sometimes a subsequent transfer of diluted product to application equipment. The data generated from this study should be sufficient to complete the data set for this mixing/loading scenario.

1.4 Timeline

Proposed Experimental Start Date: May, 2009

Proposed Experimental Termination (Field Phase) Date: July, 2010

Proposed Experimental Termination (Analytical Phase) Date: December, 2010

Proposed Final Report Issue Date: December, 2011

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.

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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

Eric D. Bruce
21 Oak Knoll Ct.
Walnut Creek, CA 94596
925-939-4987 (office) 925-708-5538 (mobile)
eybruce@pacbell.net

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

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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 told which of the above researcher(s) will be involved with monitoring his/her exposure.

1.11 Grower List

The following contractors to AHETF will be utilized to generate lists of growers and to conduct phone recruitment of those growers. These contractors have specialized training and/or experience related to phone interviewing, recruiting, or surveying.

Randy Thompson, RPT Reports
Richard Honeycutt, HERAC, Inc.

1.12 Field Facilities

This study involves multiple locations across the country and will be conducted at a variety of commercial farms in an outdoor environment. Each of the Principal Investigators listed above utilizes a mobile laboratory (a large truck or trailer) that provides the necessary private and clean environment for dressing workers, undressing workers, and collecting exposure samples from workers. Since there is no field facility *per se* at which the study is conducted, no addresses are provided.

1.13 Principal Analytical Investigator and Analytical Facility

To be determined and amended to the protocol prior to initiation of the field phase of the study. This study may involve multiple active ingredients so multiple analytical investigators and analytical facilities may be specified.

1.14 Quality Assurance Unit

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

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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 (see SOP AHETF-11.A). The protocol, informed consent form(s), California Experimental Research Subject's Bill of Rights, and other required documentation for this study will be approved by an institutional review board (IRB) and the California Department of Pesticide Regulation, 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 IRB for the proposed research shall be the Independent Investigational Review Board Inc. (IIRB) of Plantation, Florida. Complete records of the IIRB 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 (Protecting Human Research Participants (PHRP)) 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/or contract facilities).

2.1 Inclusion Criteria

AHETF inclusion criteria applicable to all AHETF studies are presented in SOP AHETF-11.B. For this mixing/loading of water soluble packets study, the following inclusion criterion also applies:

- Have experience within the past year with mixing/loading water soluble packets (including the particular equipment to be used)

2.2 Remuneration of Subjects

During recruitment, workers will be offered an opportunity to take part in a recruitment 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 in participating in the study will attend a private consent 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

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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

Five kinds of risks are associated with the conduct of this 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 surfactants

In this study risks to subjects are classified as "greater than minimal" since the likelihood of harm or discomfort is greater than what is encountered in ordinary daily life. In particular, this study involves the use of chemicals (pesticides, fertilizers, additives, etc.) that present a risk of adverse health effects. In addition, 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 mixing and loading water soluble packets into a pre-mix or application tank and diluting the product with water. Mixing/loading activities might occur indoors or outdoors and some locations and dates are likely to result in hot and/or humid conditions. 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.

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Mixer/loaders who participate in the study will handle water soluble packets that weigh significantly less than 50 pounds. This is a "light" activity as defined by the North American Free Trade Association (NAFTA) Technical Working Group on pesticides (1998), so physical exertion is relatively low which will reduce the likelihood of heat-related illness. However, each participant will be required to mix/load at least three loads of pesticide spray.

AHETF will monitor ambient conditions to determine the heat index near the mixing/loading station and base monitoring decisions on the current heat index. Exposure monitoring will be discontinued if the heat index cutoff of 120^{o}F (adjusted for direct sun, if applicable) is reached or exceeded. The Study Director or other researcher shall stop the monitoring and/or move the worker to a cooler environment until monitoring can be resumed.

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. AHETF will encourage this if it is a common practice at the field sites selected, and 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 any of the following active ingredients:

- Acephate
- Carbaryl

The pesticide products containing these active ingredients and potentially used in this study are currently registered for agricultural use. AHETF will only monitor workers mixing/loading 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 study (2,000 lb ai/day for carbaryl and 720 lb ai/day for acephate) and based on the estimated exposures for mixing/loading water soluble packets (PHED

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Scenario 5). The following table summarizes the data for these MOE calculations. The calculated MOEs meet or exceed the minimum required MOE, or level of concern (generally 100), for 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 Mixing/Loading Water Soluble Packets:

	Acephate	**Carbaryl**
Max. Daily Amount Handled	720 lb ai/day	2,000 lb ai/day
Dermal MOE	**858**	**531**
Inhalation MOE	**113**	**160**
Combined MOE	**100**	**123**
Level of Concern, Dermal	100	100
Level of Concern, Inhalation	100	100
Level of Concern, Combined	100	100

Potential surrogate products 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).

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Product	Signal Word	Acute Toxicity Summary
Acephate		
Acephate 75 WSP®	CAUTION	• Minimal eye irritation • Low toxicity for oral, dermal, and inhalation routes • Cholinesterase inhibition
Acephate 90 WSP®	CAUTION	• Moderate eye irritation • Low toxicity for oral, dermal, and inhalation routes • Cholinesterase inhibition
Carbaryl		
Sevin® 80 Solupak	WARNING	• Slight eye irritation • Low toxicity dermal and inhalation routes; moderate toxicity for oral route • Cholinesterase inhibition

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 chemical-resistant gloves) during participation.

For this mixing/loading study, exposure to the solid product itself should be negligible due to the water soluble packaging. However,

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exposure to product diluted in water is still possible since the mixing/loading system is not closed. This mixing/loading technique can lead to both dermal and inhalation exposure, however 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 via the dermal route during this study is expected to be 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 mixing/loading 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 than they would normally select or dilute the product more than usual. 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 17 or 18 to 55 pounds of AaiH (Section 7.8). 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 excessive risk.

In order to achieve diversity in AaiH at the high end, AHETF may ask some workers to use larger tank sizes than they would normally select or dilute the product less than usual. These changes might result in longer work periods and greater chemical exposure than would otherwise occur and 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.

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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.

2.3.5 Risk of Exposure to Surfactants During Face/Neck Wipe and Hand Wash Sampling

A very dilute surfactant 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 surfactant solution in pesticide exposure monitoring studies indicates the likelihood of skin or eye irritation is negligible.

In summary, this study will possibly involve an increased risk of heat illness, the usual risk of surrogate chemical toxicity, and very slight risks of skin or eye irritation from surfactant use and of embarrassment caused by pregnancy testing and/or dressing/undressing requirements. The following practices, designed to minimize these risks and respond to injuries, will be followed during this study (see AHETF SOPs 11.C, 11.E, 11.G and 11.H):

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- Selecting only experienced pesticide handlers who consider themselves to be in good health
- Requiring experience with the mixing/loading equipment to be used
- Reminding workers of safe chemical handling practices
- Practicing the face wipe and hand wash procedures with each participant before pesticide handling begins
- Identifying nearby medical treatment 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 that could adversely affect the study objectives (for example, chemical-resistant coveralls).

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 mixing/loading pesticides packaged in water soluble packets. Water soluble packets are considered an engineering control designed to reduce exposure potential for mixer/loaders. 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 not sufficient existing data suitable for use in a generic database describing the exposure to workers from mixing/loading water soluble packets, 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. 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. Pesticide products packaged in water soluble packets are becoming more common for many agricultural uses across the country and a variety of experts consulted by AHETF reported their use occurs widely throughout the country. Exposure data for this scenario meeting contemporary standards of reliability and quality will likely provide a significant benefit to society. Because margins of exposure are acceptable for the products proposed for use in this research study, 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 summary, 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 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 are described in SOPs AHETF-6.B, 6.D, 11.B, 11.D, and 11.J.

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

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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. Volunteers will be informed they must complete an IRB-approved informed consent form and a product risk statement appropriate for the pesticide they will handle. Participants in California must also sign the California Experimental Research Subject's Bill of Rights. The consenting process is conducted as described in SOP AHETF-11.J.

2.8 Study Procedures

During the consent process the Study Director or designated researcher will inform each volunteer of the procedures used during the study.

Before exposure monitoring begins, volunteers will:

1. Provide their name and age and present their government-issued photo-ID.

2. Indicate whether they have received pesticide safety training or are exempt from the requirement for pesticide safety training.

3. Tell researchers how many years of experience they have mixing/loading water soluble packets, what particular mixing/loading equipment they're accustomed to using, and when they last used it.

4. Allow researchers to record their gender, age, and ethnicity; and measure and record their height and weight.

5. Allow researcher to take notes on the discussions during the informed consent session(s).

6. Agree to allow researchers to watch all of their work activities and take notes on what they do.

7. Agree to allow photographs and video recordings to be taken for the purpose of documenting this research (see SOP AHETF-10.C for restrictions).

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Volunteers will be asked to arrive at the study site on the day of monitoring about one hour before the scheduled start of work, having bathed or showered the evening before or that morning, and wearing a freshly laundered long-sleeve shirt, long pants, shoes and socks. 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, workers may wear a hat or cap. Then, at the study site on the day of monitoring each volunteer will:

1. Go to a private changing area and, with the assistance of only a researcher of their own sex, take off their outer clothing, put on new long underwear over their personal undergarments, and then put their long-sleeved shirt, long pants, shoes, and socks back on. The long underwear will be provided by AHETF, and will be collected at the end of the study day for analysis.

2. Wear all Personal Protective Equipment (PPE) required by the label of the product to be used. In addition, when using acephate mixer/loaders must have the following PPE immediately available for use in case of emergency such as a broken package, spill, or equipment breakdown: coveralls, chemical-resistant footwear, and a dust/mist or organic vapor respirator.

3. Wear a tube attached to their shirt collar and connected to a portable air-sampling pump worn on a belt around the waist. The pump may be uncomfortable or annoying.

4. Have their hands washed with the assistance of a researcher in a mild surfactant and water mixture before monitoring begins.

5. Have their face and neck wiped by a researcher with a gauze pad moistened with a mild surfactant and water mixture before monitoring begins.

6. Work about 4 to 8 hours mixing/loading a commercial pesticide product packaged in water soluble packets according to the product label and consistent with their usual practices, preparing at least 3 loads. Researchers will watch and take notes on their work activities, and may take photographs or video recordings if necessary to document the research, protecting the privacy of subjects as much as possible. No photographs or video recordings will be made while volunteers are dressing or undressing.

7. Have their hands washed again, in mild surfactant and water, before they eat anything, any time they would normally wash their hands (such as

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before using the toilet), and at the end of the day. The water from these hand washes will be saved for analysis.

8. Have their face and neck wiped again with gauze pads moistened with a mild surfactant and water mixture before they eat anything, any time they would normally wash their face, and at the end of the day. The gauze pads used for this purpose will be saved for analysis.

9. When their work in the study is completed, return to the private changing area where, again with the help of only a researcher of the same sex, they will remove their shoes, socks, shirt, and pants and the long underwear, give the long underwear to the researcher, and put their own shirt, pants, shoes, and socks back on and return to their normal work.

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 and a comparison to the results for other workers performing the same task. Results are typically available six to nine months after monitoring occurs. The personal information related to this follow-up will be retained as described in SOP AHETF-6.D.

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 a toll-free phone number 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.J).

3.0 SITES OF THE FIELD PHASE OF THE STUDY

This study will be conducted at five locations within the United States:

- New York (EPA Growing Region I)
- Louisiana (EPA Growing Region IV)
- Michigan (EPA Growing Region V)
- California (EPA Growing Region X)
- Washington (EPA Growing Region XI)

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Within each location, a specific site will be identified that is likely to provide enough suitable crop acreage and sufficient growers to locate a pool of eligible growers that can provide 5 MUs for monitoring mixer/loader exposure. Within each selected site, exposure monitoring will be conducted at a variety of commercial agricultural operations. Exposure monitoring will be conducted on at least five different farms using five different growers within the identified counties or parishes.

The most desirable locations involve a variety of crop types (e.g., field, trellis, and orchard crops) identified in the MU Sampling Plan as being predominantly associated with surrogate use. For each selected site, researchers will identify eligible growers using a random method as described in the next Section. Full details of the grower and worker selection process and actual commercial agricultural operations utilized will be recorded in the study file. Based on these considerations, the following sites are identified:

New York (EPA Growing Region I):

The site for this cluster of MUs will be commercial farms within the contiguous counties of Chautauqua, Erie, and Niagara which reflect the largest area of grape acreage in New York as well as some apple and cherry orchards. These three crops are identified in the MU Sampling Plan as being associated with significant use of one or both of the proposed surrogates. Having a mix of field and orchard crops is desirable since this will enhance the chances of equipment diversity within the MUs. Collectively, these counties include about 22,567 acres of grapes, 3,700 acres of apples, and 1,084 acres of cherries (2002 Census of Agriculture).

Louisiana (EPA Growing Region IV):

The site for this cluster of MUs will be commercial farms within the contiguous parishes of East Carroll, Madison, and Tensas in the northeastern corner of Louisiana. This three-parish area has significant acreage of both crops associated with surrogate chemical use in this state: cotton and soybeans. Collectively, these parishes reflect the top three ranked Louisiana parishes in terms of total acres for the two important crops with about 280,991 acres, about evenly split between cotton and soybeans (2002 Census of Agriculture).

Michigan (EPA Growing Region V):

The site for this cluster of MUs will be commercial farms within the adjacent counties of Oceana and Mason on the western coast of the Michigan peninsula. This two-county area grows five of the six crops associated with surrogate chemical use in this state: apples, cherries, peaches, asparagus, and snap beans. Grape acreage is trivial for these counties. Having a mix of field and orchard crops is desirable since this will enhance the chances of equipment diversity within the MUs. Collectively, these counties reflect the first and sixth ranked Michigan counties in terms of total acres for

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the six important crops with about 36,284 acres (2002 Census of Agriculture).

California (EPA Growing Region X):

The site for this cluster of MUs will be commercial farms within the adjacent counties of Fresno and Tulare in the Central Valley of California. This two-county area includes significant acreage for grapes, oranges, peaches, plums, and tomatoes - five of the seven crops associated with surrogate use in this state. Having a mix of field, trellis, and orchard crops is desirable since this will enhance the chances of equipment diversity within the MUs. Collectively, these counties reflect the first and second ranked California counties in terms of total acres for the seven important crops with about 644,500 total acres, mostly of grapes, oranges, and tomatoes (2002 Census of Agriculture).

Washington (EPA Growing Region XI):

The site for this cluster of MUs will be commercial farms within the adjacent counties of Yakima and Benton in the Yakima district in Washington State. This two-county area includes significant acreage of all four crops associated with surrogate use in this state: apples, cherries, pears, and grapes. Having a mix of trellis and orchard crops is desirable since this will enhance the chances of equipment diversity within the MUs. Collectively, these counties reflect the first and third ranked counties in terms of total acres for the four important crops including about 67,154 acres of apples, 45,648 acres of grapes, 10,674 acres of pears, and 13,977 acres of cherries (2002 Census of Agriculture).

4.0 GROWER SELECTION

As described briefly above, growers of crops that are treated with the selected surrogate chemicals will be identified in order to identify and recruit handlers that might volunteer to participate in this study. The process that will be used for this scenario to identify and recruit growers is described in SOPs AHETF-11.K and AHETF-11.M. This process is summarized below and in SOP AHETF-1.H.

4.1 Listing Growers

For each site selected above, a list of growers will be obtained that grow at least 5 acres (if farm size information is available) of the crops identified in the MU Sampling Plan as being associated with the most use of at least one surrogate active ingredient. Eliminating small acreage growers ensures that all growers on the list are likely to be able to handle the minimum AaiH of 5 pounds of active ingredient. These grower lists are called Master Grower Lists and generally represent a random sub-sample of a Grower Universe List that includes the majority of growers in the particular site. The crops

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associated with each site in this study, and that grower lists are based on, are:

New York (Chautauqua, Erie, and Niagara Counties):

- Apples
- Grapes (any type)
- Cherries (any type)

Louisiana (East Carroll, Madison, and Tensas Parishes):

- Cotton
- Soybeans

Michigan (Oceana and Mason Counties):

- Apples
- Cherries (any type)
- Grapes (any type)
- Peaches
- Asparagus
- Snap beans

California (Fresno and Tulare Counties):

- Oranges
- Peaches
- Plums
- Grapes (any type)
- Celery
- Lettuce (any type)
- Tomatoes (any type)

Washington (Yakima and Benton Counties):

- Apples
- Cherries (any type)
- Pears
- Grapes (any type)

AHETF contractors with training or experience conducting telephone interviews will contact resources to generate the lists of growers (see SOP AHETF-11.K) and screen them for suitability for this study. This results in a randomly obtained Qualified Grower List that includes growers who might be eligible to cooperate with this study.

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4.2 Selecting Growers

AHETF researchers with training or experience conducting telephone interviews and familiarity with AHETF testing procedures will call all the growers on the Qualified Grower Lists to discuss their eligibility to cooperate with the study (see SOP AHETF-11.M). Growers are considered eligible who:

- Are willing to cooperate with AHETF, including the ethical aspects of the research,
- Are commercial agriculture operations,
- Utilize solid pesticides that are packaged in water soluble packets,
- Have at least one worker with experience mixing/loading water soluble packets,
- 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.

Growers who meet the criteria above but indicate they use commercial applicators to mix/load their products will be asked to identify their preferred commercial applicator(s). Researchers will contact them to screen them for willingness to cooperate by providing suitable equipment and allowing workers to be recruited to mix/load product for that grower. 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.

For each site, each grower identified as potentially 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:

- Specific location of mixing/loading sites
- Description of mixing/loading 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 the workers might be able to handle in a day

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If the grower calling process does not identify at least 10 workers who may potentially volunteer for the study, and at least 2 workers that are available for each of the AaiH strata, a new list of growers will be obtained and contacted until these criteria are met. This ensures a pool of potentially eligible growers and workers that is greater than are ultimately needed for the study.

This grower recruitment process results in a Potentially Eligible Grower List for each selected site and, by association, a random pool of workers associated with the growers.

4.3 Documenting Grower Selection

For each site, all discussions and decisions made during these list generation and eligibility screening processes will be documented in a detailed study notebook provided by AHETF or kept in files bearing the study number. For each site, the records shall include the number of:

- growers on the Grower Universe List
- growers on the Master Grower List
- growers on the Qualified Grower List
- growers contacted from the Qualified Grower List (direct discussion or voice message response from grower)
- growers on the Potentially Eligible Grower List (i.e., passed suitability screening, including willingness to cooperate)
- workers linked to each grower on the Potentially Eligible Grower List

5.0 EFFICIENT MU DESIGN

For each selected site, the Study Director will assemble the information obtained from the pool of potentially 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 configuration for that site (see Section 6). An efficient configuration will be comprised of a group of at least five 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. This is known as the Eligible Grower List. No grower may contribute more than one MU to this study and each MU must involve a unique worker and a different set-up of mixing/loading equipment. The growers and/or commercial applicators in the chosen configurations provide the pool of workers from which study participants will be recruited at each site.

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6.0 PARTICIPANT SELECTION

6.1 Site Inspection

For each selected site, the Study Director and/or Local Site Coordinator shall arrange to visit growers from the pool of potentially 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 farm 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. After confirmation of suitability, growers are added to the Eligible Grower List.

6.2 Participant Recruitment

For each selected site, AHETF will follow standard procedures (see SOP AHETF-11.B) to recruit potential participants for this water soluble packet mixing/loading study. Individual workers will be recruited during an initial site inspection or subsequent visit(s) to a potentially 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 using an informational recruitment flyer posted in a common work area. Such a flyer will briefly describe the research study and provide a toll-free phone number for employees to express an interest in participating 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 recruitment 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. A toll-free phone number 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

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handouts or visual aids, shall be reviewed and approved by an IRB prior to use in recruiting subjects.

For each selected site, 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 for that site. 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 one MU from any one grower or grower/commercial pesticide application company combination (this effectively requires 5 different employers since 5 MUs are desired)
- No worker may be used more than once
- No type of equipment (e.g., direct mixing into spray tank vs. mixing a slurry in a pre-mix tank) may be used more than once
- No piece of equipment may be used more than once (e.g., a particular sprayer used by two different workers from different growers)

As indicated above, the efficient configuration and Eligible Grower List must include enough growers and potential participants to fill all MUs for each selected site, 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 at that site.

6.3 Participant Selection and Consenting

For each selected site, the Study Director or designated researcher will contact workers (i.e., potential study participants) from growers in the efficient configuration to begin recruitment activities. When the pool of available worker volunteers at a site, or a particular commercial applicator operation, exceeds the number of MUs required, a simple random selection of equivalent volunteers will be made. For example, the names of the volunteers could be written on slips of paper of equal size and placed into a container and mixed thoroughly. A slip of paper would then be drawn from the container to fill the MU. All potential participants will be informed of the possibility of not being selected for this reason. Volunteer workers who are not selected will be released to resume their normal activities. The method of random selection will be documented in the study file.

Individual selected volunteers will be informed of study provisions to accommodate their language preference, to have a researcher read the consent form and other documents to non-readers, and to allow them to have a friend, family member or advisor present during an informed consent meeting. These

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language-related provisions are described in SOP AHETF-11.I.

The Study Director or designated researcher will arrange a place and schedule to conduct consent meetings with individual volunteers chosen from the eligible pool for each selected site. Prior to such meetings, accommodations will have been made for witnesses (if a non-reader is being consented) or bilingual researchers who must be present for the meeting (see SOP AHETF-11.I). Consent meetings shall be conducted as described in SOP AHETF-11.J.

6.4 Documenting Participant Selection

For each site, all discussions and decisions made during the participant recruitment and consenting processes will be documented in a detailed study notebook provided by AHETF or kept in files bearing the study number. For each site, the records shall include the number of:

- workers linked to each grower on the Eligible Grower List
- workers attending a recruitment meeting
- workers attending a consent meeting
- workers signing a consent form
- workers who signed a consent form, but were not selected for monitoring
- workers withdrawing at their own request (after monitoring began)
- workers removed from participation by AHETF
- workers completing participation

7.0 FIELD MATERIALS AND METHODS

7.1 Test System Identification - Workers

The test system for this study is the workers handling pesticides according to label directions. Workers may include farm owners, farm operators, farm employees, and contract applicator employees. Passive dermal dosimetry methods will be used to determine potential exposure of experienced workers handling the test substance. A total of 25 mixer/loaders are anticipated for this study (5 at each of five locations within the United States).

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 mixing/loading water soluble packets.

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The test substances selected for this study are registered and approved for use in a wide variety of agricultural settings. 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 Areas

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 these 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 mixing/loading 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. The most appropriate test substance, based largely on the preference of the grower, will be used at each of the individual sites.

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A different test substance may be used at each site and by each worker within a site if appropriate.

As previously described, eligible growers for each site 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 at each site, the grower will confirm the actual product he/she will be using on the day of the study. The researchers will ensure 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 monitoring 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.

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 a worker in the study 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 the 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.

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7.6 Mixing/Loading Parameters

Carrier:	Water.
Product Measurement:	Only whole packets may be used during mixing/loading.
Mixing Equipment:	A variety of mixing equipment are commonly utilized when mixing/loading water soluble packets. Within each cluster (i.e., site), at least one MU shall involve each of the following equipment-defined procedures: 1. Mixing of WSPs directly into the tank used for the application 2. Mixing of WSPs into a "pre-mix" tank in which the solution is at the same concentration as that applied to the crop 3. Mixing of WSPs into a tank (or other container) to make a concentrated solution that must be diluted & transferred to the final application tank Actual equipment and procedures used by each worker and for each load will be documented in study raw data.
Loading Equipment:	When appropriate, diluted (i.e., mixed) product may be transferred to another tank. This will most likely involve the use of pumps and hoses to transfer partially or fully diluted product from a pre-mix or holding tank to a piece of application equipment (such as a ground sprayer or aircraft). Actual equipment and procedures used by each worker and for each load will be documented in study raw data.
Route of application:	Applications might or might not be made during the mixer/loader monitoring period. Any appropriate application equipment may be utilized and study raw data will document what, if any, application equipment was used.

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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 during the mixing/loading process to measure the volume of liquid pumped into or out of a mixing or application tank.

Copies of relevant facility maintenance records (if available) for all mixing/loading equipment used for this study will be obtained and retained with the field raw data.

Workers will only be allowed to utilize equipment for which they are familiar and have used recently (within a year). 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 by each worker and other critical measurements including the volume of carrier will be determined and recorded in the raw data. Within each selected site, each worker will handle an amount of active ingredient (ai) 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 17 pounds ai handled
(2) 18 to 55 pounds ai handled
(3) 56 to 182 pounds ai handled
(4) 183 to 603 pounds ai handled
(5) 604 to 2,000 pounds ai handled

A single MU will be conducted from each of the five strata within each selected site. However, MUs handling acephate will be limited to 720 pounds of active ingredient.

Each MU shall consist of a period of at least 4 hours of mixing/loading and at least 3 tank loads of the spray mixture. 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 in SOP AHETF-10.E. Samples will be identified as described in SOP AHETF-8.F.

For this study, inner dosimeters will be cut into two sections after collection.

9.0 INHALATION EXPOSURE SAMPLING

Full details for sampling air with OSHA Versatile Sampler (OVS) tubes and personal air-sampling pumps are given in the most recent versions of SOP AHETF-8.D and 10.G.

The pumps and calibration equipment will be uniquely labeled and this information recorded in the raw data records. Each pump will be calibrated to a nominal sample flow rate of approximately 2 L/min. The OVS tubes will contain an appropriate adsorbent for the surrogate involved (e.g., chromosorb® 102 or XAD-2). The OVS tubes will be fully described in the study raw data.

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 monitoring period to be calculated. Workers will be instructed to inform a study team member if the pump fails to operate or the tubing becomes kinked.

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

Sample matrix fortifications designed to assess the stability of the active ingredient during field, transit and storage conditions in or on the sampling

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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 for each cluster of MUs, or more days as appropriate for environmental conditions. If more than one active ingredient is utilized at a particular location, at least one day of field fortifications will be conducted for each active.

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 the "by vial" spiking using active ingredient (ai) in an organic solvent will be followed for all matrices except OVS tubes. The tubes will be spiked at the laboratory with the proper amount of analytical standard.

In addition, for each fortification event, duplicate samples of the inner dosimeters fortified in the field at the highest level, and duplicate OVS tubes fortified in the laboratory at the next-to-highest fortification level, will be processed in the field 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.

For each fortification event, 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. All field fortification and untreated control samples will be identified as described in SOP AHETF-8.F.

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, 5.0, 500 and 1,000*

*The highest OVS tube fortification serves as a backup and will be analyzed if any worker OVS residues are found above 500 µg/sample.

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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. Photographs will be used to illustrate the condition of worker clothing before and after monitoring; and to provide visual documentation of the study for use by regulatory reviewers. None of the photographs shall result in identifying features of the workers.

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.

At each selected site, 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

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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 records 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.

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15.2 Analytical Methods

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.

The latest revisions of the following validated analytical methods will be used if the active ingredients are used during exposure monitoring:

Acephate Methods:

AHETF-AM-001 Determination of Acephate on Cotton Inner Dosimeters by Gary Westberg, Feb. 13, 2003

AHETF-AM-002 Determination of Acephate in Face/Neck Wipe Samples by Gary Westberg, Feb. 18, 2003

AHETF-AM-003 Determination of Acephate in Hand Wash Exposure Samples by Gary Westberg, Feb. 19, 2003

AHETF-AM-004 Determination of Acephate in OVS Air Sampling Tubes by Gary Westberg, Feb. 26, 2003

Carbaryl Methods:

AHETF method AHETF-AM-031, "Determination of Carbaryl in Cotton Inner Dosimeters Sectioned into Two Parts" by Frances Brookey and Gary Westberg, Morse Laboratories, Inc., June 5, 2008.

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.

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15.3 Analytical Calculations and Statistical Methods

Analytical calculation and statistical methods to be used are outlined in SOP AHETF-9.J.

16.0 STUDY RECORDS

16.1 Field Records

Raw data will be obtained to cover all aspects of the study and all sites, 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. Environmental conditions for the entire monitoring period, including data used for making determinations of potential heat stress indices
6. Approvals from the Institutional Review Board covering the protocol and the Informed Consent document, and all amendments to either document
7. All correspondence with the Institutional Review Board
8. 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)
9. Trial location maps, including description, dimensions, and exact locations of plots and mixing/loading stations
10. Pounds active ingredient handled, monitoring time, and volume of liquid mixed/loaded
11. Dermal exposure sampling information
12. Inhalation exposure sampling information, including pump identification, calibration, flow rates and times of sampling
13. Field recovery procedure information for all sampling media
14. Test and reference substance, and sample storage temperature records
15. Observations on work practices, including photographs
16. 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.D).

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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 request their personal study results when they are available. Individual results requested by subjects will be communicated in accordance with SOP AHETF-11.J.

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.

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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 of the study, 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

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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 by AHETF according to a standardized format. The report will contain a description of the conduct of the study and the analytical procedures and results for the study. 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 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

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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.

In accordance with the California Code of Regulations, 3 CCR 6710(h), the Study Director shall not make an amendment to the approved protocol that may impact the health of the human participants in California without approval from the Director of California Department of Pesticide Regulation (CDPR). For amendments where California participant health is potentially impacted, the Study Director shall make the request in writing.

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, laboratory SOPs or GLPs, must be communicated to the Study Director in a timely manner. Any deviations must also be reported to the study Sponsor, and the IRB. Deviations which occur in California must also be reported to CDPR. Protocol deviations are to be documented in accordance with SOP AHETF-2.C.

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English Language Consent Form

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RESEARCH INFORMATION AND INFORMED CONSENT FORM

TITLE: (PROTOCOL AHE120) Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Pesticide Products in Water Soluble Packets in the United States

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:

Eric D. Bruce
21 Oak Knoll Ct.
Walnut Creek, CA 94596
Phone: 925-939-4987
Mobile: 925-708-5538
E-mail: eybruce@pacbell.net

FIELD LOCATIONS: _____
_____
_____

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 mix/load a pesticide in water soluble packets. This will be done by measuring the pesticide in the samples we collect from you. About 25 people will take part in this study. This study will be used to estimate exposure and risks to workers that handle water soluble packets.

It is entirely up to you whether or not you take part in this study. If you do take part in this study, you must understand and sign this consent form, a Product Risk Statement, and if in California, the California Experimental Research Subject's Bill of Rights. The Product Risk Statement explains the risks from the pesticide. If we use words or give information you do not clearly understand, please ask someone on the research staff to explain. You may take an unsigned copy of this consent form to think about or discuss with family, friends, or researchers before making your decision. If you volunteer to be in this study, you will get a signed and dated copy of everything you sign.

APPROVED BY
Independent IRB
Signature 12/16/08 Date

Initials: _____
Date: _____

ELIGIBILITY
To be eligible to participate in this study you must:

1. Have mixed and loaded pesticide products packaged in water soluble packets, and used the particular mixing/loading equipment you will use in this study, within the last year.

2. Handle pesticides as part of your job.

3. Confirm that you have been trained in pesticide safety or that you are not required to take this training.

4. Provide proof you are at least 18 years old with a government-issued photo ID.

5. Confirm you do not work for a pesticide company or a contractor of AHETF.

6. Consider your general health to be good. Tell us if you have any medical conditions that affect your ability to take part in the study.

7. Not be pregnant or nursing. If you are female, you must take an over-the-counter urine pregnancy test before the study. More than one pregnancy test may be required. 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 shown to a female researcher or you cannot take part in the study.

8. Usually wear the personal protective equipment (PPE) listed on the Product Risk Statement and follow label directions.

9. 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.

10. Understand English or Spanish.

11. Understand and sign this consent form, a Product Risk Statement, and if in California the California Experimental Research Subject's Bill of Rights.

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STUDY DURATION
Your part in this study will take about 4-8 hours of your normal workday. This study may be conducted over 1 or more days.

PROCEDURES BEFORE THE START OF THE STUDY
Before you take part in the study, you will:

1. Give your name and age, as shown on a government-issued photo-ID.

2. Indicate if you have been trained in pesticide safety or if you are not required to take this training.

3. Tell researchers how many years you have been handling pesticide products packaged in water soluble packets. Tell researchers what mixing/loading equipment you normally use and when was the last time you used it.

4. Allow researchers to record your gender, age, ethnicity and preferred language. Allow researchers to measure and record your height and weight.

5. Let the researcher take notes about what is said during the consent meeting.

6. Agree to allow researchers to watch all your work activities and take notes on what you do.

7. Allow photographs and video recordings to be taken to document this research. You will not be photographed or video recorded while dressing or undressing. Your face will not be photographed. AHETF will own all rights to the photos and videos but will use them only to document this research. **If you do not want to be photographed or recorded you should not take part in this study.**

PROCEDURES ON THE DAY OF THE STUDY
On the day you are in the study you will report to work about 1 hour early to help us get you ready. You will be asked to take a bath or shower the night before or early that morning. You will be asked to wear a freshly washed long-sleeve shirt and long pants, plus shoes and socks. Then you will:

1. Go to a private changing area. Take off your shirt and pants and put on new long underwear over your own undergarments and then put your shirt and pants back on. Only a researcher of the same sex will be in the changing area to help. The long underwear will be provided by AHETF and will be collected at the end of the day.

2. Wear all of the PPE required by the label of the product to be used.

APPROVED BY
Independent IRB
Signature 12/16/08 Date

Initials: _____
Date: _____

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3. Wear a tube attached to your shirt collar and connected to a portable air-sampling pump worn on a belt around your waist. The pump may be uncomfortable or annoying.

4. Have your hands washed by a researcher before the study begins. A mild detergent and water mixture will be used.

5. Have your face and neck wiped with gauze pads moistened with a mild detergent and water mixture before the study begins.

6. Work about 4 to 8 hours mixing and loading a commercial pesticide product packaged in water soluble packets according to the product label. You will prepare at least 3 loads using your usual practices. Researchers will watch you work and take notes on what you do. Researchers may take photographs or video recordings to document the research. No photographs or video recordings will be made while you are dressing or undressing.

7. Have your hands washed with a mild detergent and water as needed for the study. Hand washes will occur before you eat anything, at any time you would normally wash your hands (such as before using the toilet), and at the end of the day. The water from these hand washes will be saved for analysis.

8. Have your face and neck wiped with gauze pads moistened with a mild detergent and water mixture before you eat anything, any time you would normally wash your face, and at the end of the day. The gauze pads will be saved for analysis.

9. At the end of the study day you will return to the private changing area. Only a researcher of the same sex will be in the changing area to help you take off your shirt and pants and the long underwear. The long underwear will be collected by the researcher. You will put your own shirt and pants back on and return to your normal work schedule.

PRODUCT HANDLED

You will be asked to mix/load a pesticide product that is registered by the US Environmental Protection Agency (EPA). This product is packaged in water soluble packets and the active ingredient will be acephate or carbaryl. The farm or operation management will choose the product that you will use. However, you will know which product you will handle before you sign this consent form.

In addition to the pesticide you will mix/load, farm or operation management may want other registered or approved products added to the mixing or spray tank. You will be told before you start which materials will be in the tank mix.

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Independent IRB
Signature 12/16/08
Date

Initials: _____
Date: _____

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RISKS AND DISCOMFORTS

You will be asked to sign a Product Risk Statement. This is a document that contains important information about the product you will use in this study. It includes the name of the product you will mix and load, how much of that product you might mix and load during the study, the risks of handling that product, and what personal protective equipment you must wear.

In addition, this document tells you of possible side-effects from using this product and how you can tell if you are overexposed. If you feel any of the side-effects or think you were overexposed during or after the workday, or do not feel well for any reason, contact a researcher right away.

The label and Material Safety Data Sheet (MSDS) for this product will be on hand for you to look over and talk about at any time you want.

Because you will wear long underwear underneath your normal work clothes, you have a risk of getting 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 right away. If you don't feel well for any reason, notify a researcher right away. A researcher will be watching you for these signs. AHETF will stop your work if the weather gets too hot.

As a safety measure, AHETF will have a medical professional on site during the study. This may be a paramedic, physician's assistant, nurse, or emergency medical technician. This professional will also watch you for signs of illness. They will provide medical attention as needed.

You may have other risks or discomforts, including:

- Eye or skin irritation from the detergent and water mixture used to wash 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

There may be other risks that are not known at this time. You will be told in a timely manner both verbally and in writing of any new information. This new information might cause you to change your mind about being in the study.

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INJURY TO PARTICIPANTS

If you are injured or get sick because of your participation in this study, medical treatment will be available at your workplace and at a nearby health care facility. If necessary, AHETF will arrange to have you taken to receive medical attention. You may refuse medical treatment *unless* you get sick from too much exposure to pesticides or from getting too hot, or if we believe you are too sick to make a rational decision about getting medical treatment.

AHETF will cover the cost of reasonable and appropriate medical attention for a study-related injury or illness that is not covered by your own insurance or insurance provided through your employer. This includes deductible costs and any out-of-pocket expenses, including co-payments, you might have. The Study Director, in consultation with the on-site medical professional, will decide if you have an illness or injury that is due to your participation in this study.

The medical treatment records will not become part of the research records. AHETF will make note of the event. The event will be reported in the study report. For further information about this, you may call the AHETF Manager (David Johnson) toll free at (866) 925-1421 (24-hour service in English or Spanish).

You will not give up any of your legal rights by signing this form.

CONFIDENTIALITY

Your name will only appear on the consent form, the Product Risk Statement, an optional form for you to request your personal study results, and if in California the California Experimental Research Subject's Bill of Rights. In all other parts of the study you will be identified by a code. Records with your name will be stored in a secure place with limited access.

Information about you taking part 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 in the study report.

We cannot promise you total confidentiality. There may be a need to give information to some organizations or to parties in legal actions, as required by law. Records which identify you may be looked at or copied by the AHETF and any consultants working with the AHETF, 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 take part are protected.

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Independent IRB
12/16/08
Signature Date

Initials: _____
Date: _____

US EPA ARCHIVE DOCUMENT

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 taking part in this study.

BENEFITS
You will not directly benefit from taking part in the study. The farm owner may benefit since AHETF will reimburse the owner for the product used in the study. Information from this study will improve our understanding of the exposure to workers who mix/load pesticides packaged in water soluble packets.

PAYMENT FOR PARTICIPATION
You will be paid $20 if you meet privately with a researcher to review this informed consent form. 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 each day you participate in the study. You will be paid $80 when you finish each sampling day and let us 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 be paid 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 will take part by picking randomly, for example by drawing names from a hat or flipping a coin. You may or may not be selected to take part. 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 take part in this study or not. Your decision to be in this study is voluntary. This decision is entirely up to you. If you decide to take part, you may change your mind and drop out of the study at any time and for any reason. A decision not to take part, or to withdraw from the study after it starts, will not affect your job or pay or include any penalty or any loss of benefits you are owed.

If you withdraw, the long underwear and air sampling pump will be removed. The hand and face/neck samples may be collected if you agree.

Your part in this study may be stopped at any time by the researchers or the AHETF. The long underwear and air sampling pump will be removed. The hand and face/neck samples may be collected if you agree.

APPROVED BY
Independent IRB
Signature 12/16/08 Date

Initials: _____
Date: _____

US EPA ARCHIVE DOCUMENT

If you withdraw or are removed from the study, you can go back to your usual work activities. If the study does not last an entire workday, you can go back to your usual work activities.

ALTERNATIVES
No one can force you to take part in this study. Taking part is totally voluntary. If you choose not to take part in this study you will perform your ordinary activities on the day of the study. Your alternative is to not take part.

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:

Eric D. Bruce (Study Director) or
David Johnson, Ph.D. (AHETF contact).
Toll free (866) 925-1421 (24-hour service in English or Spanish)

If you have any questions regarding your rights as a research volunteer, please contact Kim Lerner, Chair of the Independent Investigational Review Board, Inc. toll free at 1-(877) 888-iirb (4472) during their regular working hours. Based on your time zone, you can call during the following hours:

Eastern Time:	9:00 a.m. – 5:00 p.m.
Central Time:	8:00 a.m. – 4:00 p.m.
Mountain Time:	7:00 a.m. – 3:00 p.m.
Pacific Time:	6:00 a.m. – 2:00 p.m.

You can also contact the Independent Investigational Review Board, Inc. if you would like to report problems in a research study, express concerns, ask questions, request information, or provide input. The Independent Investigational Review Board is a committee established to protect the rights of volunteers in research studies. For more information about your rights and role as a research participant you can visit the Research Participant section of the IIRB, Inc. website at www.iirb.com.

Do not sign this consent form unless you were able to ask questions and you are happy with the answers you got.

APPROVED BY
Independent IRB
12/16/08
Signature Date

Initials: _____
Date: _____

US EPA ARCHIVE DOCUMENT

CONSENT

I have read the information in this consent form, the Product Risk Statement, and if in California the California Experimental Research Subject's Bill of Rights (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 AHETF, 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/Time Subject's Name (print)

_____
Subject's Signature

_____
Subject's Unique Worker Code

I conducted the private consent meeting with the worker named above. I confirm that the worker's consent was given voluntarily after being fully informed and having apparent understanding about the study. In addition, this worker has reviewed and signed the Product Risk Statement and if in California the California Experimental Research Subject's Bill of Rights which I will store along with this signed consent form in a secure location:

_____ _____
Date/Time 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
12/16/08
Signature Date

Initials: _____
Date: _____

US EPA ARCHIVE DOCUMENT

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

If this consent form is read to the worker because the worker is unable to read the form, a witness who is not associated with the research must be present to witness the consent process and sign the following statement:

I confirm that the information in the consent form and any other written information were accurately read to this worker.

_____ _____
Date/Time Witness' Name (print)

_____
Witness' Signature

_____
Title and Affiliation of 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: 12/16/2008

APPROVED BY
Independent IRB
12/16/08
Signature Date

Initials: _____
Date: _____

US EPA ARCHIVE DOCUMENT

English Language Product Risk Statements

US EPA ARCHIVE DOCUMENT

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE120) Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Water Soluble Packets in the United States

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:
Eric D. Bruce
21 Oak Knoll Court
Walnut Creek, CA 94596
Phone: 925-708-5538
E-mail: eybruce@pacbell.net

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: Acephate 75 WSP® (EPA Registration No. 70506-1)

Active Ingredient (AI): Acephate (insecticide, CAS No. 30560-19-1)

Formulation and Packaging: 75% AI powder in a 1 lb. water soluble packet

APPROVED BY
Independent IRB
Signature 12/16/08 Date

Initials: _____
Date: _____

US EPA ARCHIVE DOCUMENT

You may handle up to: 960 water soluble packets

Required Personal Protective Equipment (PPE) for Handling: Mixer/loaders must wear long-sleeved shirt and long pants, and shoes plus socks. You must also wear chemical-resistant gloves. In case of emergency (e.g., broken package) you must also have immediately available coveralls, chemical-resistant footwear, and an approved respirator.

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 acephate 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 minimal 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 identifier: Rev. 2/7/08 70506-1(030308-2774) (last page)
MSDS date: 12-Apr-2007 (UPI)

_____ _____
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: 12/16/2008

APPROVED BY
Independent IRB
12/16/08
Signature Date

Initials: _____
Date: _____

US EPA ARCHIVE DOCUMENT

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE120) Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Water Soluble Packets in the United States

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:
Eric D. Bruce
21 Oak Knoll Court
Walnut Creek, CA 94596
Phone: 925-708-5538
E-mail: eybruce@pacbell.net

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: Acephate 90 WSP® (EPA Registration No. 70506-2)

Active Ingredient (AI): Acephate (insecticide, CAS No. 30560-19-1)

Formulation and Packaging: 90% AI powder in a 2.5 pound water soluble packet

APPROVED BY
Independent IRB
Signature 12/16/08 Date

Initials: _____
Date: _____

US EPA ARCHIVE DOCUMENT

You may handle up to: 320 water soluble packets

Required Personal Protective Equipment (PPE) for Handling: Mixer/loaders must wear long-sleeved shirt and long pants, and shoes plus socks. You must also wear chemical-resistant gloves. In case of emergency (e.g., broken package) you must also have immediately available coveralls, chemical-resistant footwear, and an approved respirator.

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 acephate 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 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 identifier: Rev. 2/07/08 70506-2(031808-2967) (last page)
MSDS date: 12-Apr-2007 (UPI)

_____ _____
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: 12/16/2008

APPROVED BY
Independent IRB
12/16/08
Signature Date

Initials: _____
Date: _____

US EPA ARCHIVE DOCUMENT

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE120) Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Water Soluble Packets in the United States

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:
Eric D. Bruce
21 Oak Knoll Court
Walnut Creek, CA 94596
Phone: 925-708-5538
E-mail: eybruce@pacbell.net

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® 80 Solupak (EPA Registration No. 264-316)

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

APPROVED BY
Independent IRB
Signature 12/16/08 Date

Initials: _____
Date: _____

US EPA ARCHIVE DOCUMENT

You may handle up to: 2,000 water soluble packs

Required Personal Protective Equipment (PPE) for Handling: Mixer/loaders must wear long-sleeved shirt and long pants, and shoes plus socks. You must also wear chemical-resistant gloves.

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 or moderate 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: 7/19/06
MSDS date: 8/3/06 (number 102000004247)

_____ _____
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: 12/16/2008

APPROVED BY
Independent IRB
Signature 12/16/08 Date

Initials: _____
Date: _____

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English Language Recruiting Flyer

US EPA ARCHIVE DOCUMENT

Study Number: AHE120

Research Study Volunteers

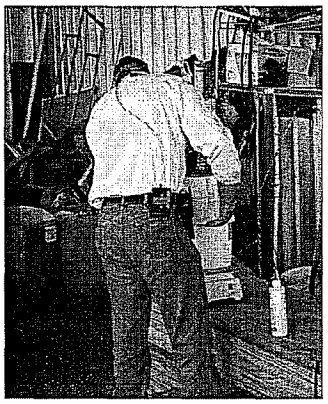
The Agricultural Handlers Exposure Task Force (AHETF) is a group of pesticide companies doing research to measure how much chemical gets on workers when they handle pesticides. The AHETF is looking for experienced workers to perform their usual work of mixing and loading pesticides packaged in water soluble bags, and to let the AHETF collect exposure data.

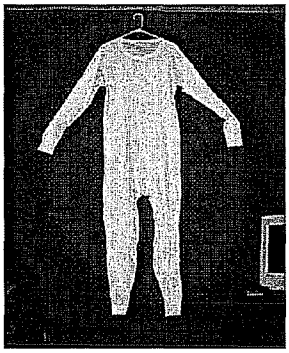
To volunteer you must:

- Be at least 18 years old with a government-issued photo ID
- Understand English or Spanish
- Be in good health
- Not work for a pesticide manufacturer or a contractor of AHETF
- Not be pregnant or nursing
- Be experienced and trained in handling pesticides

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 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 risk to agricultural workers

If you are interested, please contact the Study Director:

Eric Bruce
(866) 925-1421
Toll Free

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

APPROVED
12/16/08
Independent Investigational Review Board

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English Language Research Participant Bill of Rights

US EPA ARCHIVE DOCUMENT

Número del Estudio: AHE120 Página 1 de 1

RESEARCH PARTICIPANT BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told what the study is trying to find out.
2. To be told what will happen to me and whether any of the procedures, pesticides or devices is different from what would be used in standard practice.
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes.
4. To be told if I can expect any benefit from participating and, if so, what the benefit might be.
5. To be told the other choices I have and how they may be better or worse than being in the study.
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study.
7. To be told what sort of medical treatment is available if any complications arise.
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study.
9. To receive a copy of the signed and dated consent form.
10. To be free of pressure when considering whether I wish to agree to be in the study.

_____ _____

Signature of Subject Date

_____ _____

Signature of Witness Date

APPROVED BY
Independent IRB

Signature

12/16/08
Date

US EPA ARCHIVE DOCUMENT

Spanish Language Consent Form

US EPA ARCHIVE DOCUMENT

FORMULARIO DE INFORMACIÓN SOBRE LA INVESTIGACIÓN Y CONSENTIMIENTO INFORMADO

TÍTULO: (PROTOCOLO AHE120) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante la Mezcla/Carga de Productos Pesticidas en Paquetes Solubles en Agua, en los Estados Unidos

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: Eric D. Bruce
21 Oak Knoll Ct.
Walnut Creek, CA 94596
Teléfono: 925-939-4987
Celular: 925-708-5538
Correo electrónico [E-mail]: eybruce@pacbell.net

UBICACIONES DE CAMPO: _____
_____
_____

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 mezcla/carga un pesticida en paquetes solubles en agua. Se hará esto mediante la medición del pesticida en las muestras que nosotros recojamos de usted. Formarán parte de este estudio unas 25 personas. Se usará este estudio para estimar la exposición y los riesgos a los trabajadores que manipulan paquetes solubles en agua.

Queda librado a usted el hecho de formar parte de estudio, o no. Si usted no forma parte de este estudio, debe entender y firmar este formulario de consentimiento, una Declaración de Riesgo del Producto y si está en California, la Carta de los Derechos del Sujeto Experimental, de California. La Declaración de Riesgo del Producto explica los riesgos provenientes del pesticida. Si usamos palabras o damos información que usted no entienda con claridad, por favor pídale a alguien del personal que le explique. Usted puede llevarse una copia, sin firmar, de este formulario de consentimiento, para pensarlo o para hablar sobre esto con sus familiares, amigos, o investigadores, antes de tomar su decisión. Si usted se ofrece como voluntario para estar en este estudio, le darán una copia firmada y fechada de todo lo que usted haya firmado.

APROBADO POR
Independent IRB
Firma
16/diciembre/08
Fecha

US EPA ARCHIVE DOCUMENT

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. Manipular pesticidas como parte de su trabajo.

3. Confirmar que a usted lo han entrenado en seguridad de pesticidas o que a usted no se le requiere que tome este entrenamiento.

4. Proporcionar prueba de que tiene por lo menos 18 años de edad con una identificación con foto, emitida por el gobierno.

5. Confirmar que no trabaja para una compañía de pesticidas ni para un contratista de AHETF.

6. Considera que su salud general es buena. Díganos si tiene alguna afección [dolencia] médica que afecte a su capacidad para participar en el estudio.

7. No estar embarazada ni lactando [dándole el pecho a un niño]. Si usted es mujer, debe hacerse una prueba de embarazo por medio del análisis de orina, de las de venta libre, antes del estudio. Pudieran requerirle más de una prueba de embarazo. 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 debe mostrárselos a una investigadora o usted no puede participar en el estudio.

8. Usted usa usualmente, equipo de protección personal (PPE) que se menciona en la Declaración de Riesgo del Producto y usted sigue las instrucciones de la etiqueta.

9. 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.

10. Entender inglés ó castellano [español].

11. Entender y firmar este formulario de consentimiento, una Declaración de Riesgo del Producto y si está en California, la Carta de los Derechos del Sujeto Experimental, de California.

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LA DURACIÓN DEL ESTUDIO
Su parte en este estudio llevará alrededor de 4-8 horas de su día normal de trabajo. Este estudio pudiera llevarse a cabo durante 1 ó más días.

LOS PROCEDIMIENTOS ANTERIORES AL COMIENZO DEL ESTUDIO
Antes de que participe en este estudio, usted hará lo siguiente:

1. Proporcione su nombre y edad, según aparezca en una identificación con foto que haya sido emitida por el gobierno.

2. Indique si ha sido entrenado en seguridad de pesticidas, o si no se le requiere que haga este entrenamiento.

3. Dígales a los investigadores cuántos años ha estado usted manipulando productos de pesticidas empaquetados en paquetes solubles en agua. Dígales a los investigadores qué equipo de mezcla/carga usa usted normalmente y cuándo fue la última vez que lo usó.

4. Permítales a los investigadores que registren su género, edad, etnia e idioma preferido. Permítales a los investigadores que midan y que registren su estatura [altura] y peso.

5. Permitirles al investigador tomar notas acerca de lo que se haya dicho durante la entrevista del consentimiento.

6. Ponerse de acuerdo en permitirles a los investigadores que observen todas sus actividades laborales [de trabajo] y que tomen notas acerca de lo que usted hace.

7. Permitir que le saquen fotos y que lo graben en vídeo, con el propósito de documentar esta investigación científica. No lo fotografiarán ni lo grabarán en vídeo mientras que esté desvistiéndose y vistiéndose. No le sacarán fotos de su cara. AHETF será la propietaria exclusiva de las fotos y vídeos, pero los usará solamente para documentar esta investigación científica. **Si usted no desea que lo fotografíen o que lo graben, usted no debería participar en este estudio**.

LOS PROCEDIMIENTOS EN EL DÍA DEL ESTUDIO
El día en el que usted esté en el estudio, se presentará a trabajar alrededor de 1 hora más temprano para ayudarnos a prepararlo a usted. Le pedirán que se dé un baño o una ducha la noche anterior o temprano esa mañana. Le pedirán que use una camisa de manga larga recién lavada y pantalones largos, más zapatos y calcetines. Luego usted hará lo siguiente:

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1. Irá a un área privada para cambiarse. Se quitará su camisa y pantalones y se pondrá nueva ropa interior larga por encima de su propia ropa interior y luego se volverá a poner su camisa y pantalones. Solamente un investigador del mismo sexo estará en el área de cambiarse, para ayudar. La ropa interior larga se la proporcionará AHETF y la recogerán al final del día del estudio.

2. Use todo el PPE requerido por la etiqueta del producto a ser usado.

3. 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 pudiera ser incómoda y molesta.

4. Un investigador le lavará sus manos antes de que empiece el estudio. Se usará una mezcla de detergente suave y agua.

5. Limpiarse la cara y cuello con almohadillas de gasa humedecidas con una mezcla de detergente suave y agua, antes de que empiece el estudio.

6. Trabajará alrededor de 4 a 8 horas mezclando y cargando un producto con pesticida comercial empaquetado en paquetes solubles en agua, de acuerdo con la etiqueta del producto. Usted preparará por lo menos 3 cargas usando sus prácticas usuales. Los investigadores lo observarán trabajar y tomarán notas de lo que haga usted. Los investigadores pueden sacar fotografías o hacer grabaciones en vídeo, para documentar la investigación científica. No lo fotografiarán ni lo grabarán en vídeo, mientras que se esté vistiendo o desvistiendo.

7. Se lavará las manos con un detergente suave y agua, según lo necesite, para el estudio. Las lavadas de manos ocurrirán antes de que usted coma algo, cada vez en la que usted normalmente se lavaría las manos (tal como antes de usar el inodoro [*toilet*]) y al final del día. Guardarán el agua de estos lavados de las manos, para analizarla.

8. Limpiarse la cara y cuello con almohadillas de gasa humedecidas con una mezcla de detergente suave y agua, antes de que usted coma nada, en cualquier momento en el que usted normalmente se lavaría la cara y, al final del día. Las almohadillas de gasa se guardarán para analizarlas.

9. Al final del día del estudio usted regresará al área privada. Solamente un investigador del mismo sexo estará en el área de cambiarse, para ayudarlo a usted a quitarse su camisa y pantalones y la ropa interior larga. La ropa interior larga será recogida por el investigador. Usted volverá a ponerse su propia camisa y pantalones y regresará a su horario normal de trabajo.

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PRODUCTO MANIPULADO

Le pedirán que mezcle/cargue un producto pesticida que está registrado por la Agencia Estadounidense de Protección Medioambiental (EPA). Este producto se encuentra empaquetado en paquetes solubles en agua y el ingrediente activo será acefato [*acephate* en inglés] o carbarilo [*carbaryl* en inglés]. La granja o la administración de operaciones, elegirá el producto que usará usted. No obstante, usted sabrá cuál producto va a manipular, antes de que usted firme este formulario de consentimiento.

Además del pesticida que usted mezclará/cargará, la granja o la administración de operaciones pudiera desear otros productos registrados o aprobados que se agreguen a la mezcla o al tanque de spray. Antes de que usted empiece, le dirán cuáles materiales habrá en la mezcla del tanque.

RIESGOS Y MOLESTIAS

Le pedirán que firme la Declaración de Riesgo del Producto. Este es un documento que contiene información importante acerca del producto que usted usará en este estudio. Ella incluye el nombre del producto que usted va a mezclar y cargar, cuánto de ese producto usted podría mezclar y cargar durante el estudio, los riesgos del manipuleo de ese producto y qué equipo de protección personal debe usar usted.

Además, este documento le dice a usted acerca de posibles efectos secundarios provenientes del uso de este producto y cómo usted puede darse cuenta si usted se ha sobre-expuesto. Si usted sintiese cualquiera de los efectos secundarios o si piensa que ha estado sobre-expuesto durante ó después del día de trabajo, ó si no se sintiese bien por cualquier razón, póngase inmediatamente en contacto con un investigador.

La etiqueta y la Hoja de Datos de Seguridad del Material (MSDS) para este producto, estarán a mano para que usted las mire y hable acerca de ellas en cualquier momento que usted lo desee.

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 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 va a estar observándolo a usted por estas señales. AHETF detendrá su trabajo si el tiempo se pusiese muy cálido.

Como medida de seguridad, AHETF tendrá un profesional de la salud en el sitio durante el estudio. Éste pudiera ser un paramédico, asistente de médico, enfermera, ó un técnico en emergencias médicas. Este profesional también lo observará a usted

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para detectar señales de enfermedad. Ellos le proporcionarán atención médica, según la necesite.

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 lavarse 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. Esta información nueva podría causarle a usted cambiar su manera de pensar acerca de estar en el estudio.

LESIÓN A LOS PARTICIPANTES

Si usted se lesionase o se enfermase debido a su participación en este 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 lleven 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 para una lesión o enfermedad relacionada con el estudio, que no esté cubierta por su propio seguro o por el seguro que le proporcione su empleador. Esto incluye a los costos deducibles y a cualquier gasto que haya hecho de su propio bolsillo, incluyendo co-pagos, que usted podría tener. El Director del Estudio, en consulta con el profesional médico que se encuentre en el sitio, decidirá si usted tiene una enfermedad o lesión que se deba a su participación en este estudio.

Los expedientes del tratamiento médico no se convertirán en parte de los expedientes de la investigación científica. AHETF tomará nota del evento. Este evento se reportará en el informe del estudio. Para más información acerca de esto, usted puede llamar al Administrador de AHETF (David Jonson) al teléfono gratuito (866) 925-1421 (servicio de 24 horas en inglés o en español).

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Usted no renunciará a ninguno de sus derechos legales por firmar este formulario.

CONFIDENCIALIDAD

Su nombre aparecerá solamente en el formulario de consentimiento, en la Declaración de Riesgo del Producto, en un formulario optativo para que usted solicite sus resultados personales del estudio y si está en California, la Carta de los Derechos del Sujeto Experimental, de California. En todas las otras partes del estudio, usted será identificado por un código. Los expedientes que contengan su nombre se almacenarán en un lugar seguro con acceso limitado.

La información acerca de su participación en este estudio no se la darán 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 en el informe del estudio.

Nosotros no podemos prometerle a usted una confidencialidad total. Pudiera haber una necesidad de darles información a algunas organizaciones o a partes [a terceros] en acciones legales, según lo requiera la ley. Los expedientes que lo identifiquen a usted, pueden ser mirados o copiados por AHETF y por cualquier consultor(es) que esté trabajando con AHETF, 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 su participación en el estudio. El propietario de la granja pudiera beneficiarse, dado que AHETF lo reembolsará al propietario por el producto usado en el estudio. La información proveniente de este estudio mejorará nuestro entendimiento de la exposición de los trabajadores quienes mezclan/cargan pesticidas empaquetados en paquetes solubles en agua.

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EL PAGO POR LA PARTICIPACIÓN

Le pagarán $20 si usted se reúne en privado con un investigador para repasar este formulario de 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 cada día que usted participe en el estudio. Le pagarán $80 cuando usted termine cada 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, aún le pagarán $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 al azar, por ejemplo sacando nombre de un sombrero o arrojando una moneda al aire. 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, o no. Su decisión de estar en este estudio es voluntaria. Esta decisión queda librada enteramente a usted. Si usted decide participar, usted pudiera 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. Las muestras de las manos y cara/cuello pudieran recogerse, si usted se pone de acuerdo.

Su parte en este estudio pudiera ser detenida en cualquier momento por los investigadores o por AHETF. La ropa interior larga y la bomba de muestreo de aire se los removerán. Las muestras de las manos y cara/cuello pudieran recogerse, si usted se pone de acuerdo.

Si usted se retirase del estudio, o si lo quitasen del estudio, usted puede volver a sus actividades laborales [de trabajo] usuales. Si el estudio no durase un día entero de trabajo, usted puede volver a sus actividades laborales usuales.

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ALTERNATIVAS

Nadie puede forzarlo a usted para que participe en este estudio. La participación es totalmente voluntaria. Si usted opta por no participar en este estudio, usted desempeñará sus actividades normales y corrientes en el día del estudio. Su alternativa es la de no participar.

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:

Eric D. Bruce (Director del Estudio) ó
David Johnson, PhD (contacto de AHETF)
Teléfono gratuito (866) 925-1421 (servicio de 24 horas en inglés o español)

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 1-(877) 888-iirb (4472) durante horas regulares de trabajo de ellos. Basándose en su zona horaria, usted puede llamar durante las siguientes horas:

Horario del Este: 9:00 a.m. – 5:00 p.m.
Horario Central: 8:00 a.m. – 4:00 p.m.
Horario de la Montaña: 7:00 a.m. – 3:00 p.m.
Horario del Pacífico: 6:00 a.m. – 2:00 p.m.

Usted también puede contactarse con el Independent Investigational Review Board, Inc. si quisiera reportar problemas en un estudio de investigación científica, expresar inquietudes, hacer preguntas, solicitar información, o proporcionar información. El Independent Investigational Review Board es un comité que se ha establecido con el propósito de proteger los derechos de los participantes en estudios de investigación científica. Para más información acerca de sus derechos y papel [*rol*] en calidad de participante de una investigación científica, usted puede visitar la sección de Participante de una Investigación Científica [*Research Participant*] del IIRB, Inc., en el Sitio Web en www.iirb.com.

No firme este formulario al menos que usted haya podido hacer preguntas y que esté conforme con las respuestas que haya recibido.

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CONSENTIMIENTO

Yo he leído la información existente en este formulario de consentimiento, en la Declaración de Riesgo del Producto y si está en California, la Carta de los Derechos del Sujeto Experimental, de California (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, a AHETF, 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/Hora

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. Yo confirmo que el consentimiento del trabajador fue dado voluntariamente después de haber sido informado plenamente y después de haber entendido, aparentemente, el estudio. Además, este trabajador ha revisado y firmado la Declaración de Riesgo del Producto y si está en California, la Carta de los Derechos del Sujeto Experimental, de California, la cual yo almaceno junto con este formulario de consentimiento firmado, en un lugar seguro:

Fecha/Hora

Nombre de la Persona que está Dirigiendo la Discusión del Consentimiento Informado (en letra de molde; de imprenta)

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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.

---------- 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 quien no esté asociado con la investigación, para atestiguar el proceso del consentimiento y firmar la siguiente declaración:

Yo confirmo que la información existente en este formulario de consentimiento y cualquier otra información escrita, le fue leída con precisión a este trabajador.

Fecha/Hora

Nombre del Testigo (en letra de molde; de imprenta)

Firma del Testigo

Título y Afiliación del Testigo

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: 16/diciembre/08

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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

December 19, 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:

Informed Consent Form
(PROTOCOL AHE120) Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Pesticide Products in Water Soluble Packets in the United States
(Protocol: AHE120) (Version: 12/16/08) (Study Director: Eric D. Bruce)
(Agricultural Handlers Exposure Task Force [AHETF], c/o David R. Johnson, PhD)

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:

Formulario de Consentimiento Informado
(PROTOCOLO AHE120) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante la Mezcla/Carga de Productos Pesticidas en Paquetes Solubles en Agua, en los Estados Unidos
(Protocolo: AHE120) (Versión: 16/diciembre/08) (Director del Estudio: Eric D. Bruce)
(Agricultural Handlers Exposure Task Force [AHETF], a cargo de David R. Johnson, PhD)

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*

ata A member of the American Translators Association.
Associate Membership since 1997.

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Spanish Language Research Participant Bill of Rights

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CARTA DE LOS DERECHOS DEL PARTICIPANTE EN UNA INVESTIGACIÓN CIENTÍFICA

Los derechos mencionados a continuación, constituyen los derechos de cada persona a quien se le pida que tome parte de un estudio de investigación científica.
En calidad de sujeto experimental, yo tengo los siguientes derechos:

1. Que se me informe qué es lo que el estudio está tratando de averiguar.
2. Que se me informe qué me sucederá y si algunos de los procedimientos, pesticidas ó dispositivos, son diferentes a los que se usan en la práctica normal.
3. Que se me informe acerca de los riesgos, efectos secundarios [colaterales], o molestias, frecuentes y/ó importantes, de las cosas que me sucederán para los propósitos de la investigación científica.
4. Que se me informe si puedo esperar algún beneficio por participar y, si es así, cuál sería el beneficio.
5. Que se me informe acerca de otras opciones que tengo y acerca de cómo ellas pudieran ser mejores o peores que estar en el estudio.
6. Que se me permita hacer cualquier pregunta(s) relacionada con el estudio, tanto como antes de acceder a participar, así como durante el transcurso del estudio.
7. Que se me informe qué tipo de tratamiento médico se encuentra disponible, si surgiese cualquier complicación(es).
8. Rehusarme a participar en absoluto ó cambiar mi parecer acerca de la participación, después que el estudio haya comenzado. Esta decisión no afectará mi derecho de recibir la atención que yo recibiría, si no estuviese en el estudio.
9. Recibir una copia del formulario de consentimiento firmado y fechado.
10. Estar libre de presión cuando esté tomando en consideración si deseo acceder estar en el estudio.

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma del Testigo Fecha

APROBADO POR
Independent IRB

Firma 10/diciembre/08
Fecha

US EPA ARCHIVE DOCUMENT

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

December 19, 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:

RESEARCH PARTICIPANT'S BILL OF RIGHTS
(Protocol: AHE120) (Approved: 12/16/08) (Study Director: Eric D. Bruce)
(Agricultural Handlers Exposure Task Force [AHETF], c/o David R. Johnson, PhD)

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:

CARTA DE LOS DERECHOS DEL PARTICIPANTE DE LA INVESTIGACIÓN CIENTÍFICA
(Protocolo: AHE120) (Aprobada: 16/diciembre/08) (Director del Estudio: Eric D. Bruce)
(Agricultural Handlers Exposure Task Force [AHETF], a cargo de David R. Johnson, PhD)

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*

ata A member of the American Translators Association. Associate Membership since 1997.

US EPA ARCHIVE DOCUMENT

Spanish Language Product Risk Statements

US EPA ARCHIVE DOCUMENT

Declaración de Riesgo del Producto
Riesgo de Toxicidad del Producto Pesticida Manipulado
(Debe adjuntarse al Formulario de Consentimiento Informado)

TÍTULO: (PROTOCOLO AHE120) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante la Mezcla/Carga de Productos Pesticidas en Paquetes Solubles en Agua, en los Estados Unidos

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: Eric D. Bruce
21 Oak Knoll Ct.
Walnut Creek, CA 94596
Teléfono: 925-939-4987
Celular: 925-708-5538
Correo electrónico [E-mail]: eybruce@pacbell.net

UBICACIONES DE CAMPO: _____
_____
_____

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: Sevin® 80 Solupak (Registro de EPA № 264-316)

Ingrediente Activo (AI): Carbarilo (insecticida, CAS № 63-25-2)

Formulación y Embalaje: 80% AI polvo seco en un envase de 1,25 libra soluble en agua.

Usted puede manipular hasta: 2.000 [dos mil] envases solubles en agua.

APROBADO POR
Independent IRB
Firma
16/diciembre/08
Fecha

Iniciales: _____
Fecha: _____

US EPA ARCHIVE DOCUMENT

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los mezcladores/cargadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Usted también debe usar guantes resistentes a las 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: Pudieran 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 está clasificado como de baja o moderada 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: 19-julio-06
Fecha de la MSDS: 3-agosto-06 (número 102000004247)

_____ _____
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: 16/diciembre/08

Versión: 11/diciembre/08
Protocolo: AHE120
Sevin® 80 Solupak
Declaración de Riesgo del Producto

APROBADO POR
Independent IRB
Firma
16/diciembre/08
Fecha

Iniciales: _____
Fecha: _____

US EPA ARCHIVE DOCUMENT

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Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

December 19, 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:

Product Risk Statement: Sevin® 80 Solupak
(PROTOCOL AHE120) Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Pesticide Products in Water Soluble Packets in the United States
(Protocol: AHE120) (Version: 12/11/08) (Study Director: Eric D. Bruce)
(Agricultural Handlers Exposure Task Force [AHETF], c/o David R. Johnson, PhD)

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:

Declaración de Riesgo del Producto: Sevin® 80 Solupak
(PROTOCOLO AHE120) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante la Mezcla/Carga de Productos Pesticidas en Paquetes Solubles en Agua, en los Estados Unidos
(Protocolo: AHE120) (Versión: 11/diciembre/08) (Director del Estudio: Eric D. Bruce)
(Agricultural Handlers Exposure Task Force [AHETF], a cargo de David R. Johnson, PhD)

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*

ata A member of the American Translators Association.
Associate Membership since 1997.

US EPA ARCHIVE DOCUMENT

Declaración de Riesgo del Producto
Riesgo de Toxicidad del Producto Pesticida Manipulado
(Debe adjuntarse al Formulario de Consentimiento Informado)

TÍTULO: (PROTOCOLO AHE120) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante la Mezcla/Carga de Productos Pesticidas en Paquetes Solubles en Agua, en los Estados Unidos

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: Eric D. Bruce
21 Oak Knoll Ct.
Walnut Creek, CA 94596
Teléfono: 925-939-4987
Celular: 925-708-5538
Correo electrónico [E-mail]: eybruce@pacbell.net

UBICACIONES DE CAMPO: _____
_____
_____

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: Acefato 90 WSP® (Registro de EPA № 70506-2)

Ingrediente Activo (AI): Acefato (insecticida, CAS № 30560-19-1)

Formulación y Embalaje: 90% AI polvo en un paquete de 2,5 libras soluble en agua.

Usted puede manipular hasta: 320 paquetes solubles en agua.

APROBADO POR
Independent IRB
Firma
16/diciembre/08
Fecha

Iniciales: _____
Fecha: _____

US EPA ARCHIVE DOCUMENT

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los mezcladores/cargadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Usted también debe usar guantes resistentes a las substancias químicas. En caso de emergencia (p. ej., paquete roto), usted también debe tener inmediatamente a disposición overoles [*coveralls* en inglés], calzado resistente a las substancias químicas y un respirador aprobado.

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: Pudieran 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 acefato 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, 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.

Identificador de la etiqueta: Rev. 2/07/08 70506-2(031808-2967) (última página)
Fecha de la MSDS: 12-abril-2007 (UPI)

_____ _____
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: 16/diciembre/08

APROBADO POR
Independent IRB
Firma 16/diciembre/08 Fecha

Iniciales: _____
Fecha: _____

US EPA ARCHIVE DOCUMENT

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December 19, 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:

Product Risk Statement: Acephate 90 WSP®
(PROTOCOL AHE120) Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Pesticide Products in Water Soluble Packets in the United States
(Protocol: AHE120) (Version: 12/11/08) (Study Director: Eric D. Bruce)
(Agricultural Handlers Exposure Task Force [AHETF], c/o David R. Johnson, PhD)

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:

Declaración de Riesgo del Producto: Acefato 90 WSP®
(PROTOCOLO AHE120) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante la Mezcla/Carga de Productos Pesticidas en Paquetes Solubles en Agua, en los Estados Unidos
(Protocolo: AHE120) (Versión: 11/diciembre/08) (Director del Estudio: Eric D. Bruce)
(Agricultural Handlers Exposure Task Force [AHETF], a cargo de David R. Johnson, PhD)

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Signature of Américo Gómez/*Firma de Américo Gómez*

ata A member of the American Translators Association.
Associate Membership since 1997.

US EPA ARCHIVE DOCUMENT

Declaración de Riesgo del Producto
Riesgo de Toxicidad del Producto Pesticida Manipulado
(Debe adjuntarse al Formulario de Consentimiento Informado)

TÍTULO: (PROTOCOLO AHE120) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante la Mezcla/Carga de Productos Pesticidas en Paquetes Solubles en Agua, en los Estados Unidos

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: Eric D. Bruce
21 Oak Knoll Ct.
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Celular: 925-708-5538
Correo electrónico [E-mail]: eybruce@pacbell.net

UBICACIONES DE CAMPO: _____
_____
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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: Acefato 75 WSP® (Registro de EPA № 70506-1)

Ingrediente Activo (AI): Acefato (insecticida, CAS № 30560-19-1)

Formulación y Embalaje: 75% AI polvo en un paquete de 1 libra soluble en agua.

Usted puede manipular hasta: 960 paquetes solubles en agua.

APROBADO POR
Independent IRB
Firma
16/diciembre/08
Fecha

Iniciales: _____
Fecha: _____

US EPA ARCHIVE DOCUMENT

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los mezcladores/cargadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Usted también debe usar guantes resistentes a las substancias químicas. En caso de emergencia (p. ej., paquete roto), usted también debe tener inmediatamente a disposición overoles [*coveralls* en inglés], calzado resistente a las substancias químicas y un respirador aprobado.

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: Pudieran 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 acefato 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 mínima 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.

Identificador de la etiqueta: Rev. 2/7/08 70506-1(030308-2774) (última página)
Fecha de la MSDS: 12-abril-2007 (UPI)

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: 16/diciembre/08

Versión: 11/diciembre/08
Protocolo: AHE120
Acefato 75 WSP®
Declaración de Riesgo del Producto

APROBADO POR
Independent IRB
Firma 16/diciembre/08 Fecha

Iniciales: _____
Fecha: _____

US EPA ARCHIVE DOCUMENT

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December 19, 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:

Product Risk Statement: Acephate 75 WSP®
(PROTOCOL AHE120) Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Pesticide Products in Water Soluble Packets in the United States
(Protocol: AHE120) (Version: 12/11/08) (Study Director: Eric D. Bruce)
(Agricultural Handlers Exposure Task Force [AHETF], c/o David R. Johnson, PhD)

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:

Declaración de Riesgo del Producto: Acefato 75 WSP®
(PROTOCOLO AHE120) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante la Mezcla/Carga de Productos Pesticidas en Paquetes Solubles en Agua, en los Estados Unidos
(Protocolo: AHE120) (Versión: 11/diciembre/08) (Director del Estudio: Eric D. Bruce)
(Agricultural Handlers Exposure Task Force [AHETF], a cargo de David R. Johnson, PhD)

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Signature of Américo Gómez/*Firma de Américo Gómez*

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Associate Membership since 1997.

US EPA ARCHIVE DOCUMENT

Spanish Language Recruiting Flyer

US EPA ARCHIVE DOCUMENT

Número del Estudio: AHE120

Voluntarios para un Estudio de Investigación Científica

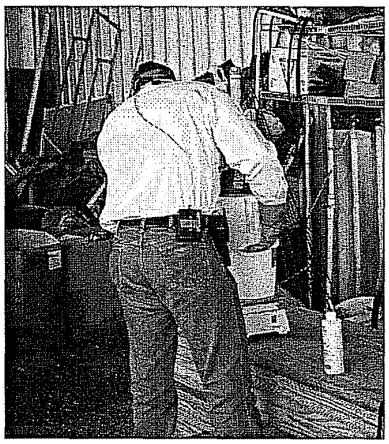
La Agricultural Handlers Exposure Task Force (AHETF) es un grupo de compañías de pesticidas que están llevando a cabo investigación científica para medir cuánta substancia química se agarran los trabajadores cuando ellos manipulan pesticidas. La AHETF está buscando trabajadores experimentados para que desempeñen su trabajo usual de mezclar y cargar pesticidas envasados en bolsas solubles en agua y permitirle a AHETF que recopile datos de la exposición.

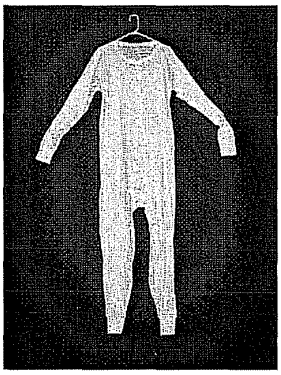
Para ofrecerse como voluntario usted debe:

- Tener por lo menos 18 años de edad y una identificación, con foto, emitida por el gobierno
- Entender el idioma inglés o el español
- Gozar de buena salud
- No trabajar para un fabricante de pesticidas ni para un contratista de AHETF
- No estar embarazada ni lactando [dando el pecho]
- Ser experimentado y estar entrenado en el manipuleo de pesticidas

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:

Eric Bruce
(866) 925-1421
Teléfono Gratuito

Él puede responder a cualquiera de sus preguntas y darle más detalles.

APPROVED
12/16/08
Independent Investigational
Review Board

US EPA ARCHIVE DOCUMENT

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
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December 19, 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:

Recruitment Flyer - "Research Study Volunteers"
(PROTOCOL AHE120) Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Pesticide Products in Water Soluble Packets in the United States
(Protocol: AHE120) (Approved: 12/16/08) (Study Director: Eric D. Bruce)
(Agricultural Handlers Exposure Task Force [AHETF], c/o David R. Johnson, PhD)

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:

Volante de Incorporación – «Voluntarios para un Estudio de Investigación Científica»
(PROTOCOLO AHE120) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante la Mezcla/Carga de Productos Pesticidas en Paquetes Solubles en Agua, en los Estados Unidos
(Protocolo: AHE120) (Aprobado: 16/diciembre/08) (Director del Estudio: Eric D. Bruce)
(Agricultural Handlers Exposure Task Force [AHETF], a cargo de David R. Johnson, PhD)

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*

ata A member of the American Translators Association.
Associate Membership since 1997.

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Part D: Records of IRB Review of Study AHE120

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Initial Submission of 12/11/08 to IRB

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12/11/08 Email Message from Eric Bruce to Robert Roogow

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From: Eric Bruce [mailto:eybruce@pacbell.net]
Sent: Thursday, December 11, 2008 2:28 PM
To: rroogow@iirb.com
Cc: ycrespo@iirb.com; davejohn@marktwain.net
Subject: Emailing: AHE120 IIRB Submission 12-11-08

Robert Roogow:
Attached is a zipped folder containing the materials associated with a new study review request.

This study, AHE120, is sponsored by the Agricultural Handlers Exposure Task Force and is very similar to other studies IIRB, Inc. has reviewed in the past. Two important differences are:

- This study involves multiple sites (5 locations across U.S.), but all under my control and IIRB review
- A Data and Safety Monitoring Plan is included (as we discussed on the phone, this will alleviate concerns expressed by the EPA and the Human Studies Review Board for earlier studies)

You should find the following items in the attached folder:

- Submission Letter (in Word)
- Site Questionnaire – Single Site (in Adobe, signed)
- Data and Safety Monitoring Plan (in Adobe, signed)
- Study Setup Form (in Word)
- Study Protocol (in Word)
- Informed Consent Form – English (in Word)
- California Experimental Research Subject's Bill of Rights – English and Spanish (in Word)
- Recruitment Flyer – English (in Word)
- 3 Product Risk Statements (in Word)
- 3 Pesticide product Labels (in Adobe)
- 3 Pesticide product MSDSs (in Adobe)
- Researcher CVs (in Word or Adobe)
- Researcher HRP Training Certifications (in Word or Adobe)
- Standard Operating Procedures referenced in the protocol (in Adobe)

Please let me know if you need anything else.
I will be out of the office tomorrow (Friday), but might be reached on my cell phone.
Thank You,
Eric Bruce
925-708-5538 (cell)
925-939-4987 (office)

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Submission Letter dated 12/11/08

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INDEPENDENT INVESTIGATIONAL REVIEW BOARD INC.

SUBMI ION LETTER

DATE: 12/11/2008
TO: Kim Lerner, Chair or
Anita McSharry, Vice Chair
Independent Investigational Review Board, Inc.

FROM: Eric D. Bruce
SUBJECT: Please forward for IRB review
Please indicate the type of review you are requesting
New Study for IRB Approval
Additional Site for an Approved Protocol
Modification to Already Approved Research

Principal Investigator:Eric D. Bruce
Protocol Number: AHE120
Sponsor:Agricultural Handlers Exposure Task Force (AHETF)
Protocol Title:Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Pesticide Products Packaged in Water Soluble Packets in the United States

Study Protocol *(must be a Final version)*

Clinical Investigator's Brochure/Prescribing Information (Package Insert)/Device Brochure (if applicable)

Draft Informed Consent Form (*e-mail or include disc) * If you do not have a draft Informed Consent Form, contact the IIRB, Inc. for drafting ICF services.*

Patient Payment *(if not included in draft Informed Consent Form draft or Site Questionnaire)*

CV's and License (*for all investigator's listed on 1572 (if applicable) or participating in the study, and anyone conducting the consenting process*)

Human Research Protection Training *(please include any HRP training that has been completed including, CITI Program, SOCRA, OHRP, NIH, ACRP, or any other relevant training)*

Site Questionnaire *(including any addendums and supporting documentation to the Site Questionnaire)*

Facility License/Certification *(if research is conducted in a hospital/outpatient center)*

IRB Facility Waiver (*if research is conducted in a hospital/outpatient center, federal or state funded clinic, or facility with a local IRB)*

Data and Safety Monitoring Plan (if you more than minimal risks and no Data Safety Monitoring Board is established.)

FDA Form 1572 *(if applicable) Please send signed copy, and maintain original for your file.*

Advertisements and Recruitment Material *(please note, all advertisements and recruitment material must be approved by the IIRB, Inc. prior to utilization)*

Study Specific Instruction Form *(provides shipping and invoicing information)*

Site Conflict of Interest and Disclosure Form *(if COI is identified on the Site Questionnaire that may apply to current study)*
Other Study Document(s) *(i.e. questionnaires, subject diaries)*

Indicate documents: *California Experimental Subject's Bill of Rights, 3 Product Risk Statements, 3 Product Labels, 3 Material Safety Data Sheets (MSDSs), and Standard Operating Procedures referenced in the study protocol.*

Refer to IRB Meeting Schedule located at www.iirb.com for IRB meeting dates and submission deadlines. If all material is not available by the deadline please call the IIRB, Inc. to discuss. (Additional meetings can be scheduled if necessary). Submission may be emailed to your assigned project leader or to submission@iirb.com or mailed to our office. **Please note that no research activities can commence until the research has received all required approvals.**

Please call if you have any questions. Thank you.

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Site Questionnaire

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INDEPENDENT INVESTIGATIONAL REVIEW BOARD INC.

SITE QUESTIONNAIRE
Single Site Study

I. GENERAL SITE INFORMATION

Protocol Number: **AHE120**

Sponsor: **Agricultural Handlers Exposure Task Force (AHETF)**

Complete Study Title: **Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Pesticide Products in Water Soluble Packets in the United States**

Principal Investigator: **Eric D. Bruce**

After Hours or 24 Hour Phone Number: (emergency contact for subjects)

(866) 925-1421 (English or Spanish)

925-708-5538 (English only)

Sub Investigator(s): **Randy Thompson and Rich Honeycutt (recruit growers); Vicky Standart (obtain consent from Spanish-speakers); TBD: Tami Belcher, Brian Lange, and/or Aaron Rotondaro (monitor exposure)**

Site Address: **5 sites, commercial farms in: New York, Louisiana, Michigan, California, and Washington.**

Mail documents here

Principal Investigator's Mailing Address: (If different)

Eric Bruce
21 Oak Knoll Ct.
Walnut Creek, California
94596

Mail documents here

Regulatory/Study Coordinator: **Eric D. Bruce**

Phone: **925-708-5538**

Fax Number: **925-939-4987**

Main Office Phone: **925-939-4987**

Email: **eybruce@pacbell.net**

Is this study being conducted internationally? . Yes* No
* If yes, please complete an International Addendum located under forms at www.iirb.com.

Is this study being conducted at more than one location under the oversight of the Principal Investigator?
. Yes* No

*If yes is the Principal Investigator affiliated with the additional site(s)? . Yes No**
**If no, please complete a Multiple-Center Research Form located on our website at www.iirb.com.

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If the study is being conducted at multiple locations under the same Principal Investigator, and information requested differs for each location, please complete an Additional Location Form for each additional location. (Note: This does not apply to locations only performing diagnostic testing).

II. STUDY INFORMATION You may attach copies of relevant procedures.

1. Does this study require review under U.S. Department of Health and Human Services (DHHS) standards?
☐ Yes* ☒ No

* If yes, is the informed consent form you are submitting considered a DHHS approved sample consent document? ☐ Yes ☐ No

* If yes, what is the site's FWA number?

2. Does this study have an investigational new drug (IND) number?

☐ Yes, Indicate number: _____
☒ No IND is required, please explain why: **This study does not involve drugs.**

If this study has an IND number indicate which documentation of it you are submitting (one must be checked):

☐ Industry sponsored protocol with IND.
☐ Letter from FDA.
☐ Letter from industry sponsor.
☐ Other document and/or communication verifying the IND.

Note: The Investigator's Brochure is not adequate documentation of an IND number.

Is the IND in the FDA 30 day waiting period? ☐ Yes ☐ No

3. Does this research involve an Investigational Device? ☐ Yes* ☒ No

*If yes, please attach one of the following:
☐ FDA letter granting an IDE for the proposed use, or
☐ Letter from sponsor explaining why the investigation is exempt from the IDE requirements under 21 CFR 812.2(c)(1)-(7), or
☐ Letter from sponsor explaining why the device meets criteria for non-significant risk device determination. (meets the abbreviated IDE requirements under 21 CFR 812.2(b)).

4. Has this study for this site been reviewed by another IRB? ☐ Yes* ☒ No

*If yes, include a copy of the IRB's letter (i.e., approval, disapproval, deferred), and when appropriate a study closeout letter from the other IRB.

5. Does the Principal Investigator, Sub Investigator(s), key personnel or any of their immediate family members have a conflict of interest with the study sponsor, sponsor representatives or other study related entities as described in the Investigators' Guidebook available on our website? ☐ Yes** ☒ No*

** Checking No indicates your understanding of a conflict of interest as outlined in the Investigators Guidebook.*
***If yes, please complete the Site Conflict of Interest and Disclosure Form located under forms at www.iirb.com for each individual with a conflict of interest.*

6. Is the language for research-related injuries listed in the submitted Informed Consent Form consistent with the Sponsor contract?

☒ Yes ☐ No

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7. Will the Investigator act as the sponsor of this research study? ☐ Yes* ☒ No

* If yes, does the Investigator agree to conduct research in accordance to the regulatory responsibilities of a sponsor as listed in Investigator's Guidebook? ☐ Yes ☐ No**

** If no, explain.

8. Indicate how data and subject safety monitoring is conducted at the site (i.e., initiation and monitoring visits, monitoring of laboratory results, general subject safety mechanisms).

See the Data and Safety Monitoring Plan form submitted with this application.

III. SITE QUALIFICATIONS

9. Describe the setting(s) where the study will be conducted.

☐ private office ☐ research clinic ☐ hospital environment** ☒ Other **: **Commercial farms.**

**If being conducted in a hospital environment (i.e Hospital or Outpatient Surgery Center) or in another setting (i.e home, school, or lab) where administrative or corporate approval is required, please provide a copy of that facility's license/accreditation (if applicable) and/or Facility Waiver Form.

10. Describe any state or clinic policies for this site that are outside the norm of clinical research practices (i.e., legal age of consent is not 18, a separate HIV consent is required, site monitoring by the IRB is required, etc.).

N/A. This study is not clinical research.

11. Describe the resources that are accessible to the Investigator, Sub Investigators, and staff to accommodate this research study (i.e., trained personnel that are familiar with the protocol, adequate space and storage, necessary equipment, sufficient time, etc.).

All researchers have specialized training in the conduct of exposure studies and subjects' usual equipment, practices, and timing are utilized.

12. Describe the site's policies and procedures for protecting the privacy of subjects related to study visits and procedures performed (i.e., providing private interview areas and private examination space).

Consent meetings, pregnancy testing, and dressing/undressing are all performed in quiet and private locations as described in AHETF Standard Operating Procedures.

13. Confirm that your facility maintains the confidentiality of data and personal health information (i.e. HIPAA, HIV status, etc.) through AT LEAST the following measures (by placing check marks in each of the first 3 boxes).

☒ All of the study staff have agreed to not disclose any identifiable health information.
☒ Electronic files will only be accessible to the study staff which will require a password to access the information, or ☐ no electronic files are used.
☒ Paper-based records and files will be stored in a location that is secure and is only accessible to the authorized study staff.

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☐ Other, explain:

14. Describe the on-site emergency equipment and rescue medications available for the subjects:
A portable emergency eye wash station and a medical professional (e.g., nurse or paramedic).

15. Distance between the research site and nearest hospital:
TBD; expected to be less than 30 miles.

16. Describe how the site will store, secure, and/or dispense investigational materials.
N/A.

17. Describe the practices in place for notifying subjects of positive results of infectious diseases (i.e. HIV and hepatitis , VDRL) and reporting these results to governing agencies. Indicate a N/A if no infectious disease testing is being conducted. **N/A.**

18. How long has the PI been conducting research with human subjects? **11** years _____ months

19. **HUMAN RESEARCH PARTICIPANT PROTECTION TRAINING:** Attach certificate of training of the investigators. If no certificate of completion is available please include a signed note to file by the investigators attesting to completion of HRP training and include objectives and date of completion.

If no specific training has been completed access to CITI HRP Training is available through Independent Investigational Review Board, Inc. at no cost. Information about accessing the program is available in the Investigator Guidebook and through the website www.IIRB.com entering through the "Investigator Door".

20. Is the PI knowledgeable of Good Clinical Practices (GCP) 21 CFR 312, Subpart D, "Responsibilities of Sponsors and Investigators?" ☐ Yes ☒ No

20a. Is the PI knowledgeable of Good Clinical Practices (GCP) 21 CFR 812, Subpart E, "Responsibilities of Investigators" for device studies? ☐ Yes ☒ No

21. Is the PI and research team knowledgeable of the ethical principles of the Belmont Report?
☒ Yes ☐ No*

** If no, please explain:*

22. Has the FDA/OHRP/EPA or any State Medical Board ever sanctioned or suspended the Principal Investigator?
☐ Yes* ☒ No **If yes, please provide a summary of the action and applicable correspondence.*

23. Within the past 3 years has the FDA/OHRP/EPA audited your site/Principal Investigator?
☐ Yes* ☒ No

**If yes, please provide a copy* of the Established Inspection Report (EIR) and any other supporting documentation.

24. Has an IRB ever terminated a study for any reason or imposed any sanctions or restrictions on the PI?
☐ Yes* ☒ No **If yes, please provide a summary of the action and applicable correspondence.*

IV. RECRUITMENT AND INFORMED CONSENT

25. Are subjects recruited from the Principal Investigator's Clinical Practice?

☐ Yes* ☒ No

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(Note: If yes, there must be protections in place, in light of the physician-patient relationship and trust, so that a patient will not be unduly influenced to participate as a subject in a research study).

*If yes, are any subjects categorically excluded (other than for study design purposes) from the Principal Investigator's Clinical Practice ☐ Yes** ☐ No

** *If yes, please explain:*

26. Are subjects recruited from a database of potential Subjects ☐ Yes* ☒ No (See Investigator's Guidebook for recommendations for database management)

*If yes, is the database comprised of only individuals who have given prior approval to be contacted?
☐ Yes ☐ No**

***If no, please explain*:

27. Other recruitment methods: ☐ None

☒ Advertising in the community* *(*advertisements Must be approved by the IIRB, Inc.)*
☐ Existing Subjects (rollover subjects, study extension)
☐ Physician Referral **
☒ Other *(please specify):* **Cooperating growers will be identified first and with their permission an Investigator will recruit workers directly. An introductory meeting without supervisors and/or posting of a flyer will identify interested workers. Private consent meetings in English or Spanish will be conducted for potential subjects. When more workers are available than needed, one will be selected randomly.**

** HIPAA regulations prohibit physician-to-physician referral; patients must first be informed of a trial and agree to be contacted before any physician referral can be initiated.

28. Are there practices and measures in place to assure that recruitment and selection of subjects for participation in research is fair and is made without bias from social, racial, sexual and cultural institutions in society.

☒ Yes ☐ No*
**If no, please explain*:

29. Will you be conducting telephone screenings? ☐ Yes* ☒ No

* If yes, do you have policies in place to ensure the following regarding telephone screenings:
☐ The potential subject will be asked if they would like their information kept on file or in a database in order to be contacted for future studies.
☐ If the potential subject does not want their information stored on file or in a database, the site will properly destroy (i.e. delete electronic files, shred documents, etc.) the information collected during the telephone screening.
☐ Only authorized personnel will have access to the database or records on file pertaining to personal health information.
☐ The database or on file records will be stored in a secure location.
☒ Other: **Subjects are recruited via face-to-face meetings.**

30. What are community attitudes toward research in your local community?
☒ Neutral ☐ Positive ☐ Negative*

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** If negative, please attach explanation*.

31. 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? ☐ Yes* ☒ No

*If yes, please explain how coercion will be avoided.

32. Indicate the approximate demographics of your site's anticipated subject population:

8% African American **56**% Caucasian **27**% Hispanics **4** % Asian **5**% Other

98 % Male **2** % Female

33. Do you have access to a population that would allow recruitment of the required number of subjects?

☒ Yes ☐ No* * If No, explain:

34. Will you be enrolling subjects who do not speak English in this study? ☒ Yes* ☐ No

*If Yes, indicate the translation needed: ☒ Spanish ☐ Other:

Note: A certified translation must be reviewed by IIRB, Inc. prior to use.

35. If you are enrolling subjects that do not speak English is there a person available and fluent in the translated study documents requested during the informed consent process and duration of the study?

☒Yes ☐No ☐N/A

36. Does a person fluent in the translation review the approved translated study documents prior to being used to ensure that the translation is consistent with any local dialect? ☐ Yes ☐ No ☒ N/A

37. Does this study require you to recruit subjects from vulnerable study populations or other populations that require additional safeguards? ☐ Yes ☒ No*

* If no, do you anticipate enrolling any of the populations listed above anyway?
☒ Yes ☐ No, If no, skip question #38. If yes, *provide justification for inclusion of these populations if they are being enrolled.* **AHETF anticipates some agricultural workers will be non-readers and has procedures in place to deal with non-readers.**

38. Indicate which populations you anticipate enrolling (either because the protocol requires enrollment or demographics of your site) and attach a copy of your consenting procedures that are relevant to additional safeguards you have in place to protect the rights and welfare of each selected population. *Checking a box below indicates your understanding of how to protect that group as outlined in the Investigator's Guidebook available on our website.*

☐	Educationally Disadvantaged/Illiterate	☐	Members of the Armed Forces
☐	Nursing Home Resident	☐	Patients with incurable disease
☐	Patients in emergency situations	☐	Economically Disadvantaged
☐	Mentally disabled	☐	Employees (Site/Sponsor/CRO)
☐	Children*	☐	Disabled
☐	Pregnant women**	☒	Other: **Non-readers**

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** If children will be enrolled, submit a completed Research Involving Children Addendum.*
*** If you are enrolling pregnant women, complete the Pregnant Women and Fetuses Addendum.*

Note: The IIRB, Inc. does not review research studies with prisoners as research subjects.

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

☒ Principal Investigator ☐ Sub Investigator ☐ Study Coordinator ☒ Other: **Bilingual researcher for Spanish-speakers.**

40. Describe the qualifications and training of the individuals communicating information to the subject or the legally authorized representative during the consent process (i.e., trained in consenting procedures, and that the information is provided in a language that the subject or the representative understands well). **Principal Investigator and bilingual researcher are trained in the conduct of exposure studies for EPA data needs and have experience obtaining consent from agricultural workers for exposure studies. The PI is fluent in English and the bilingual researcher is fluent in English and Spanish.**

Attach your consenting process/procedures. If you do not have written operating procedures that adequately address the following questions, answer questions 41 through 48 listed below.

41. Describe how the investigator or designee will ensure that the language is understandable to the subject, based on the subject's education level and language ability. **Potential subjects will be asked to identify their preferred language: English or Spanish. Workers who understand only other languages are not eligible to participate. Workers who identify themselves as non-readers will have a witness present to confirm all written information is fully read to the potential subject. Reading ability of those who do not self-identify as non-readers will be ascertained by the person obtaining consent by asking the potential subject to read a passage from the consent form to themselves and tell the researcher what it means.**

42. Describe where the consenting process will take place (i.e., private room, quiet area, etc.). **In a private and quiet room, generally at the agricultural worker's place of business.**

43. Describe the steps taken to minimize the possibility of coercion or undue influence (i.e. giving sufficient opportunity and privacy to voluntarily consider whether to participate). **Supervisors of potential subjects are asked to sign a statement indicating they will not urge or discourage their employees to participate and that a decision to participate or not will have no impact on their employment status or availability of work on study days. Potential subjects are provided a copy of this signed statement. Potential subjects are given a copy of the consent form in advance to review with family or friends, if desired. Potential subjects are allowed to bring an advisor or friend to the consent meeting. Consent meetings include sufficient time for potential subjects to ask questions.**

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44. Will the subject be given the consent form to bring home and discuss with their family? ☒ Yes ☐ No*
* If no, explain:

45. Describe how the investigator or designee will obtain the legally effective informed consent of the subject or the subject's legally authorized representative. **Informed consent will be obtained only from subects themselves. Minors are not eligible to participate and proof of age is required.**

46. Describe the content of the information communicated to the subject or the representative during the consent process (i.e., specific to not include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights). **All sections of the informed consent form will be discussed with potential subjects during the consent meeting. In addition, a Product Risk Statement which describes the risk of handling a specific pesticide product will be discussed and signed by the subject. For subjects in California, the California Experimental Research Subject's Bill of Rights will also be reviewed and signed.**

47. Describe how you evaluate subjects' capacity, understanding, and informed consent or assent (i.e., ask open ended questions, have subject repeat information about what has been discussed, etc.) **All potential subjects will be asked a standard series of questions about various important parts of the consent form. If necessary, additional discussion will take place until the person obtaining consent confirms understanding by the subject. Subjects will be allowed to sign the consent form only if the person obtaining consent is satisfied they understand all information presented and discussed.**

48. Will subjects with legally authorized representatives (LAR) be enrolled? ☐ Yes* ☒ No
*If yes, how will you verify who constitutes an LAR in your state?

☐ legal counsel ☐ sponsor/CRO ☐ state law reference material ☐ state law codes and statutes
☐ other:

V. PAYMENT TO SUBJECT(S)

49. Will subjects be paid for participation in this study? ☒ Yes ☐ No

50. What is the amount per visit? **$20 for consent meeting; $80 for exposure monitoring**
Note: If amount per visit differs, indicate each amount or attach a separate schedule.

51. What is the total payment: **$ 100**

52. When will payment occur? **at each visit** *(i.e. at each visit, at the last visit, within 2 weeks of the last visit).*

53. Will subjects be paid for additional unscheduled visits? ☒ Yes* ☐ No If yes, indicate amount: **$80 if exposure monitoring is ended prematurely.**

Note: Payments must be made on at least a yearly basis for studies with durations longer than 12 months, and

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must be within the guidelines listed in the Investigator's Guidebook.

VI. SITE SPECIFIC INFORMED CONSENT FORM INFORMATION

54. Is there any site specific language needed for the Informed Consent Form (other than PI name, contact information, and payment information). ☒ Yes* ☐ No

If yes, please specify the additional wording below, or attach a copy of the ICF with the site specific information included.* **Participants in California must understand and sign the California Experimental Research Subject's Bill of Rights (submitted with this application).

INVESTIGATOR ACKNOWLEDGMENT

On behalf of all of the investigators listed on page 1, I agree:

- that the responses provided on this Site Questionnaire are true and accurate to the best of my knowledge and I agree to notify the Independent Investigational Review Board, Inc. of any changes in the research activities.
- to report any problems that require prompt reporting.
- not to make any changes in the research without IIRB, Inc. approval.
- that study personnel are familiar with the study and are educated on human research programs including underlying ethical principles from the Belmont Report.
- that the research-related injury statement in the submitted informed consent form, or informed consent form template on file is consistent with the sponsor contract in order to ensure the rights and welfare of subject with injuries during participation in this study.
- that either an Investigator or designee will orally explain the Informed Consent Form to all prospective subjects before obtaining their signed informed consent form and will see that no subject is coerced to participate in a research study.
- that all study records and related documentation are accessible to an authorized representative of the Independent Investigational Review Board, Inc. at reasonable times and in a reasonable manner.

I have been informed that the Investigator's Guidebook is located on the IIRB, Inc. website, and agree to operate in compliance with the information within the Guidebook. 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, and all state and federal regulations.

Name and title of individual completing Site Questionnaire: **Eric D. Bruce**	Phone Number: **925-708-5538**
Print Name of Principal Investigator: ERIC D. BRUCE	
Signature of Principal Investigator: Eric Dean Bruce	Date: 12/11/08

Please contact the IIRB, Inc., if you have any questions regarding this questionnaire at 954.327.0778

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Protocol No.: AHE120

Supplemental information for Question 32.

The information presented on the form for Question 32 reflects the approximate demographics of the subject population for the entire study based on 2000 U.S. Population Census data (Census Bureau, Department of Commerce). However, this study will be conducted in five locations throughout the U.S. and the demographics are not the same between these sites. The following information presents expected demographics for each individual site:

African American	Caucasian	Hispanics	Asian	Other*
Site = New York (Chautauqua, Erie, and Niagara Counties)				
11 %	**83 %**	**3 %**	**1 %**	**2 %**
Site = Louisiana (East Carroll, Madison, and Tensas Parishes)				
61 %	**36 %**	**2 %**	**0 %**	**1 %**
Site = Michigan (Oceana and Mason Counties)				
1 %	**89 %**	**7 %**	**0 %**	**3 %**
Site = California (Fresno and Tulare Counties)				
6 %	**13 %**	**63 %**	**9 %**	**9 %**
Site = Washington (Yakima and Benton Counties)				
1 %	**57 %**	**32 %**	**2 %**	**8 %**

* “Other” includes Native Americans, Hawaiian / Pacific Islanders, and Multi-Race categories. Census data also includes a response of “other” for which there is no indication of the race. These responses may reflect people who decline to state their race/ethnicity and these responses were apportioned to the other categories in a proportional manner.

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Data and Safety Monitoring Plan

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INDEPENDENT INVESTIGATIONAL REVIEW BOARD INC.

DATA AND SAFETY MONITORING PLAN

For research studies that involve the potential for more than minimal risks to the subjects, the IIRB, Inc. requires that a data and safety monitoring plan be submitted at the time of the initial submission. Please note: a data safety monitoring plan does not have to be submitted, if the research protocol has a Data and Safety Monitoring Board (DSMB) in place, and the elements below are adequately addressed. For more information refer to the Investigator's Guidebook.

Protocol Number: AHE120	
Principal Investigator: Eric D. Bruce	**Phone:** 925-708-5538
Does this study involve the potential for more than minimal risks to the subjects? ☒ Yes ☐ No* *If no, this form is not required for initial submissions unless specifically warranted by the IIRB, Inc.	
The following criteria will be considered when evaluating whether the plan is adequate. Include a brief description for each area. A separate document may be attached as necessary.	
Reporting mechanisms. Heat illness has been identified as a risk that may be greater than minimal for subjects in this study since participants must wear an extra layer of clothing. If heat illness occurs, it will become apparent during the single day that constitutes study participation. A medical professional will be on site to assess heat illness and will provide medical treatment, if needed. Any incidence of heat illness, or any other adverse event that is unanticipated and possibly study-related, will be reported promptly to the IIRB as described in Standard Operating Procedure AHETF-11.F.	
The frequency of the monitoring, such as points in time or after a specific number of participants are enrolled. Subjects will be observed continuously during their participation by a reaearcher, except when this would interfere with the subject's privacy, such as when they use a restroom.	
The entity that will conduct the monitoring, such as a data monitoring committee, data and safety monitoring board, medical monitor, investigator, or independent physician. Study researchers will observe subjects continuously and the on-site medical professional will observe subjects periodically throughout the study. If needed, the subject will be transported to a nearby medical facility such as a clinic or hospital emergency room for further evaluation. Exposure monitoring data generated will be audited by the AHETF Quality Assurance Unit (QAU) and the QAU of the analytical laboratory.	
The specific data to be monitored. During the study, observations will involve looking for early signs and symptoms of heat illness as described in SOP AHETF-11.G and asking subjects if they feel any of these symptoms. In addition, the ambient heat index (calculated from temperature and relative humidity) will be determined at leasat hourly if the ambient temperature is 70 degrees F or greater and study participation will be stopped if it gets too hot as described in SOP AHETF-11.G. After study conduct, analytical results of chemical residues in/on exposure matrices will indicate exposure levels.	
Procedures for analysis and interpretation of the data. If the Heat Index reaches 120 degrees F, after adjustment for direct sun if present, study participation will be stopped. In addition, the study will be stopped if any signs or symptoms of heat illness become apparent in a subject. Resulting exposure levels (i.e., from analysis of subject samples) will be compared to expected levels and new findings of potential adverse effects will be reported to EPA in accordance with FIFRA Section 6(a)(2) as described in SOP AHETF-1.F.	

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Actions to be taken upon specific events or end points. Subjects who experience signs or symptoms of heat illness will be taken immediately to a shady or cool environment and checked by the Principal Investigator and the on-site medical professional. Subjects will be urged to drink fluids and if needed, first aid measures will be administered by the medical professional. Study participation may continue only if the subject cools off, feels OK to continue his tasks, and the Principal Investigator and medical professional concur. If additional medical attention is needed, the subject will be transported to a nearby medical facility.
Procedures for communication from the data monitor to the IRB and sites. Any unexpected and possibly study-related adverse effect from any site will be reported to the IRB in writing within 10 days of the occurrence as specified in SOP AHETF-11.F.

PI Signature: Eric Dean Rick	**Date: 12-11-08** 12/11/08

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Study Setup Form

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INDEPENDENT INVESTIGATIONAL REVIEW BOARD INC.

STUDY ETUP FORM

PROTOCOL TITLE: DETERMINATION OF DERMAL AND INHALATION EXPOSURE TO WORKERS DURING MIXING/LOADING OF PESTICIDE PRODUCTS IN WATER SOLUBLE PACKETS IN THE UNITED STATES

SPONSOR: AGRICULTURAL HANDLERS EXPOSURE TASK FORCE (AHETF)

Sponsor Contact Information
Contact/Title: David R. Johnson, Ph.D. Phone/Fax: 660-395-9590 Email:davejohn@marktwain.net
Address: Agricultural Handlers Exposure Task Force (AHETF)
1720 Prospect Drive
Macon, Missouri 63552

CRO: Eric D. Bruce

CRO Contact Information
Contact/Title: Eric D. Bruce Phone/Fax: 925-708-5538 Email: eybruce@pacbell.net

Address: 21 Oak Knoll Ct.
Walnut Creek, California 94596

STUDY STATUS
If the IIRB, Inc. is acting as the Central IRB on a study, please check Multiple Sites. If the study protocol is being conducted at only one site, or at more than one site but the IIRB, Inc, is not acting as the Central IRB, please check single site.

Single Site Multiple Sites

INFORMED CONSENT PROCEDURES
Do changes to the Informed Consent Form need to be reviewed by any of the parties involved (i.e. Sponsor, CRO) prior to review by the IIRB, Inc.?

No Yes, if yes please indicate party Sponsor CRO Other:

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

Use translations Services through IIRB, Inc. (Americo Gomez)
We will provide our own Spanish Translations

*Please note that Americo Gomez serves as an independent contractor of Independent Investigational Review Board, Inc. Americo Gomez is a certified translator with a long standing working relationship with the IIRB, Inc. and his credentials are recognized and found acceptable by the IIRB, Inc. Due to being a separate entity, you will receive a separate invoice for his translating services.

Additional questions regarding translation services can be sent to AGomez5634@aol.com.

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* Please note that translations for other languages must be arranged for by the site, sponsor, or CRO. In addition, appropriate supporting documentation (i.e. certified letter of translation and curriculum vitae of certified translator) is necessary.		
MAILING INSTRUCTIONS: address for Sites do NOT need to be listed – just identify as "sites" (so that we have on file who receives copies of documents and who gets originals!)		
Originals to: ☐ Sponsor ☐ CRO ☒ Site	Send by (choose one): ☒ FedEX ☐ UPS ☐ DHL ☐ USPS ☐Other:	
Address: Eric D. Bruce 21 Oak Knoll Ct. Walnut Creek, California 94596	Account #: 1841-4121-3	
Copies to: ☒ Sponsor ☐ CRO ☐ Site	Send by (choose one): ☐ FedEX ☐ UPS ☐ DHL ☐ USPS ☒ Email ☐Other:	
Address: AHETF 1720 Prospect Drive Macon, Missouri 63552	Account #: Email Address: davejohn@marktwain.net	
Notes: Please include any additional instructions for mailing. Include if copies of routine correspondence get sent to CRO/Sponsor, sent US Mail, etc. Routine correspondence may be sent via e-mail to Sponsor and CRO.		
BILLING INSTRUCTIONS: ☒ Sponsor ☐ CRO ☐Site ☐ Other:		
Billing Contact Information ☒ **same as listed above**		
Contact/Title:	Phone/Fax:	Email:
Address:		
Purchase Order # (if applicable):		
TODAY'S DATE:12/11/08		

Study AHE120 Protocol

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AGRICULTURAL HANDLERS EXPOSURE TASK FORCE (AHETF)

STUDY No. AHE120

Study Title: Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Pesticide Products in Water Soluble Packets in the United States

PROTOCOL AUTHORIZATION

Read and Approved by:

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

Signature _____

Date _____

Study Director: Eric D. Bruce

Signature _____

Date _____

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1.0 GENERAL INFORMATION

1.1 Study Title

Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading Pesticide Products in Water Soluble Packets in the United States

1.2 Study No. AHE120

1.3 Objective

The objective of this study is to develop data to determine the potential exposure for workers who mix and load solid pesticide products packaged in water soluble packets in five regions of the United States. This activity involves adding water soluble packets (generally a soluble or wettable powder in a plastic film pouch) into a variety of mixing, holding, or application equipment; dilution with water; and sometimes a subsequent transfer of diluted product to application equipment. The data generated from this study should be sufficient to complete the data set for this mixing/loading scenario.

1.4 Timeline

Proposed Experimental Start Date: May, 2009

Proposed Experimental Termination (Field Phase) Date: July, 2010

Proposed Experimental Termination (Analytical Phase) Date: December, 2010

Proposed Final Report Issue Date: December, 2011

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.

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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

Eric D. Bruce
21 Oak Knoll Ct.
Walnut Creek, CA 94596
925-939-4987 (office) 925-708-5538 (mobile)
eybruce@pacbell.net

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

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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 told which of the above researcher(s) will be involved with monitoring his/her exposure.

1.11 Grower List

The following contractors to AHETF will be utilized to generate lists of growers and to conduct phone recruitment of those growers. These contractors have specialized training and/or experience related to phone interviewing, recruiting, or surveying.

Randy Thompson, RPT Reports
Richard Honeycutt, HERAC, Inc.

1.12 Field Facilities

This study involves multiple locations across the country and will be conducted at a variety of commercial farms in an outdoor environment. Each of the Principal Investigators listed above utilizes a mobile laboratory (a large truck or trailer) that provides the necessary private and clean environment for dressing workers, undressing workers, and collecting exposure samples from workers. Since there is no field facility *per se* at which the study is conducted, no addresses are provided.

1.13 Principal Analytical Investigator and Analytical Facility

To be determined and amended to the protocol prior to initiation of the field phase of the study. This study may involve multiple active ingredients so multiple analytical investigators and analytical facilities may be specified.

1.14 Quality Assurance Unit

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

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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 (see SOP AHETF-11.A). The protocol, informed consent form(s), California Experimental Research Subject's Bill of Rights, and other required documentation for this study will be approved by an institutional review board (IRB) and the California Department of Pesticide Regulation, 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 IRB for the proposed research shall be the Independent Investigational Review Board Inc. (IIRB) of Plantation, Florida. Complete records of the IIRB 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 (Protecting Human Research Participants (PHRP)) 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/or contract facilities).

2.1 Inclusion Criteria

AHETF inclusion criteria applicable to all AHETF studies are presented in SOP AHETF-11.B. For this mixing/loading of water soluble packets study, the following inclusion criterion also applies:

- Have experience within the past year with mixing/loading water soluble packets (including the particular equipment to be used)

2.2 Remuneration of Subjects

During recruitment, workers will be offered an opportunity to take part in a recruitment 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 in participating in the study will attend a private consent 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

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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

Five kinds of risks are associated with the conduct of this 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 surfactants

In this study risks to subjects are classified as "greater than minimal" since the likelihood of harm or discomfort is greater than what is encountered in ordinary daily life. In particular, this study involves the use of chemicals (pesticides, fertilizers, additives, etc.) that present a risk of adverse health effects. In addition, 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 mixing and loading water soluble packets into a pre-mix or application tank and diluting the product with water. Mixing/loading activities might occur indoors or outdoors and some locations and dates are likely to result in hot and/or humid conditions. 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.

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Mixer/loaders who participate in the study will handle water soluble packets that weigh significantly less than 50 pounds. This is a "light" activity as defined by the North American Free Trade Association (NAFTA) Technical Working Group on pesticides (1998), so physical exertion is relatively low which will reduce the likelihood of heat-related illness. However, each participant will be required to mix/load at least three loads of pesticide spray.

AHETF will monitor ambient conditions to determine the heat index near the mixing/loading station and base monitoring decisions on the current heat index. Exposure monitoring will be discontinued if the heat index cutoff of 120^{o}F (adjusted for direct sun, if applicable) is reached or exceeded. The Study Director or other researcher shall stop the monitoring and/or move the worker to a cooler environment until monitoring can be resumed.

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. AHETF will encourage this if it is a common practice at the field sites selected, and 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 any of the following active ingredients:

- Acephate
- Carbaryl

The pesticide products containing these active ingredients and potentially used in this study are currently registered for agricultural use. AHETF will only monitor workers mixing/loading 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 study (2,000 lb ai/day for carbaryl and 720 lb ai/day for acephate) and based on the estimated exposures for mixing/loading water soluble packets (PHED

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Scenario 5). The following table summarizes the data for these MOE calculations. The calculated MOEs meet or exceed the minimum required MOE, or level of concern (generally 100), for 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 Mixing/Loading Water Soluble Packets:

	Acephate	**Carbaryl**
Max. Daily Amount Handled	720 lb ai/day	2,000 lb ai/day
Dermal MOE	**858**	**531**
Inhalation MOE	**113**	**160**
Combined MOE	**100**	**123**
Level of Concern, Dermal	100	100
Level of Concern, Inhalation	100	100
Level of Concern, Combined	100	100

Potential surrogate products 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).

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Product	Signal Word	Acute Toxicity Summary
Acephate		
Acephate 75 WSP®	CAUTION	• Minimal eye irritation • Low toxicity for oral, dermal, and inhalation routes • Cholinesterase inhibition
Acephate 90 WSP®	CAUTION	• Moderate eye irritation • Low toxicity for oral, dermal, and inhalation routes • Cholinesterase inhibition
Carbaryl		
Sevin® 80 Solupak	WARNING	• Slight eye irritation • Low toxicity dermal and inhalation routes; moderate toxicity for oral route • Cholinesterase inhibition

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 chemical-resistant gloves) during participation.

For this mixing/loading study, exposure to the solid product itself should be negligible due to the water soluble packaging. However,

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exposure to product diluted in water is still possible since the mixing/loading system is not closed. This mixing/loading technique can lead to both dermal and inhalation exposure, however 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 via the dermal route during this study is expected to be 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 mixing/loading 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 than they would normally select or dilute the product more than usual. 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 17 or 18 to 55 pounds of AaiH (Section 7.8). 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 excessive risk.

In order to achieve diversity in AaiH at the high end, AHETF may ask some workers to use larger tank sizes than they would normally select or dilute the product less than usual. These changes might result in longer work periods and greater chemical exposure than would otherwise occur and 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.

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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.

2.3.5 Risk of Exposure to Surfactants During Face/Neck Wipe and Hand Wash Sampling

A very dilute surfactant 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 surfactant solution in pesticide exposure monitoring studies indicates the likelihood of skin or eye irritation is negligible.

In summary, this study will possibly involve an increased risk of heat illness, the usual risk of surrogate chemical toxicity, and very slight risks of skin or eye irritation from surfactant use and of embarrassment caused by pregnancy testing and/or dressing/undressing requirements. The following practices, designed to minimize these risks and respond to injuries, will be followed during this study (see AHETF SOPs 11.C, 11.E, 11.G and 11.H):

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- Selecting only experienced pesticide handlers who consider themselves to be in good health
- Requiring experience with the mixing/loading equipment to be used
- Reminding workers of safe chemical handling practices
- Practicing the face wipe and hand wash procedures with each participant before pesticide handling begins
- Identifying nearby medical treatment 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 that could adversely affect the study objectives (for example, chemical-resistant coveralls).

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 mixing/loading pesticides packaged in water soluble packets. Water soluble packets are considered an engineering control designed to reduce exposure potential for mixer/loaders. 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 not sufficient existing data suitable for use in a generic database describing the exposure to workers from mixing/loading water soluble packets, 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. 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. Pesticide products packaged in water soluble packets are becoming more common for many agricultural uses across the country and a variety of experts consulted by AHETF reported their use occurs widely throughout the country. Exposure data for this scenario meeting contemporary standards of reliability and quality will likely provide a significant benefit to society. Because margins of exposure are acceptable for the products proposed for use in this research study, 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 summary, 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 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 are described in SOPs AHETF-6.B, 6.D, 11.B, 11.D, and 11.J.

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

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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. Volunteers will be informed they must complete an IRB-approved informed consent form and a product risk statement appropriate for the pesticide they will handle. Participants in California must also sign the California Experimental Research Subject's Bill of Rights. The consenting process is conducted as described in SOP AHETF-11.J.

2.8 Study Procedures

During the consent process the Study Director or designated researcher will inform each volunteer of the procedures used during the study.

Before exposure monitoring begins, volunteers will:

1. Provide their name and age and present their government-issued photo-ID.

2. Indicate whether they have received pesticide safety training or are exempt from the requirement for pesticide safety training.

3. Tell researchers how many years of experience they have mixing/loading water soluble packets, what particular mixing/loading equipment they're accustomed to using, and when they last used it.

4. Allow researchers to record their gender, age, and ethnicity; and measure and record their height and weight.

5. Allow researcher to take notes on the discussions during the informed consent session(s).

6. Agree to allow researchers to watch all of their work activities and take notes on what they do.

7. Agree to allow photographs and video recordings to be taken for the purpose of documenting this research (see SOP AHETF-10.C for restrictions).

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Volunteers will be asked to arrive at the study site on the day of monitoring about one hour before the scheduled start of work, having bathed or showered the evening before or that morning, and wearing a freshly laundered long-sleeve shirt, long pants, shoes and socks. 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, workers may wear a hat or cap. Then, at the study site on the day of monitoring each volunteer will:

1. Go to a private changing area and, with the assistance of only a researcher of their own sex, take off their outer clothing, put on new long underwear over their personal undergarments, and then put their long-sleeved shirt, long pants, shoes, and socks back on. The long underwear will be provided by AHETF, and will be collected at the end of the study day for analysis.

2. Wear all Personal Protective Equipment (PPE) required by the label of the product to be used. In addition, when using acephate mixer/loaders must have the following PPE immediately available for use in case of emergency such as a broken package, spill, or equipment breakdown: coveralls, chemical-resistant footwear, and a dust/mist or organic vapor respirator.

3. Wear a tube attached to their shirt collar and connected to a portable air-sampling pump worn on a belt around the waist. The pump may be uncomfortable or annoying.

4. Have their hands washed with the assistance of a researcher in a mild surfactant and water mixture before monitoring begins.

5. Have their face and neck wiped by a researcher with a gauze pad moistened with a mild surfactant and water mixture before monitoring begins.

6. Work about 4 to 8 hours mixing/loading a commercial pesticide product packaged in water soluble packets according to the product label and consistent with their usual practices, preparing at least 3 loads. Researchers will watch and take notes on their work activities, and may take photographs or video recordings if necessary to document the research, protecting the privacy of subjects as much as possible. No photographs or video recordings will be made while volunteers are dressing or undressing.

7. Have their hands washed again, in mild surfactant and water, before they eat anything, any time they would normally wash their hands (such as

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before using the toilet), and at the end of the day. The water from these hand washes will be saved for analysis.

8. Have their face and neck wiped again with gauze pads moistened with a mild surfactant and water mixture before they eat anything, any time they would normally wash their face, and at the end of the day. The gauze pads used for this purpose will be saved for analysis.

9. When their work in the study is completed, return to the private changing area where, again with the help of only a researcher of the same sex, they will remove their shoes, socks, shirt, and pants and the long underwear, give the long underwear to the researcher, and put their own shirt, pants, shoes, and socks back on and return to their normal work.

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 and a comparison to the results for other workers performing the same task. Results are typically available six to nine months after monitoring occurs. The personal information related to this follow-up will be retained as described in SOP AHETF-6.D.

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 a toll-free phone number 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.J).

3.0 SITES OF THE FIELD PHASE OF THE STUDY

This study will be conducted at five locations within the United States:

- New York (EPA Growing Region I)
- Louisiana (EPA Growing Region IV)
- Michigan (EPA Growing Region V)
- California (EPA Growing Region X)
- Washington (EPA Growing Region XI)

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Within each location, a specific site will be identified that is likely to provide enough suitable crop acreage and sufficient growers to locate a pool of eligible growers that can provide 5 MUs for monitoring mixer/loader exposure. Within each selected site, exposure monitoring will be conducted at a variety of commercial agricultural operations. Exposure monitoring will be conducted on at least five different farms using five different growers within the identified counties or parishes.

The most desirable locations involve a variety of crop types (e.g., field, trellis, and orchard crops) identified in the MU Sampling Plan as being predominantly associated with surrogate use. For each selected site, researchers will identify eligible growers using a random method as described in the next Section. Full details of the grower and worker selection process and actual commercial agricultural operations utilized will be recorded in the study file. Based on these considerations, the following sites are identified:

New York (EPA Growing Region I):

The site for this cluster of MUs will be commercial farms within the contiguous counties of Chautauqua, Erie, and Niagara which reflect the largest area of grape acreage in New York as well as some apple and cherry orchards. These three crops are identified in the MU Sampling Plan as being associated with significant use of one or both of the proposed surrogates. Having a mix of field and orchard crops is desirable since this will enhance the chances of equipment diversity within the MUs. Collectively, these counties include about 22,567 acres of grapes, 3,700 acres of apples, and 1,084 acres of cherries (2002 Census of Agriculture).

Louisiana (EPA Growing Region IV):

The site for this cluster of MUs will be commercial farms within the contiguous parishes of East Carroll, Madison, and Tensas in the northeastern corner of Louisiana. This three-parish area has significant acreage of both crops associated with surrogate chemical use in this state: cotton and soybeans. Collectively, these parishes reflect the top three ranked Louisiana parishes in terms of total acres for the two important crops with about 280,991 acres, about evenly split between cotton and soybeans (2002 Census of Agriculture).

Michigan (EPA Growing Region V):

The site for this cluster of MUs will be commercial farms within the adjacent counties of Oceana and Mason on the western coast of the Michigan peninsula. This two-county area grows five of the six crops associated with surrogate chemical use in this state: apples, cherries, peaches, asparagus, and snap beans. Grape acreage is trivial for these counties. Having a mix of field and orchard crops is desirable since this will enhance the chances of equipment diversity within the MUs. Collectively, these counties reflect the first and sixth ranked Michigan counties in terms of total acres for

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the six important crops with about 36,284 acres (2002 Census of Agriculture).

California (EPA Growing Region X):

The site for this cluster of MUs will be commercial farms within the adjacent counties of Fresno and Tulare in the Central Valley of California. This two-county area includes significant acreage for grapes, oranges, peaches, plums, and tomatoes - five of the seven crops associated with surrogate use in this state. Having a mix of field, trellis, and orchard crops is desirable since this will enhance the chances of equipment diversity within the MUs. Collectively, these counties reflect the first and second ranked California counties in terms of total acres for the seven important crops with about 644,500 total acres, mostly of grapes, oranges, and tomatoes (2002 Census of Agriculture).

Washington (EPA Growing Region XI):

The site for this cluster of MUs will be commercial farms within the adjacent counties of Yakima and Benton in the Yakima district in Washington State. This two-county area includes significant acreage of all four crops associated with surrogate use in this state: apples, cherries, pears, and grapes. Having a mix of trellis and orchard crops is desirable since this will enhance the chances of equipment diversity within the MUs. Collectively, these counties reflect the first and third ranked counties in terms of total acres for the four important crops including about 67,154 acres of apples, 45,648 acres of grapes, 10,674 acres of pears, and 13,977 acres of cherries (2002 Census of Agriculture).

4.0 GROWER SELECTION

As described briefly above, growers of crops that are treated with the selected surrogate chemicals will be identified in order to identify and recruit handlers that might volunteer to participate in this study. The process that will be used for this scenario to identify and recruit growers is described in SOPs AHETF-11.K and AHETF-11.M. This process is summarized below and in SOP AHETF-1.H.

4.1 Listing Growers

For each site selected above, a list of growers will be obtained that grow at least 5 acres (if farm size information is available) of the crops identified in the MU Sampling Plan as being associated with the most use of at least one surrogate active ingredient. Eliminating small acreage growers ensures that all growers on the list are likely to be able to handle the minimum AaiH of 5 pounds of active ingredient. These grower lists are called Master Grower Lists and generally represent a random sub-sample of a Grower Universe List that includes the majority of growers in the particular site. The crops

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associated with each site in this study, and that grower lists are based on, are:

New York (Chautauqua, Erie, and Niagara Counties):

- Apples
- Grapes (any type)
- Cherries (any type)

Louisiana (East Carroll, Madison, and Tensas Parishes):

- Cotton
- Soybeans

Michigan (Oceana and Mason Counties):

- Apples
- Cherries (any type)
- Grapes (any type)
- Peaches
- Asparagus
- Snap beans

California (Fresno and Tulare Counties):

- Oranges
- Peaches
- Plums
- Grapes (any type)
- Celery
- Lettuce (any type)
- Tomatoes (any type)

Washington (Yakima and Benton Counties):

- Apples
- Cherries (any type)
- Pears
- Grapes (any type)

AHETF contractors with training or experience conducting telephone interviews will contact resources to generate the lists of growers (see SOP AHETF-11.K) and screen them for suitability for this study. This results in a randomly obtained Qualified Grower List that includes growers who might be eligible to cooperate with this study.

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4.2 Selecting Growers

AHETF researchers with training or experience conducting telephone interviews and familiarity with AHETF testing procedures will call all the growers on the Qualified Grower Lists to discuss their eligibility to cooperate with the study (see SOP AHETF-11.M). Growers are considered eligible who:

- Are willing to cooperate with AHETF, including the ethical aspects of the research,
- Are commercial agriculture operations,
- Utilize solid pesticides that are packaged in water soluble packets,
- Have at least one worker with experience mixing/loading water soluble packets,
- 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.

Growers who meet the criteria above but indicate they use commercial applicators to mix/load their products will be asked to identify their preferred commercial applicator(s). Researchers will contact them to screen them for willingness to cooperate by providing suitable equipment and allowing workers to be recruited to mix/load product for that grower. 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.

For each site, each grower identified as potentially 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:

- Specific location of mixing/loading sites
- Description of mixing/loading 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 the workers might be able to handle in a day

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If the grower calling process does not identify at least 10 workers who may potentially volunteer for the study, and at least 2 workers that are available for each of the AaiH strata, a new list of growers will be obtained and contacted until these criteria are met. This ensures a pool of potentially eligible growers and workers that is greater than are ultimately needed for the study.

This grower recruitment process results in a Potentially Eligible Grower List for each selected site and, by association, a random pool of workers associated with the growers.

4.3 Documenting Grower Selection

For each site, all discussions and decisions made during these list generation and eligibility screening processes will be documented in a detailed study notebook provided by AHETF or kept in files bearing the study number. For each site, the records shall include the number of:

- growers on the Grower Universe List
- growers on the Master Grower List
- growers on the Qualified Grower List
- growers contacted from the Qualified Grower List (direct discussion or voice message response from grower)
- growers on the Potentially Eligible Grower List (i.e., passed suitability screening, including willingness to cooperate)
- workers linked to each grower on the Potentially Eligible Grower List

5.0 EFFICIENT MU DESIGN

For each selected site, the Study Director will assemble the information obtained from the pool of potentially 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 configuration for that site (see Section 6). An efficient configuration will be comprised of a group of at least five 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. This is known as the Eligible Grower List. No grower may contribute more than one MU to this study and each MU must involve a unique worker and a different set-up of mixing/loading equipment. The growers and/or commercial applicators in the chosen configurations provide the pool of workers from which study participants will be recruited at each site.

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6.0 PARTICIPANT SELECTION

6.1 Site Inspection

For each selected site, the Study Director and/or Local Site Coordinator shall arrange to visit growers from the pool of potentially 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 farm 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. After confirmation of suitability, growers are added to the Eligible Grower List.

6.2 Participant Recruitment

For each selected site, AHETF will follow standard procedures (see SOP AHETF-11.B) to recruit potential participants for this water soluble packet mixing/loading study. Individual workers will be recruited during an initial site inspection or subsequent visit(s) to a potentially 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 using an informational recruitment flyer posted in a common work area. Such a flyer will briefly describe the research study and provide a toll-free phone number for employees to express an interest in participating 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 recruitment 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. A toll-free phone number 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

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handouts or visual aids, shall be reviewed and approved by an IRB prior to use in recruiting subjects.

For each selected site, 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 for that site. 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 one MU from any one grower or grower/commercial pesticide application company combination (this effectively requires 5 different employers since 5 MUs are desired)
- No worker may be used more than once
- No type of equipment (e.g., direct mixing into spray tank vs. mixing a slurry in a pre-mix tank) may be used more than once
- No piece of equipment may be used more than once (e.g., a particular sprayer used by two different workers from different growers)

As indicated above, the efficient configuration and Eligible Grower List must include enough growers and potential participants to fill all MUs for each selected site, 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 at that site.

6.3 Participant Selection and Consenting

For each selected site, the Study Director or designated researcher will contact workers (i.e., potential study participants) from growers in the efficient configuration to begin recruitment activities. When the pool of available worker volunteers at a site, or a particular commercial applicator operation, exceeds the number of MUs required, a simple random selection of equivalent volunteers will be made. For example, the names of the volunteers could be written on slips of paper of equal size and placed into a container and mixed thoroughly. A slip of paper would then be drawn from the container to fill the MU. All potential participants will be informed of the possibility of not being selected for this reason. Volunteer workers who are not selected will be released to resume their normal activities. The method of random selection will be documented in the study file.

Individual selected volunteers will be informed of study provisions to accommodate their language preference, to have a researcher read the consent form and other documents to non-readers, and to allow them to have a friend, family member or advisor present during an informed consent meeting. These

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language-related provisions are described in SOP AHETF-11.I.

The Study Director or designated researcher will arrange a place and schedule to conduct consent meetings with individual volunteers chosen from the eligible pool for each selected site. Prior to such meetings, accommodations will have been made for witnesses (if a non-reader is being consented) or bilingual researchers who must be present for the meeting (see SOP AHETF-11.I). Consent meetings shall be conducted as described in SOP AHETF-11.J.

6.4 Documenting Participant Selection

For each site, all discussions and decisions made during the participant recruitment and consenting processes will be documented in a detailed study notebook provided by AHETF or kept in files bearing the study number. For each site, the records shall include the number of:

- workers linked to each grower on the Eligible Grower List
- workers attending a recruitment meeting
- workers attending a consent meeting
- workers signing a consent form
- workers who signed a consent form, but were not selected for monitoring
- workers withdrawing at their own request (after monitoring began)
- workers removed from participation by AHETF
- workers completing participation

7.0 FIELD MATERIALS AND METHODS

7.1 Test System Identification - Workers

The test system for this study is the workers handling pesticides according to label directions. Workers may include farm owners, farm operators, farm employees, and contract applicator employees. Passive dermal dosimetry methods will be used to determine potential exposure of experienced workers handling the test substance. A total of 25 mixer/loaders are anticipated for this study (5 at each of five locations within the United States).

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 mixing/loading water soluble packets.

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The test substances selected for this study are registered and approved for use in a wide variety of agricultural settings. 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 Areas

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 these 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 mixing/loading 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. The most appropriate test substance, based largely on the preference of the grower, will be used at each of the individual sites.

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A different test substance may be used at each site and by each worker within a site if appropriate.

As previously described, eligible growers for each site 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 at each site, the grower will confirm the actual product he/she will be using on the day of the study. The researchers will ensure 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 monitoring 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.

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 a worker in the study 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 the 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.

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7.6 Mixing/Loading Parameters

Carrier:	Water.
Product Measurement:	Only whole packets may be used during mixing/loading.
Mixing Equipment:	A variety of mixing equipment are commonly utilized when mixing/loading water soluble packets. Within each cluster (i.e., site), at least one MU shall involve each of the following equipment-defined procedures: 1. Mixing of WSPs directly into the tank used for the application 2. Mixing of WSPs into a "pre-mix" tank in which the solution is at the same concentration as that applied to the crop 3. Mixing of WSPs into a tank (or other container) to make a concentrated solution that must be diluted & transferred to the final application tank Actual equipment and procedures used by each worker and for each load will be documented in study raw data.
Loading Equipment:	When appropriate, diluted (i.e., mixed) product may be transferred to another tank. This will most likely involve the use of pumps and hoses to transfer partially or fully diluted product from a pre-mix or holding tank to a piece of application equipment (such as a ground sprayer or aircraft). Actual equipment and procedures used by each worker and for each load will be documented in study raw data.
Route of application:	Applications might or might not be made during the mixer/loader monitoring period. Any appropriate application equipment may be utilized and study raw data will document what, if any, application equipment was used.

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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 during the mixing/loading process to measure the volume of liquid pumped into or out of a mixing or application tank.

Copies of relevant facility maintenance records (if available) for all mixing/loading equipment used for this study will be obtained and retained with the field raw data.

Workers will only be allowed to utilize equipment for which they are familiar and have used recently (within a year). 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 by each worker and other critical measurements including the volume of carrier will be determined and recorded in the raw data. Within each selected site, each worker will handle an amount of active ingredient (ai) 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 17 pounds ai handled
(2) 18 to 55 pounds ai handled
(3) 56 to 182 pounds ai handled
(4) 183 to 603 pounds ai handled
(5) 604 to 2,000 pounds ai handled

A single MU will be conducted from each of the five strata within each selected site. However, MUs handling acephate will be limited to 720 pounds of active ingredient.

Each MU shall consist of a period of at least 4 hours of mixing/loading and at least 3 tank loads of the spray mixture. 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 in SOP AHETF-10.E. Samples will be identified as described in SOP AHETF-8.F.

For this study, inner dosimeters will be cut into two sections after collection.

9.0 INHALATION EXPOSURE SAMPLING

Full details for sampling air with OSHA Versatile Sampler (OVS) tubes and personal air-sampling pumps are given in the most recent versions of SOP AHETF-8.D and 10.G.

The pumps and calibration equipment will be uniquely labeled and this information recorded in the raw data records. Each pump will be calibrated to a nominal sample flow rate of approximately 2 L/min. The OVS tubes will contain an appropriate adsorbent for the surrogate involved (e.g., chromosorb® 102 or XAD-2). The OVS tubes will be fully described in the study raw data.

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 monitoring period to be calculated. Workers will be instructed to inform a study team member if the pump fails to operate or the tubing becomes kinked.

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

Sample matrix fortifications designed to assess the stability of the active ingredient during field, transit and storage conditions in or on the sampling

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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 for each cluster of MUs, or more days as appropriate for environmental conditions. If more than one active ingredient is utilized at a particular location, at least one day of field fortifications will be conducted for each active.

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 the "by vial" spiking using active ingredient (ai) in an organic solvent will be followed for all matrices except OVS tubes. The tubes will be spiked at the laboratory with the proper amount of analytical standard.

In addition, for each fortification event, duplicate samples of the inner dosimeters fortified in the field at the highest level, and duplicate OVS tubes fortified in the laboratory at the next-to-highest fortification level, will be processed in the field 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.

For each fortification event, 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. All field fortification and untreated control samples will be identified as described in SOP AHETF-8.F.

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, 5.0, 500 and 1,000*

*The highest OVS tube fortification serves as a backup and will be analyzed if any worker OVS residues are found above 500 µg/sample.

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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. Photographs will be used to illustrate the condition of worker clothing before and after monitoring; and to provide visual documentation of the study for use by regulatory reviewers. None of the photographs shall result in identifying features of the workers.

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.

At each selected site, 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

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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 records 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.

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15.2 Analytical Methods

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.

The latest revisions of the following validated analytical methods will be used if the active ingredients are used during exposure monitoring:

Acephate Methods:

AHETF-AM-001 Determination of Acephate on Cotton Inner Dosimeters by Gary Westberg, Feb. 13, 2003

AHETF-AM-002 Determination of Acephate in Face/Neck Wipe Samples by Gary Westberg, Feb. 18, 2003

AHETF-AM-003 Determination of Acephate in Hand Wash Exposure Samples by Gary Westberg, Feb. 19, 2003

AHETF-AM-004 Determination of Acephate in OVS Air Sampling Tubes by Gary Westberg, Feb. 26, 2003

Carbaryl Methods:

AHETF method AHETF-AM-031, "Determination of Carbaryl in Cotton Inner Dosimeters Sectioned into Two Parts" by Frances Brookey and Gary Westberg, Morse Laboratories, Inc., June 5, 2008.

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.

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15.3 Analytical Calculations and Statistical Methods

Analytical calculation and statistical methods to be used are outlined in SOP AHETF-9.J.

16.0 STUDY RECORDS

16.1 Field Records

Raw data will be obtained to cover all aspects of the study and all sites, 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. Environmental conditions for the entire monitoring period, including data used for making determinations of potential heat stress indices
6. Approvals from the Institutional Review Board covering the protocol and the Informed Consent document, and all amendments to either document
7. All correspondence with the Institutional Review Board
8. 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)
9. Trial location maps, including description, dimensions, and exact locations of plots and mixing/loading stations
10. Pounds active ingredient handled, monitoring time, and volume of liquid mixed/loaded
11. Dermal exposure sampling information
12. Inhalation exposure sampling information, including pump identification, calibration, flow rates and times of sampling
13. Field recovery procedure information for all sampling media
14. Test and reference substance, and sample storage temperature records
15. Observations on work practices, including photographs
16. 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.D).

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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 request their personal study results when they are available. Individual results requested by subjects will be communicated in accordance with SOP AHETF-11.J.

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.

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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 of the study, 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

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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 by AHETF according to a standardized format. The report will contain a description of the conduct of the study and the analytical procedures and results for the study. 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 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

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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.

In accordance with the California Code of Regulations, 3 CCR 6710(h), the Study Director shall not make an amendment to the approved protocol that may impact the health of the human participants in California without approval from the Director of California Department of Pesticide Regulation (CDPR). For amendments where California participant health is potentially impacted, the Study Director shall make the request in writing.

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, laboratory SOPs or GLPs, must be communicated to the Study Director in a timely manner. Any deviations must also be reported to the study Sponsor, and the IRB. Deviations which occur in California must also be reported to CDPR. Protocol deviations are to be documented in accordance with SOP AHETF-2.C.

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Study AHE120 Informed Consent Form

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RESEARCH INFORMATION AND INFORMED CONSENT FORM

TITLE: (PROTOCOL AHE120) Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Pesticide Products in Water Soluble Packets in the United States

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:

Eric D. Bruce
21 Oak Knoll Ct.
Walnut Creek, CA 94596
Phone: 925-939-4987
Mobile: 925-708-5538
E-mail: eybruce@pacbell.net

FIELD LOCATIONS: _____
_____
_____

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 mix/load a pesticide in water soluble packets. This will be done by measuring the pesticide in the samples we collect from you. About 25 people will take part in this study. This study will be used to estimate exposure and risks to workers that handle water soluble packets.

It is entirely up to you whether or not you take part in this study. If you do take part in this study, you must understand and sign this consent form, a Product Risk Statement, and if in California the California Experimental Research Subject's Bill of Rights. The Product Risk Statement explains the risks from the pesticide. If we use words or give information you do not clearly understand, please ask me to explain. You may take an unsigned copy of this consent form to think about or discuss with family, friends, or researchers before making your decision. If you volunteer to be in this study, you will get a signed and dated copy of everything you sign.

ELIGIBILITY

To be eligible to participate in this study you must:

1. Have mixed and loaded pesticide products packaged in water soluble packets, and used the particular mixing/loading equipment you will use in this study, within the last year.

2. Handle pesticides as part of your job.

3. Confirm that you have been trained in pesticide safety or that you are not required to take this training.

4. Provide proof you are at least 18 years old with a government-issued photo ID.

5. Confirm you do not work for a pesticide company or a contractor of AHETF.

6. Consider your general health to be good Tell us if you have any medical conditions that affect your ability to take part in the study.

7. Not be pregnant or nursing. If you arefemale, you must take an over-the-counter urine pregnancy test before the study. More than one pregnancy test may be required. 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 shown to a female researcher or you cannot take part in the study.

8. Usually wear the personal protective equipment (PPE) listed on the Product Risk Statement and follow label directions.

9. 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.

10. Understand English or Spanish.

11. Understand and sign this consent form, a Product Risk Statement, and if in California the California Experimental Research Subject's Bill of Rights.

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STUDY DURATION

Your part in this study will take about 4-8 hours of your normal workday. This study may be conducted over 1 or more days.

PROCEDURES BEFORE THE START OF THE STUDY

Before you take part in the study, you will:

1. Give your name and age, as shown on a government-issued photo-ID.

2. Indicate if you have been trained in pesticide safety or if you are not required to take this training.

3. Tell researchers how many years you have been handling pesticide products packaged in water soluble packets. Tell researchers what mixing/loading equipment you normally use and when was the last time you used it.

4. Allow researchers to record your gender, age, ethnicity and preferred language. Allow researchers to measure and record your height and weight.

5. Let the researcher take notes about what is said during the consent meeting.

6. Agree to allow researchers to watch all your work activities and take notes on what you do.

7. Allow photographs and video recordings to be taken to document this research. You will not be photographed or video recorded while dressing or undressing. Your face will not be photographed. AHETF will own all rights to the photos and videos but will use them only to document this research. **If you do not want to be photographed or recorded you should not take part in this study.**

PROCEDURES ON THE DAY OF THE STUDY

On the day you are in the study you will report to work about 1 hour early to help us get you ready. You will be asked to take a bath or shower the night before or early that morning. You will be asked to wear a freshly washed long-sleeve shirt and long pants, plus shoes and socks. Then you will:

1. Go to a private changing area. Takeoff your shirt and pants and put on new long underwear over your own undergarments and then put your shirt and pants back on. Only a researcher of the same sex will be in the changing area to help. The long underwear will be provided by AHETF and will be collected at the end of the day.

2. Wear all of the PPE required by the label of the product to be used.

3. Wear a tube attached to your shirt collar and connected to a portable air-sampling pump worn on a belt around your waist. The pump may be uncomfortable or annoying.

4. Have your hands washed by a researcher before the study begins. A mild detergent and water mixture will be used.

5. Have your face and neck wiped with gauze pads moistened with a mild detergent and water mixture before the study begins.

6. Work about 4 to 8 hours mixing and loading a commercial pesticide product packaged in water soluble packets according to the product label. You will prepare at least 3 loads using your usual practices. Researchers will watch you work and take notes on what you do. Researchers may take photographs or video recordings to document the research. No photographs or video recordings will be made while you are dressing or undressing.

7. Have your hands washed with a mild detergent and water as needed for the study. Hand washes will occur before you eat anything, at any time you would normally wash your hands (such as before using the toilet), and at the end of the day. The water from these hand washes will be saved for analysis.

8. Have your face and neck wiped with gauze pads moistened with a mild detergent and water mixture before you eat anything, any time you would normally wash your face, and at the end of the day. The gauze pads will be saved for analysis.

9. At the end of the study day you will return to the private changing area. Only a researcher of the same sex will be in the changing area to help you take off your shirt and pants and the long underwear. The long underwear will be collected by the researcher. You will put your own shirt and pants back on and return to your normal work schedule.

PRODUCT HANDLED

You will be asked to mix/load a pesticide product that is registered by the US Environmental Protection Agency (EPA). This product is packaged in water soluble packets and the active ingredient will be acephate or carbaryl. The farm or operation management will choose the product that you will use. However, you will know which product you will handle before you sign this consent form.

In addition to the pesticide you will mix/load, farm or operation management may want other registered or approved products added to the mixing or spray tank. You will be told before you start which materials will be in the tank mix.

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RISKS AND DISCOMFORTS

You will be asked to sign a Product Risk Statement. This is a document that contains important information about the product you will use in this study. It includes the name of the product you will mix and load, how much of that product you might mix and load during the study, the risks of handling that product, and what personal protective equipment you must wear.

In addition, this document tells you of possible side-effects from using this product and how you can tell if you are overexposed. If you feel any of the side-effects or think you were overexposed during or after the workday, or do not feel well for any reason, contact a researcher right away.

The label and Material Safety Data Sheet (MSDS) for this product will be on hand for you to look over and talk about at any time you want.

Because you will wear long underwear underneath your normal work clothes, you have a risk of getting 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 right away. If you don't feel well for any reason, notify a researcher right away. A researcher will be watching you for these signs. AHETF will stop your work if the weather gets too hot.

As a safety measure, AHETF will have a medical professional on site during the study. This may be a paramedic, physician's assistant, nurse, or emergency medical technician. This professional will also watch you for signs of illness. They will provide medical attention as needed.

You may have other risks or discomforts, including:

- Eye or skin irritation from the detergent and water mixture used to wash 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

There may be other risks that are not known at this time. You will be told in a timely manner both verbally and in writing of any new information. This new information might cause you to change your mind about being in the study.

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INJURY TO PARTICIPANTS

If you are injured or get sick because of your participation in this study, medical treatment will be available at your workplace and at a nearby health care facility. If necessary, AHETF will arrange to have you taken to receive medical attention. You may refuse medical treatment *unless* you get sick from too much exposure to pesticides or from getting too hot, or if we believe you are too sick to make a rational decision about getting medical treatment.

AHETF will cover the cost of reasonable and appropriate medical attention for a study-related injury or illness that is not covered by your own insurance or insurance provided through your employer. This includes deductible costs and any out-of-pocket expenses, including co-payments, you might have. The Study Director, in consultation with the on-site medical professional, will decide if you have an illness or injury that is due to your participation in this study.

The medical treatment records will not become part of the research records. AHETF will make note of the event. The event will be reported in the study report. For further information about this, you may call the AHETF Manager (David Johnson) toll free at (866) 925-1421 (24-hour service in English or Spanish).

You will not give up any of your legal rights by signing this form.

CONFIDENTIALITY

Your name will only appear on the consent form, the Product Risk Statement, an optional form for you to request your personal study results, and if in California the California Experimental Research Subject's Bill of Rights. In all other parts of the study you will be identified by a code. Records with your name will be stored in a secure place with limited access.

Information about you taking part 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 in the study report.

We cannot promise you total confidentiality. There may be a need to give information to some organizations or to parties in legal actions, as required by law. Records which identify you may be looked at or copied by the AHETF and any consultants working with the AHETF, 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 take part are protected.

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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 taking part in this study.

BENEFITS

You will not directly benefit from taking part in the study. The farm owner may benefit since AHETF will reimburse the owner for the product used in the study. Information from this study will improve our understanding of the exposure to workers who mix/load pesticides packaged in water soluble packets.

PAYMENT FOR PARTICIPATION

You will be paid $20 if you meet privately with a researcher to review this informed consent form. 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 each day you are in the study. You will be paid $80 when you finish each sampling day and let us 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 be paid 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 will take part by picking randomly, for example by drawing names from a hat or flipping a coin. You may or may not be selected to take part. 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 take part in this study or not. Your decision to be in this study is voluntary. This decision is entirely up to you. If you decide to take part, you may change your mind and drop out of the study at any time and for any reason. A decision not to take part, or to withdraw from the study after it starts, will not affect your job or pay or include any penalty or any loss of benefits you are owed.

If you withdraw, the long underwear and air sampling pump will be removed. The hand and face/neck samples may be collected if you agree.

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Your part in this study may be stopped at any time by the researchers or the AHETF. The long underwear and air sampling pump will be removed. The hand and face/neck samples may be collected if you agree.

If you withdraw or are removed from the study, you can go back to your usual work activities. If the study does not last an entire workday, you can go back to your usual work activities.

ALTERNATIVES

No one can force you to take part in this study. Taking part is totally voluntary. If you choose not to take part in this study you will perform your ordinary activities on the day of the study. Your alternative is to not take part.

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:

Eric D. Bruce (Study Director) or
David Johnson, Ph.D. (AHETF contact).
Toll free (866) 925-1421 (24-hour service in English or Spanish)

If you have any questions regarding your rights as a research volunteer, please contact Kim Lerner, Chair of the Independent Investigational Review Board, Inc. toll free at 1-(877) 888-iirb (4472) during their regular working hours. Based on your time zone, you can call during the following hours:

Eastern Time: 9:00 a.m. – 5:00 p.m.
Central Time: 8:00 a.m. – 4:00 p.m.
Mountain Time: 7:00 a.m. – 3:00 p.m.
Pacific Time: 6:00 a.m. – 2:00 p.m.

You can also contact the Independent Investigational Review Board, Inc. if you would like to report problems in a research study, express concerns, ask questions, request information, or provide input. The Independent Investigational Review Board is a committee established to protect the rights of volunteers in research studies. For more information about your rights and role as a research participant you can visit the Research Participant section of the IIRB, Inc. website at www.iirb.com.

Do not sign this consent form unless you were able to ask questions and you are happy with the answers you got.

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CONSENT

I have read the information in this consent form, the Product Risk Statement, and if in California the California Experimental Research Subject's Bill of Rights (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 AHETF, 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/Time Subject's Name (print)

_____
Subject's Signature

_____
Subject's Unique Worker Code

I conducted the private consent meeting with the worker named above. I confirm that the worker's consent was given voluntarily after being fully informed and having apparent understanding about the study. In addition, this worker has reviewed and signed the Product Risk Statement and if in California the California Experimental Research Subject's Bill of Rights which I will store along with this signed consent form in a secure location:

_____ _____
Date/Time 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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---------- Use the following only if applicable ----------

If this consent form is read to the worker because the worker is unable to read the form, a witness who is not associated with the research must be present to witness the consent process and sign the following statement:

I confirm that the information in the consent form and any other written information were accurately read to this worker.

_____ _____
Date/Time Witness' Name (print)

_____
Witness' Signature

_____
Title and Affiliation of 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) _____

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California Experimental Research Subject's Bill of Rights – English and Spanish

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RESEARCH PARTICIPANT BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told what the study is trying to find out.
2. To be told what will happen to me and whether any of the procedures, pesticides or devices is different from what would be used in standard practice.
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes.
4. To be told if I can expect any benefit from participating and, if so, what the benefit might be.
5. To be told the other choices I have and how they may be better or worse than being in the study.
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study.
7. To be told what sort of medical treatment is available if any complications arise.
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study.
9. To receive a copy of the signed and dated consent form.
10. To be free of pressure when considering whether I wish to agree to be in the study.

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DECLARACION DE DERECHOS
DE PERSONAS QUE PARTICIPAN EN UNA INVESTIGACION

Toda persona que participa en un estudio tiene los derechos aquí enumerados. Yo, como participante en una investigación tengo los siguientes derechos:

1. A ser informado del propósito del estudio.

2. A ser informado que me pasará y si alguno de los procedimientos, pesticidas o aparatos a usarse son distintos de los que se usan en la práctica normal.

3. A ser informado de los riesgos frecuentes y de importancia, los efectos secundarios o los malestares a que me veré sometido durante este estudio.

4. A ser informado si puedo esperar algún beneficio por participar en el estudio y si es así, cuales serían estos beneficios.

5. A ser informado si tengo otras alternativas y si estas serían mejores o peores que participar en el estudio.

6. A que se me permita hacer cualquier pregunta relacionada con el estudio, ya sea antes o después de acceder a participar en él, o durante el transcurso de este.

7. A ser informado que tratamientos médicos existen en caso que surgiera alguna complicación.

8. A rehusar totalmente a participar en el estudio, o a salirme de este cuando ha comenzado. Esta decisión no afectará mi derecho a recibir el tratamiento que recibiría si no participara en la investigación.

9. A recibir una copia del documento de consentimiento fechada y firmada.

10. A no ser presionado en forma alguna respecto a la decisión de participar o no en el estudio.

Recruitment Flyer

US EPA ARCHIVE DOCUMENT

Study Number: AHE120

Research Study Volunteers

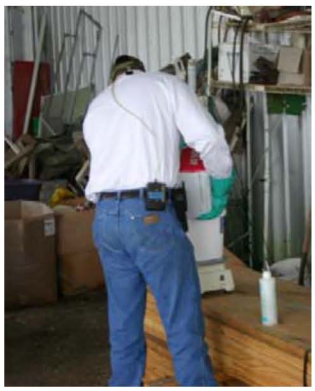
The Agricultural Handlers Exposure Task Force (AHETF) is a group of pesticide companies doing research to measure how much chemical gets on workers when they handle pesticides. The AHETF is looking for experienced workers to perform their usual work of mixing and loading pesticides packaged in water soluble bags, and to let the AHETF collect exposure data.

To volunteer you must:

- Be at least 18 years old with a government-issued photo ID
- Understand English or Spanish
- Be in good health
- Not work for a pesticide manufacturer or a contractor of AHETF
- Not be pregnant or nursing
- Be experienced and trained in handling pesticides

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 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 risk to agricultural workers

If you are interested, please contact the Study Director:

Eric Bruce
(866) 925-1421
Toll Free

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

US EPA ARCHIVE DOCUMENT

Product Risk Statements

US EPA ARCHIVE DOCUMENT

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE120) Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Water Soluble Packets in the United States

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:
Eric D. Bruce
21 Oak Knoll Court
Walnut Creek, CA 94596
Phone: 925-708-5538
E-mail: eybruce@pacbell.net

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: Acephate 75 WSP® (EPA Registration No. 70506-1)

Active Ingredient (AI): Acephate (insecticide, CAS No. 30560-19-1)

Formulation and Packaging: 75% AI powder in a 1 lb. water soluble packet

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You may handle up to: 960 water soluble packets

Required Personal Protective Equipment (PPE) for Handling: Mixer/loaders must wear long-sleeved shirt and long pants, and shoes plus socks. You must also wear chemical-resistant gloves. In case of emergency (e.g., broken package) you must also have immediately available coveralls, chemical-resistant footwear, and an approved respirator.

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 acephate 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 minimal 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 identifier: Rev. 2/7/08 70506-1(030308-2774) (last page)
MSDS date: 12-Apr-2007 (UPI)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

US EPA ARCHIVE DOCUMENT

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE120) Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Water Soluble Packets in the United States

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:
Eric D. Bruce
21 Oak Knoll Court
Walnut Creek, CA 94596
Phone: 925-708-5538
E-mail: eybruce@pacbell.net

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.

The product you will handle is identified as follows:

Name: Acephate 90 WSP® (EPA Registration No. 70506-2)

Active Ingredient (AI): Acephate (insecticide, CAS No. 30560-19-1)

Formulation and Packaging: 90% AI powder in a 2.5 pound water soluble packet

US EPA ARCHIVE DOCUMENT

You may handle up to: 320 water soluble packets

Required Personal Protective Equipment (PPE) for Handling: Mixer/loaders must wear long-sleeved shirt and long pants, and shoes plus socks. You must also wear chemical-resistant gloves. In case of emergency (e.g., broken package) you must also have immediately available coveralls, chemical-resistant footwear, and an approved respirator.

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 acephate 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 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 identifier: Rev. 2/07/08 70506-2(031808-2967) (last page)
MSDS date: 12-Apr-2007 (UPI)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Product Risk Statement
Risk of Toxicity from Pesticide Product Handled
(Must be attached to the Informed Consent Form)

TITLE: (PROTOCOL AHE120) Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Water Soluble Packets in the United States

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:
Eric D. Bruce
21 Oak Knoll Court
Walnut Creek, CA 94596
Phone: 925-708-5538
E-mail: eybruce@pacbell.net

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® 80 Solupak (EPA Registration No. 264-316)

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

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You may handle up to: 2,000 water soluble packs

Required Personal Protective Equipment (PPE) for Handling: Mixer/loaders must wear long-sleeved shirt and long pants, and shoes plus socks. You must also wear chemical-resistant gloves.

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 or moderate 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: 7/19/06
MSDS date: 8/3/06 (number 102000004247)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

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Pesticide Product Labels

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Acephate 75 WSP®

Insecticide

(Soluble Powder Insecticide in Water-Soluble Pouches)

ACTIVE INGREDIENT	By Wt.
Acephate (O, S-Dimethyl acetylphosphoramidothioate)	75%
OTHER INGREDIENTS	25%
TOTAL	100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

Contains an organophosphate that inhibits cholinesterase.

If swallowed	• Call a poison control center or doctor immediately for treatment advice. • 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 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 by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.

FOR EMERGENCY MEDICAL ASSISTANCE, CALL THE ROCKY MOUNTAIN POISON CENTER 1-866-673-6671.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN

Acephate is a cholinesterase inhibitor. If signs of cholinesterase inhibition appear, atropine is antidotal. 2-PAM may also be used in conjunction with atropine but should not be used alone.

FOR CHEMICAL EMERGENCY: Spill, leak, fire, exposure, or accident, call CHEMTREC 1-800-424-9300

EPA Reg. No. 70506-1

EPA Est. No. 65387-AR-002

Net Contents: 5-1 lb. bags

United Phosphorus, Inc.
630 Freedom Business Center, Suite 402
King of Prussia, PA 19406
1-800-438-6071 • www.upi-usa.com

PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND DOMESTIC ANIMALS

Caution. Harmful if swallowed. Causes eye irritation.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are butyl, nitrile and neoprene. If you want more options, follow the instructions for category A on an EPA chemical-resistance category selection chart.

Mixers, Loaders, Applicators, and Other Handlers must wear: Long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves for all mixers and loaders and for applicators using hand held application equipment.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

See engineering controls for additional requirements.

ENGINEERING CONTROLS

Water-soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must:

- wear the personal protective equipment required above for mixers/loaders and
- be provided, must have immediately available and must use in an emergency, such as a broken package, spill, or equipment breakdown the following PPE: coveralls, chemical-resistant footwear and a NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH-approved respirator with any N, R, P, or HE filter.

Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)].

The use of human flaggers is prohibited.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE 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 birds. 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 cleaning equipment or disposing of equipment washwaters.

Cover or soil-incorporate spills.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Eliminations System (NPDES) permitted and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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 while 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.

READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.

Do not apply using low pressure handwand equipment.

Not for indoor residential use. For greenhouse use, use is limited to commercial greenhouses for use on ornamental, floral and foliage plants, and tobacco (float bed application).

For use on turf, use limited to sod farms and golf courses, except when applying to mound or spot treatment for fire ant control.

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.

DRIFT MANAGEMENT

A variety of factors including weather conditions, (e.g. wind direction, wind speed, temperature, relative humidity) and method of application (e.g. ground, aerial, Airblast, chemigation) can influence pesticide drift. The applicator and grower must evaluate all factors and make appropriate adjustments when applying this product.

Observe the following precautions to minimize drift:

- All aerial, ground and air-assisted/airblast application equipment must be properly maintained and calibrated using water as carrier. Do not apply this product as an ultralow (ULV) spray or in any carrier other than water except when specified by the Use Instructions.
- Use the largest droplet size consistent with good pest control. Small droplets are more prone to spray drift and can be minimized by appropriate nozzle selection, by orienting nozzles away from the air stream as much as possible, and by avoiding excessive spray boom pressure.
- Do not apply at wind speeds greater than 10 mph at the application site.
- Make applications when wind velocity favors on-target product deposition (approximately 3 to 10 mph).
- Apply as close to target plants as practical to obtain a good spray pattern for adequate coverage.
- For aerial applications, do not apply at heights greater than 10 feet (consistent with flight safety).
- For airblast applications, direct spray above foliage and turn off outward pointing nozzles at row ends and outer rows.
- For aerial applications, the spray boom should be mounted on the aircraft so as to minimize drift caused by wing tip vortices. The minimum practical boom length should be used and must not exceed 75% of wing span or rotor diameter.
- For ground applications, do not apply at heights greater than 4 feet.

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.

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 until restricted-entry interval (REI) of **24 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 made of any waterproof material, and shoes plus socks

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, or greenhouses.

Do not enter or allow others to enter until sprays have dried.

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DIRECTIONS

CHEMIGATION

Apply to cranberries only by sprinkler irrigation systems. Do not apply by chemigation to any other crop, or this crop using any other type of irrigation system.

TANK MIXES

NOTICE: Tank mixing of this product with any other product which is not specifically and expressly authorized by the label shall be the exclusive risk of the user, applicator and/or application advisor.

Read and follow the entire label of each product to be used in the tank mix with this product.

TABLE OF EQUIVALENTS

1 Lb. Water Soluble Pouch

AMOUNT OF ACEPHATE 75 WSP PER ACRE	ACRES TREATED BY A 1 LB. PACKAGE (1 LB. WATER-SOLUBLE POUCH)	ACRES TREATED BY A 5 LB. PACKAGE (5 X 1 LB. WATER-SOLUBLE POUCHES)
⅛ lb.	8.00	40.00
⅙ lb.	6.00	30.00
3 oz.	5.33	26.67
4 oz.	4.00	20.00
⅓ lb.	3.00	15.00
⅔ lb.	1.50	7.50
1 lb.	1.00	5.00
1 ⅓ lbs.	0.75	3.75

⅓ Lb. Water Soluble Pouch

AMOUNT OF ACEPHATE 75 WSP PER ACRE	ACRES TREATED PER ⅓ LB. PACKAGE (⅓ LB. WATER-SOLUBLE POUCH)	ACRES TREATED BY A 1 LB. PACKAGE (3 x ⅓ LB. WATER-SOLUBLE POUCHES)
4 oz.	1.3	4.00
⅓ lb.	1	3.00
⅔ lb.	0.5	1.50
1 lb.	0.33	1.00
1 ⅓ lbs.	0.25	0.75
2 ⅔ lbs.	0.125	0.375
6 ⅔ lbs.	0.05	0.15

GENERAL INFORMATION

ACEPHATE 75 WSP is an insecticide for control of pests on selected agricultural crops and in certain non-crop areas. The active ingredient in ACEPHATE 75 WSP is acephate, a water soluble insecticide readily absorbed by plant roots and foliage to give systemic control of feeding insects. Insect pests are generally controlled more effectively by ACEPHATE 75 WSP through ingestion than by contact. Application of ACEPHATE 75 WSP to maintain control should be repeated only as directed.

FAILURE TO FOLLOW THE DIRECTION FOR USE AND PRECAUTIONS ON THIS LABEL MAY RESULT IN POOR INSECT CONTROL, CROP INJURY, AND/OR ILLEGAL RESIDUES.

Do not apply under conditions involving possible drift to food, forage or other plantings that might be damaged or the crops thereof rendered unfit for sale, use or consumption.

NOTE: This product is sold by weight and package is full when packed, but due to the product's nature, settling is likely to occur.

HANDLING

The enclosed pouches are water-soluble. **Do not** allow pouches to become wet prior to adding to the spray tank. **Do not** handle pouches with wet hands or wet gloves. Always reseal overwrap bag to protect remaining unused pouches. **Do not** remove water-soluble pouches from overwrap except to add directly to the spray tank.

PREPARATION OF SPRAY SOLUTION

To prepare spray solution, drop the unopened packet(s) of ACEPHATE 75 WSP into a spray tank containing at least one-half of the total quantity of water required. Add remaining water with the agitator running until the spray volume is reached. Do not add any liquid fertilizers, micronutrients or adjuvants to the spray solution until the ACEPHATE 75 WSP has completely dissolved. ACEPHATE 75 WSP should completely dissolve in approximately five minutes. Dissolution rate may be slowed by cold water, lack of agitation, or water containing high concentrations of boron or sulfur.

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BEANS AND LIMA BEANS – Dry and Succulent Forms

INSECTS	AMOUNT ACEPHATE 75 WSP PER ACRE	USE INSTRUCTIONS	DAYS TO HARVEST
Fleahoppers Grasshoppers	⅓ to ⅔ lb.	Apply in water at a minimum of 2 gals. spray per acre by air or 20 to 100 gals. spray per acre by ground. Apply when eggs or insects first appear. Repeat at 3 day intervals for application rates up to ⅔ lb./A and 7 day intervals for application rates greater than ⅔ lb./A but do not exceed maximum application rate of 2 ⅔ lbs. of ACEPHATE 75 WSP per acre per crop cycle. For severe insect infestations, use higher rates.	1 (lima beans – succulent form) 14 (snap-beans – succulent or dry beans)
Aphids (excluding Black Bean Aphid) Bean Leaf Beetle Bean Leafroller Cabbage Looper Cutworms Green Cloverworm Leafhoppers Mexican Bean Beetle Plant Bugs (Lygus) Soybean Looper Thrips Whitefly (Except Sweetpotato or Silverleaf Whitefly)	⅔ to 1 ⅓ lbs.		
Armyworms (excluding Beet Armyworm) Corn Earworm European Corn Borer	1 to 1 ⅓ lbs.		

USE PRECAUTIONS:

- Do not apply more than 2 ⅔ lbs. of ACEPHATE 75 WSP per acre per crop cycle.
- Do not feed treated vines to livestock.

CELERY

INSECTS	AMOUNT ACEPHATE 75 WSP PER ACRE	USE INSTRUCTIONS	DAYS TO HARVEST
Green Peach Aphid	⅔ to 1 ⅓ lbs.	Apply in water at 50 to 100 gals. spray per acre by ground or in a minimum of 5 gals. per acre by air. Apply when eggs or insects first appear. Repeat at 3 day intervals for application rates up to ⅔ lb./A and at 7 day intervals for application rates greater than ⅔ lb./A but do not exceed maximum application rate of 2 ⅔ lbs. of ACEPHATE 75 WSP per acre per crop cycle.	21
Fall Armyworms Cabbage Looper	1 ⅓ lbs.		

USE PRECAUTIONS:

- All celery must be trimmed (tops removed) before shipment for use.
- Do not use trimmed (tops) for food or feed.
- Do not apply more than 2 ⅔ lbs. of ACEPHATE 75 WSP per acre per crop cycle.

COLE CROPS
Brussels Sprouts & Cauliflower

INSECTS	AMOUNT ACEPHATE 75 WSP PER ACRE	USE INSTRUCTIONS	DAYS TO HARVEST
Green Peach Aphid	⅔ to 1 ⅓ lbs.	Apply in water at 25 to 150 gals. spray per acre by ground or a minimum of 5 gals. spray per acre by air. Use the higher rate when heavy infestations of aphids are present. Begin application when insects or eggs first appear. Repeat at 3 day intervals for application rates up to ⅔ lb./A and 7 day intervals for application rates greater than ⅔ lb./A but do not exceed maximum application rate of 2 ⅔ lbs. of ACEPHATE 75 WSP per acre per crop cycle. Diamondback Moth Larvae – This insect has demonstrated an ability to develop resistance to various classes of insecticides. Consult your local Agricultural Extension Service for current recommended control practices for this insect.	14
Cabbage Looper Diamondback Moth Larvae Imported Cabbage Worm	1 ⅓ lbs.		

USE PRECAUTIONS:
- Do not apply more than 2 ⅔ lbs. of ACEPHATE 75 WSP per acre per crop cycle.
- Do not feed trimmings to livestock or allow animals to graze in treated areas.

COTTON

GENERAL USE PRECAUTIONS:
Do not feed gin trash or treated forage to livestock.

Do not allow animals to graze on treated areas.

Do not apply more than 5 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle. This limitation includes all methods of application; i.e. in-furrow, and foliar.

When applied by air, do not apply more than 1 lb. a.i./A in California and Arizona. Do not apply more than 0.75 lb. a.i. for all other areas of the US.

COTTON IN-FURROW APPLICATION

INSECTS	AMOUNT ACEPHATE 75 WSP PER ACRE	USE INSTRUCTIONS
Aphids* Thrips Black (Greasy) Cutworm (Except CA) *Excluding Cotton Aphids in AZ & CA	⅔ to 1 ⅓ lbs. NOTE: for the Blacklands of Texas use 1 ⅓ lbs. per acre ACEPHATE 75 WSP	Apply ACEPHATE 75 WSP in 3 to 5 gals. of water per acre as an in-furrow spray. ACEPHATE 75 WSP can be mixed with fungicides that are sprayed in-furrow for disease control. Flat-fan nozzles used for in-furrow application should be set so that the fanned spray pattern is aligned with the row to insure good spray deposition in the seed furrow. Cone type nozzles may not provide a spray pattern that insures maximum spray deposition in the seed furrow, and should be avoided. Spray systems that employ metal or plastic tubing for delivery of spray solution into the seed furrow should have tubing securely fastened to the furrow opener and should be checked frequently to insure that the tubing is properly positioned to deposit spray solution into the seed furrow.

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FOLIAR APPLICATION

INSECTS	AMOUNT ACEPHATE 75 WSP PER ACRE	USE INSTRUCTIONS	DAYS TO HARVEST
Thrips	3 to 4 oz.	Apply in water at 3 to 10 gals. spray per acre by air (minimum 5 gals. per acre in CA and AZ) or 10 to 25 gals. spray per acre by ground. By Air: Do not apply more than 1 ⅓ lbs./A to cotton grown in California and Arizona. Do not apply more than 1 lb./A for all other areas of the United States. Apply when eggs or insects first appear. Repeat at 3 day intervals for application rates up to ⅔ lb./A and 7 day intervals for application rates greater than ⅔ lb./A. Do not exceed maximum application rate of 5 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle. Lygus – Use higher rate for lygus adults that have migrated into cotton. Cotton Aphid – This insect may develop resistance to various classes of insecticides. Consult your local Agricultural Extension Service for current control recommendations. Armyworms & Cabbage Looper – Apply when eggs appear and repeat at 7 day spray intervals but, do not exceed maximum application rate of 5 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle. Bollworm and Tobacco Budworm – Early season light infestation use ⅔ lb. per acre. Mid and late season moderate to severe infestations use 1 to 1 ⅓ lbs. per acre. Apply when eggs appear and repeat at 7 day spray interval but, do not exceed maximum application rate of 5 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle. Adult/Larvae: Moths are controlled when they come in direct contact with spray particles during application. Moth kill is most likely to occur when application is made late in the evenings during periods of peak activity. DEADHATCH®: Control of emerging larvae by consumption of treated egg casings. Pink Bollworm – Apply when insects appear and repeat at a 7 day spray interval but, do not exceed maximum application rate of 5 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle.	21
Plant Bugs (Lygus)	⅓ to 1 ⅓ lbs. 1 to 1 ⅓ lbs. (CA and AZ)		
Fleahopper	⅓ lb.		
Cotton Aphid (excluding AZ and CA)	⅔ to 1 ⅓ lbs.		
Whitefly (excluding Sweetpotato/ Silverleaf Whitefly)	⅔ to 1 ⅓ lbs.		
Armyworms (excluding Beet Armyworm) Cabbage Looper	1 ⅓ lbs.		
Bollworm Tobacco Budworm Adults Larvae Eggs (DEADHATCH®)	⅔ to 1 ⅓ lbs. (East of Rockies) 1 ⅓ lbs. (CA & AZ)		
Stinkbugs	1 lb.		
Pink Bollworm (AZ & CA)	1 ⅓ lbs.		
Cutworms	1 lb.	Cutworms – Ground application is recommended. Aerial applications are less effective, but may be used. For Air: Do not apply more than 1 lb./A. Control is most effective when ground application is made in the evenings and sprays are directed toward the base and lower portion of plant. Apply when insects first appear or damage is first noted and repeat at 3 day intervals for application rates up to ⅔ lb./A and 7 day intervals for application rates greater than ⅔ lb./A. Do not exceed maximum application rate of 5 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle.	21

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COTTON TANK MIXES

GENERAL USE PRECAUTIONS:

Do not feed gin trash or treated forage to livestock.

Do not allow livestock to graze on treated areas.

Do not apply more than 5 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle. This limitation includes all methods of application; i.e. in-furrow, and foliar.

Always read and follow all label directions when using any pesticide alone or in tank mix combinations. Observe all restrictions and precautions which appear on all product labels. The most restrictive labeling applies when using a tank mix.

RESISTANCE-MANAGEMENT

Cotton pest control programs, especially those for control of Sweetpotato/Silverleaf Whitefly populations, should employ a properly designed resistance-management strategy. Such resistance-management strategies include mixture or rotation of alternative classes of chemistry including organophosphates, carbamates, pyrethroids or insect growth regulators. Consult your state or area agricultural extension service for local resistance-management strategies and advice on alternative insecticides.

INSECTS	AMOUNT ACEPHATE 75 WSP + LORSBAN® 4E PER ACRE	USE INSTRUCTIONS	DAYS TO HARVEST
Armyworms (excluding Beet Armyworm) Bollworms Cabbage Looper Cotton Aphid Cutworms Fleahopper Grasshoppers Pink Bollworm Plant Bugs (Lygus, Mirids) Salt Marsh Caterpillar Thrips Tobacco Budworm Whitefly (excluding Sweetpotato/ Silverleaf Whitefly)	⅓ to 1 ⅓ lbs. ACEPHATE 75 WSP + 1 to 2 pts. LORSBAN® 4E	Always read and follow all label directions when using any pesticide alone or in tank mix combinations. Observe all restrictions and precautions which appear on all product labels. The most restrictive labeling applies when using a tank mix. Cutworms: Use 1 lb. per acre of ACEPHATE 75 WSP. By Ground: Ground application is recommended. Apply in 10 to 25 gals. of spray per acre. Control is most effective when ground application is made in the evenings and sprays are directed toward the base and lower portion of plant. By Air: Aerial applications are less effective, but may be used. Apply in 3 to 10 gals. spray per acre (minimum 5 gals. spray per acre in CA). Do not apply more than 1 ⅓ lbs./A of ACEPHATE 75 WSP to cotton grown in California and Arizona. Do not apply more than 1 lb./A for all other areas of the United States. Apply when insects first appear or when damage is first noted and repeat at 3 day intervals for application rates up to ⅔ lb./A of ACEPHATE 75 WSP and 7 day intervals for application rates greater than ⅔ lb./A of ACEPHATE 75 WSP but, do not exceed maximum application rate of 5 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle.	21

INSECTS	AMOUNT ACEPHATE 75 WSP + DANITOL® 2.4 EC PER ACRE	USE INSTRUCTIONS	DAYS TO HARVEST
Sweetpotato Whitefly (Silverleaf Whitefly)	⅔ lb. ACEPHATE 75 WSP + 10 ⅔ to 16 fl. oz. DANITOL® 2.4 EC	Apply in water at 3 to 10 gals. spray per acre by air (minimum 5 gals. per acre in CA) or 10 to 25 gals. spray per acre by ground. By Air: Do not apply more than ⅔ lb./A of ACEPHATE 75 WSP. Always read and follow all label directions when using any pesticide alone or in tank mix combinations. Observe all restrictions and precautions which appear on all product labels. The most restrictive labeling applies when using a tank mix. Apply when insects first appear or when damage is first noted and repeat at 3 day intervals. Do not exceed maximum application rate of 5 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle.	21

COTTON TANK MIXES WITH PYRETHROIDS

GENERAL USE PRECAUTIONS:

Do not feed gin trash or treated forage to livestock.

Do not allow livestock to graze on treated areas.

Do not apply more than 5 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle. This limitation includes all methods of application; i.e. in-furrow, and foliar.

Synthetic Pyrethroids should be used within the guidelines of state and/or regional resistance-management programs and recommendations.

Always read and follow all label directions when using any pesticide alone or in tank mix combinations. Observe all restrictions and precautions which appear on all product labels. The most restrictive labeling applies when using a tank mix.

RESISTANCE-MANAGEMENT

Cotton pest control programs, especially those for control of Sweetpotato/Silverleaf Whitefly populations, should employ a properly designed resistance-management strategy. Such resistance-management strategies include mixture or rotation of alternative classes of chemistry including organophosphates, carbamates, pyrethroids or insect growth regulators. Consult your state or area agricultural extension service for local resistance-management strategies and advice on alternative insecticides.

INSECTS	ACEPHATE 75 WSP AND TANK MIX PARTNER	AMOUNT OF ACEPHATE 75 WSP + TANK MIX PARTNER PER ACRE	USE INSTRUCTIONS	DAYS TO HARVEST
Aphids Bollworm Cabbage Looper Cotton Leaf Perforator Cutworms* Fall Armyworm Fleahoppers Pink Bollworm (AZ & CA) Plantbugs Stinkbugs* Sweetpotato/ Silverleaf Whitefly Tobacco Thrips Tobacco Budworm Whitefly	ACEPHATE 75 WSP + one of the following	⅔ to 1 ⅓ lbs. per acre + one of the following	Apply in water at 3 to 10 gals. spray per acre by air (minimum 5 gals. per acre in CA) or 10 to 25 gals. spray per acre by ground. Begin applications when eggs or insects appear and repeat at 3 day intervals for application rates up to ⅔ lb./A of ACEPHATE 75 WSP and 7 day intervals for application rates greater than ⅔ lb./A of ACEPHATE 75 WSP but, do not exceed maximum application rate of 5 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle. * Stinkbugs: Use 1 lb. per acre of ACEPHATE 75 WSP. * Cutworms: Use 1 lb. per acre of ACEPHATE 75 WSP By Ground: Ground application is recommended. Control is most effective when ground application is made in the evenings and sprays are directed toward the base and lower portion of the plant. By Air: Aerial applications are less effective, but may be used. Apply when eggs or insects first appear or damage is first noted. Do not apply more than 1 ⅓ lbs./A of ACEPHATE 75 WSP to cotton grown in California and Arizona. Do not apply more than 1 lb./A of ACEPHATE 75 WSP for all other areas of the United States. Repeat at 3 day intervals for application rates up to ⅔ lb./A of ACEPHATE 75 WSP and 7 day intervals for application rates greater than ⅔ lb./A of ACEPHATE 75 WSP but do not exceed maximum application rate of 5 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle.	21
	AMMO® 2.5 EC*	Refer to the AMMO® 2.5 EC* approved label for use instructions.		
	ASANA® XL*	Refer to the ASANA® XL approved label for use instructions.		
	BAYTHROID® 2 EC	Refer to the BAYTHROID® 2 EC approved label for use instructions.		
	CAPTURE® 2 EC	Refer to the CAPTURE® 2 EC approved label for use instructions.		
	KARATE® 1 EC (Except CA)	Refer to the KARATE® 1 EC approved label for use instructions.		
	SCOUT® X-TRA (Except CA)	Refer to the SCOUT® X-TRA approved label for use instructions.		

US EPA ARCHIVE DOCUMENT

CRANBERRIES

INSECTS	AMOUNT ACEPHATE 75 WSP PER ACRE	USE INSTRUCTIONS	DAYS TO HARVEST
Cranberry Blossom Worm Gypsy Moth False Armyworm Fireworms Spanworms Sparganothis	1 ⅓ lbs.	Apply in water by air, ground or with sprinklers. Use a minimum of 2 gals. spray per acre by air. Use sufficient water to give thorough coverage with ground or sprinkler equipment. Limit to one application per growing season. Do not apply more than 1 ⅓ lbs./A (1 lb. a.i./A) per season. Do not apply from start of bloom until all berries set.	90

SPRINKLER IRRIGATION APPLICATION TO CRANBERRIES: This product may only be applied through sprinkler irrigation systems including center pivot, lateral move, end tow, side (wheel) roll, travelers, big gun, solid set, or hand move. Do not apply this product through any other type of irrigation system.

Crop injury, lack of effectiveness, or illegal pesticide residues in the crop may result from non-uniform 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 label-prescribed safety devices for public water supplies are in place.

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.

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 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.

Do not apply when wind speed favors drift beyond the area intended for treatment.

Solid Set Systems: Apply specified dosage for the entire length of the irrigation period or for a 30 to 60 minute period at the end of a regular irrigation set or as a 30 to 60 minute injection as a separate application not associated with a regular irrigation. Allow time for all lines to flush the pesticide through all nozzles before turning off irrigation water. To insure the lines are flushed and free of remaining pesticide, a dye indicator may be injected into the lines to mark the end of the application period. See NOTE.

Center Pivot Systems: Inject the specified dosage per acre continuously for one complete revolution of the system. See NOTE.

NOTE: Constant agitation must be maintained in the chemical supply tank during the entire period of insecticide application. Inject the product with a positive displacement pump into the main line ahead of a right angle turn to insure adequate mixing.

Application of more than label recommended quantities of irrigation water per acre may result in decreased product performance by removing the chemical from the zone of effectiveness.

US EPA ARCHIVE DOCUMENT

HEAD LETTUCE – Crisphead type only

INSECTS	AMOUNT ACEPHATE 75 WSP PER ACRE	USE INSTRUCTIONS	DAYS TO HARVEST
Aster Leafhopper Green Peach Aphid	⅔ to 1 ⅓ lbs.	Apply in water at 5 to 10 gals. of spray per acre by air or 10 to 60 gals. of spray per acre (broadcast) by ground. Repeat at 3 day intervals for application rates up to ⅔ lb./A and 7 day intervals for application rates greater than ⅔ lb./A but do not exceed maximum application rate of 2 ⅔ lbs. of ACEPHATE 75 WSP per acre per crop cycle.	21 Spring, summer and early fall crops in all areas and winter crops in Florida and Texas, late fall crops in Arizona, winter crops in Arizona and California
Cabbage Looper Armyworms (excluding Beet Armyworm)	1 ⅓ lbs.		

USE PRECAUTIONS:

- Do not apply after first head begins to form to crops which germinate from mid-September through November in desert areas of AZ and CA.
- Do not feed trimmings to livestock or allow animals to graze on treated areas.
- Do not apply more than 2 ⅔ lbs. of ACEPHATE 75 WSP per acre per crop cycle.

MINT
Spearmint and Peppermint

INSECTS	AMOUNT ACEPHATE 75 WSP PER ACRE	USE INSTRUCTIONS	DAYS TO HARVEST
Alfalfa Looper Aphids Cutworms	1 ⅓ lbs.	Apply in water at 5 to 10 gals. per acre by air or 20 to 100 gals. spray per acre by ground. Apply when eggs or insects first appear. Make one repeat application at no less than a 7 day interval if necessary, to maintain control, but do not exceed maximum application rate of 2 ⅔ lbs. ACEPHATE 75 WSP per acre per crop cycle.	14

USE PRECAUTIONS:

- Do not use spent mint hay for feed for dairy animals.
- Do not graze treated areas.
- Do not apply more than 2 ⅔ lbs. of ACEPHATE 75 WSP per acre per season.

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NON-BEARING CITRUS

GENERAL USE PRECAUTIONS:

Do not graze treated areas.

DO NOT HARVEST citrus for one year after treatment.

INSECTS	AMOUNT OF ACEPHATE 75 WSP PER ACRE	TIME OF APPLICATION	USE INSTRUCTIONS
Aphids Grasshoppers Katydid Mealybugs Orangedogs Plant Bugs Thrips Whiteflies (except Sweetpotato/ Silverleaf)	⅔ lb.	Apply as needed for control of existing populations. Repeat at 3 day intervals.	Apply ACEPHATE 75 WSP in 100 to 200 gals. of water per acre. Spray individual juvenile or non-bearing trees for coverage with total application not to exceed specified rate in lbs. per acre. Length of residual activity will depend upon spray coverage and the amount of moisture following application.
Citrus Blackfly	⅔ to 1 lb.	Apply when eggs or insects first appear. Repeat at 3 day intervals for application rates up to ⅔ lb./A and 7 day intervals for application rates greater than ⅔ lb./A	
Ants (Imported Fire Ants and Harvester Ants only)	Mound Treatment Method: Mix 1 oz. in 5 gals. of water (1-1 lb. pouch in 80 gals. of water)	Apply as needed for control of existing populations.	Apply 1 gal. of mix to each mound area by sprinkling the mound until it is wet and treat a four (4) foot diameter circle around the mound.

NON-CROP AREAS

FIELD BORDERS, FENCEROWS, ROADSIDES, DITCHBANKS, BORROW PITS

INSECTS	AMOUNT OF ACEPHATE 75 WSP PER ACRE	USE INSTRUCTIONS
Grasshoppers	⅓ lb.	For early to mid-season application. Apply in water at 1 to 5 gals. spray per acre by air (minimum 5 gals. per acre in CA) or 10 to 25 gals. spray per acre by ground. Use the higher volumes when spraying dense foliage. An approved drift retardant may be added to aid in controlling drift and reducing evaporation of aerial sprays.

USE PRECAUTIONS:

- Do not graze or feed vegetation cut from treated areas.

WASTELAND (NON-FOOD/NON-FEED PRODUCING AREAS)

INSECTS	AMOUNT ACEPHATE 75 WSP PER ACRE	USE INSTRUCTIONS
Black Grass Bugs Grasshoppers Mormon Crickets	⅛ to ⅙ lb.	Apply in water at ½ gal. Spray per acre by air (minimum of 5 gals. per acre in CA) or 10 to 20 gals. Spray per acre by ground. Use higher volumes when spraying dense foliage. An approved drift retardant may be added to aid in controlling drift and reducing evaporation of aerial sprays.

USE PRECAUTIONS:

- Do not make more than one application per season.
- Do not graze or feed vegetation cut from treated areas.

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PEANUTS

INSECTS	AMOUNT ACEPHATE 75 WSP PER ACRE	USE INSTRUCTIONS	DAYS TO HARVEST
Grasshoppers	⅓ to ⅔ lb.	Apply in water at 10 to 50 gals. spray per acre by ground or in 5 to 10 gals. spray per acre by air. Begin applications when eggs or insects first appear and repeat at 3 day intervals for application rates up to ⅔ lb./A and 7 day intervals for application rates greater than ⅔ lb./A but do not exceed maximum application rate of 5 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle. ACEPHATE 75 WSP can be tank mixed with at-cracking and early post emergence peanut herbicides, provided those products do not prohibit tank mixes, provided the most restrictive of label limitations and precautions are observed, and provided no label dosage rates are exceeded. To determine physical compatibility, pour the recommended proportions of each chemical with the same proportion of water as will be present in the chemical supply tank into a suitable container, mix thoroughly and allow to stand for five minutes. If the combination remains mixed, or can be remixed readily, the mixture is considered physically compatible. When mixing wettable powder or dry flowable formulations, add and disperse these first, then add liquid pesticides. Combinations should be kept agitated and should be applied immediately. Do not allow combinations to set for prolonged periods in the chemical supply tank.	14 (of digging)
Thrips	½ to 1 lb.		
Corn Earworm Fall Armyworm Leafhoppers Loopers Velvetbean Caterpillar	1 to 1 ⅓ lbs.		

USE PRECAUTIONS:

- Do not apply more than 5 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle.
- Do not feed treated forage or hay to livestock or allow animals to graze treated areas.

PEPPERS

BELL PEPPERS

INSECTS	AMOUNT ACEPHATE 75 WSP PER ACRE	USE INSTRUCTIONS	DAYS TO HARVEST
Grasshoppers	⅓ to ⅔ lb.	Apply in water at a minimum of 3 gals. spray per acre (minimum 5 gals. spray per acre in CA) by air or 25 to 150 gals. spray per acre by ground. Apply when eggs or insects appear. Repeat at 3 day intervals for application rates up to ⅔ lb./A and 7 day intervals for application rates greater than ⅔ lb./A until insects have been reduced below economic numbers but do not exceed maximum application rate of 2 ⅔ lbs. of ACEPHATE 75 WSP per acre per crop cycle.	7
Cabbage Looper Green Peach Aphid Tobacco Hornworm	⅔ to 1 ⅓ lbs.		
European Corn Borer	1 to 1 ⅓ lbs.		

USE PRECAUTIONS:

- Do not apply more than 2 ⅔ lbs. of ACEPHATE 75 WSP per acre per crop cycle.

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NON-BELL PEPPERS

For Use in Midwestern, Eastern States and Puerto Rico Only.

INSECTS	AMOUNT ACEPHATE 75 WSP PER ACRE	USE INSTRUCTIONS	DAYS TO HARVEST
Aphids	⅔ lb.	Apply in water at 40 to 150 gals. spray per acre with ground equipment. Repeat at 3 day intervals. Do not exceed maximum application rate of 1 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle.	7
USE PRECAUTIONS: • Do not apply more than 1 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle.			

TOBACCO

GENERAL USE PRECAUTIONS:

Do not apply more than 5 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle.

TOBACCO FLOATBED APPLICATIONS

INSECTS	AMOUNT ACEPHATE 75 WSP PER ACRE	USE INSTRUCTIONS
Cutworms Flea Beetle Green Peach Aphid Tobacco Aphid	1 lb.	Mix 1 pouch (1 lb.) in 96 gals. of water. Apply 3 gals. to foliage per every 1,000 sq. ft. of bed. Apply evenly to ensure thorough coverage. NOTE: Floatbed water should be disposed of in the transplant field, through the transplant water or through foliar spray. Repeat at 7 day intervals but do not exceed maximum application rate of 5 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle. This applies to all methods of application.

TOBACCO PLANT BED APPLICATION

INSECTS	AMOUNT ACEPHATE 75 WSP PER ACRE	USE INSTRUCTIONS
Flea Beetle Green Peach Aphid Tobacco Aphid Cutworm	1 lb.	Mix 1 pouch (1 lb.) in 32 gals. of water. Apply 1 gal. to foliage per every 1,000 sq. ft. of bed. Apply evenly to ensure thorough coverage. Repeat at 7 day intervals but do not exceed maximum application rate of 5 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle. This applies to all methods of application.

TOBACCO TRANSPLANT WATER APPLICATION

INSECTS	AMOUNT ACEPHATE 75 WSP PER ACRE	USE INSTRUCTIONS
Flea Beetle Green Peach Aphid Tobacco Aphid Cutworms Tobacco Thrips	1 lb.	Make transplant-water applications using mechanical transplant equipment only. Using such equipment, the insecticide/water mixture is mechanically applied directly into the soil along with the transplanted plants. Provides control of early season flea beetles, green peach aphids, tobacco aphids, and cutworms for approximately 3 to 4 weeks after transplanting. For later season control of these insects, apply a foliar spray of ACEPHATE 75 WSP. Apply in a minimum of 100 gals. of transplant water per acre.
USE PRECAUTIONS: • Use of more than 1 lb. of ACEPHATE 75 WSP per acre as a transplant-water application may cause some phytotoxicity.		

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TOBACCO FOLIAR APPLICATION

INSECTS	AMOUNT ACEPHATE 75 WSP PER ACRE	USE INSTRUCTIONS	DAYS TO HARVEST
Grasshoppers	⅓ to ⅔ lb.	Apply in 10 to 50 gals. water per acre with ground equipment or a minimum of 3 gals. per acre by air. Repeat at 3 day intervals for application rates up to ⅔ lb./A but do not exceed maximum application rate of 5 ⅓ lbs. of ACEPHATE 75 WSP per acre per crop cycle. This applies to all methods of application.	3
Green Peach Aphid Flea Beetle Hornworm Tobacco Thrips	⅔ lb.		
Tobacco Aphid Vegetable Weevils Stinkbugs	⅔ to 1 lb.		
Budworm Cabbage Looper Cutworm	1 lb.		

TOBACCO SOIL APPLICATION

INSECTS	AMOUNT ACEPHATE 75 WSP PER ACRE	USE INSTRUCTIONS	DAYS TO HARVEST
Ants (Imported Fire Ants and Harvester Ants only)	Drench Method: Mix 1 oz. in 5 gals. of water (1-1 lb. pouch in 80 gals. of water) Apply 1 gal. of mix to each mound area by sprinkling the mound until it is wet and treat a four (4) foot diameter circle around the mound.	For best results apply the material in the early morning or late afternoon when the ants are most active. Applications made under prolonged hot and dry conditions may be ineffective due to the location of the ants deep within the nest.	3

USE PRECAUTIONS:

- Treat a maximum of 13 mounds per acre.
- Do not treat more than once per season.

COMMERCIAL TURFGRASS: SOD FARMS AND GOLF COURSES ONLY

Do not allow livestock to graze treated areas. Do not feed treated grass to livestock. Use is limited to sod farms and golf courses, except when applying by mound or spot treatment for fire ant control.

PLANTS	INSECTS	SQUARE FEET TREATED PER 1 LB. POUCH (lb. per acre)	TIME OF APPLICATION	USE INSTRUCTIONS
Turfgrass (Golf Courses and Sod Farms Only)	Fall Armyworm Yellow Striped Armyworm Southern Armyworm	13,400 to 32,700 (3 ¼ to 1 ⅓ lbs. per acre)	As the insects appear. A repeat application at 2 week intervals may be necessary.	Apply the specified amount of ACEPHATE 75 WSP per 1,000 sq. ft. Use a minimum of 5 gals. water per 1,000 sq. ft. to obtain good coverage.
	Cutworms	Golf Courses: 8,172 to 13,400 (5 ⅓ to 3 ¼ lbs. per acre) Sod Farms: 10,890 to 13,400 (4 to 3 ¼ lbs. per acre)		

USE PRECAUTIONS:

- Do not apply more than 4 lbs./A to Sod Farms and 5 ⅓ lbs./A to Golf Courses.
- Aerial applications to turf are prohibited.
- Do not apply at less than 7 day intervals.
- Allow at least 3 days between last application and harvesting of sod.

COMMERCIAL TURFGRASS INCLUDING GOLF COURSES AND SOD FARMS ONLY (Continued)

PLANTS	INSECTS	SQUARE FEET TREATED PER 1 LB. POUCH (lb. per acre)	TIME OF APPLICATION	USE INSTRUCTIONS
Turfgrass (Golf Courses and Sod Farms Only)	Chinch bugs	Golf Courses: 8,172 to 13,400 (5 ⅛ to 3 ¼ lbs. per acre) Sod Farms: 10,890 to 13,400 (4 to 3 ¼ lbs. per acre)	Apply as needed for adult population knockdown (not less than 7 to 14 days).	Apply the specified amount of ACEPHATE 75 WSP per 1,000 sq. ft. Use 1 to 15 gals. water per 1,000 sq. ft. to obtain good coverage.
	Sod Webworm (Crambus spp.)	16,300 to 32,700 (2 ⅜ to 1 ⅛ lbs. per acre)	As sod webworms begin to appear. Use the higher amount when quick knock-down is needed or with heavy infestations. Repeat application may be necessary. Do not repeat at more than 1 week intervals.	
	Leafhopper	16,300 (2 ⅜ lbs. per acre)	As the leafhoppers begin to appear. A repeat application at 1 week intervals may be necessary.	
	Mole Crickets (Except CA) Spittlebug (Except CA)	Golf Courses: 8,375 to 16,300 (5.2 to 2.66 lbs. per acre) Sod Farms: 10,890 to 16,300 (4 to 2.66 lbs. per acre)	As mole crickets begin to appear. For knockdown of existing populations, more than one application may be required throughout the growing season. For heavy infestations, use the higher dosage rate.	Apply the specified amount of ACEPHATE 75 WSP per 1,000 sq. ft. Use 1 to 15 gals. water per 1,000 sq. ft. to obtain good coverage. Apply during late afternoon or early evening hours and after an irrigation. Do not irrigate after application.
	The use of a lemon fragrance substance in the spray mix may enhance control by acting as a flushing agent and thus provide increased mole cricket contact with the acephate. The following lemon-scented products have been shown to be effective flushing agents: Lemon Joy, Lemon Palmolive, and Mighty Products Manufacture-Base pure lemon fragrance. The use rate for these lemon-scented products is 2 teaspoons per gallon of water for small total mix volume or 6 fl. oz. per 50 gals. of water for large mix volume.			

USE PRECAUTIONS:

- Do not apply more than 4 lbs./A to Sod Farms and 5 ⅓ lbs./A to Golf Courses.
- Aerial applications to turf are prohibited.
- Do not apply at less than 7 day intervals.
- Allow at least 3 days between last application and harvesting of sod.

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COMMERCIAL TURFGRASS INCLUDING GOLF COURSES AND SOD FARMS ONLY (Continued)

PLANTS	INSECTS	SQUARE FEET TREATED PER 1 LB. POUCH (lb. per acre)	TIME OF APPLICATION	USE INSTRUCTIONS
Turfgrass (Golf Courses and Sod Farms Only)	Greenbug (Schizaphis graminum) Grasshoppers	32,700 (1 ⅓ lbs. per acre)	Apply when insects or their damage first appears. Repeat as necessary. Application is not to be repeated at more than 1 week intervals.	Apply the specified amount of ACEPHATE 75 WSP. Use 4 gals. of water per 1,000 sq. ft. to obtain good coverage. Do not mow turfgrass for at least 24 hours after application.
	Black Turfgrass Ataenius (Except CA)	Golf Courses: 8,375 to 10,600 (5.2 to 4.1 lbs. per acre) Sod Farms: 10,890 (4 lbs. per acre)	Apply when insects or their damage first appear.	Apply the specified amount of ACEPHATE 75 WSP per 1,000 sq. ft. Use a minimum of 5 gals. water per 1,000 sq ft. Irrigate lightly after application (not more than ½ inch). Use the higher rate for severe infestations.
Dichondra (Golf Courses and Sod Farms Only)	Cutworm Flea Beetle Southern Armyworm Yellow Striped Armyworm	Golf Courses: 8,375 to 16,300 (5.2 to 2.66 lbs. per acre) Sod Farms: 10,890 to 16,300 (4 to 2.66 lbs. per acre)	As the insects appear. Repeat at 2 week intervals as necessary.	Apply the specified amount of ACEPHATE 75 WSP per 1,000 sq. ft. Use a minimum of 15 gals. water per 1,000 sq. ft. to obtain good coverage.

USE PRECAUTIONS:

- Do not apply more than 4 lbs./A to Sod Farms and 5 ⅓ lbs./A to Golf Courses.
- Aerial applications to turf are prohibited.
- Do not apply at less than 7 day intervals.
- Allow at least 3 days between last application and harvesting of sod.

COMMERCIAL MOUND TREATMENT OF FIRE ANTS IN TURFGRASS

PLANTS	INSECTS	APPLICATION RATE	TIME OF APPLICATION	USE INSTRUCTIONS
Turfgrass and Non-Crop Areas (field borders, fencerows, roadsides, ditch-banks, borrow pits)	Imported Fire Ants	Mound Treatment — Drench Method: Mix 1 pouch (⅓ lb.) in 20 gals. of water. Apply 1 gal. of mix to each mound area by sprinkling the mound until it is wet and treat a four (4) foot diameter circle around the mound.	For best results apply the material in the early morning or late afternoon when the ants are most active. Applications made under prolonged hot and dry conditions may be ineffective due to the location of the ants deep within the nest.	Apply the specified amount of ACEPHATE 75 WSP as directed. Grass in treated area may be injured. Do not treat mound more than once per season.

USE PRECAUTIONS:

- Do not apply more than 4 lbs./A to Sod Farms and 5 ⅓ lbs./A to Golf Courses.
- Do not allow livestock to graze treated areas.
- Do not feed treated grass to livestock.

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SPECIALTY USES

CONTAINER GROWN NURSERY STOCK

PLANTS	INSECTS	AMOUNT ACEPHATE WSP PER ACRE (lb. Product)	TIME OF APPLICATION	USE INSTRUCTIONS
Container Grown Nursery Stock (Arborvitae Azalea Camellia Rhododendron Roses Viburnum Yew)	Black Vine Weevil Strawberry Root Weevil	1 lb.	Application should be made by mid-September for greenhouse stock and by mid-October for outdoor stock. Consult your local county extension agent for information on the identification and control of root weevils on ornamentals.	Apply the specified amount ACEPHATE 75 WSP Spray per 100 gals. of solution so as to thoroughly drench the root system. Do not apply more than 1 ⅓ lbs./A per 100 gals. of water.
	Ants (excluding fire, harvester, carpenter and pharaoh ants)	1 lb.	Apply as needed to control the pest.	

ORNAMENTAL TREES AND SHRUBS

PLANTS	INSECTS	AMOUNT ACEPHATE WSP PER ACRE (lb. Product)	TIME OF APPLICATION	USE INSTRUCTIONS
Trees and Shrubs (except Flowering Crabapple and Douglas Fir, see below)	Aphids Bagworms Birch Leafminer Tent Caterpillar* Lace Bugs Leafrollers	⅓ lb.	As the insects begin to appear.	Apply the specified amount of ACEPHATE 75 WSP in 100 gals. water with a hydraulic sprayer. The addition of a suitable sticker improves control of Gypsy Moth larvae. Unless a longer interval is specified, apply at 3 day intervals for application rates up to and including 0.5 lb./A and 7 days for application rates greater than 0.5 lb./A. * Mist blower application: Adjust rates to 1⅓ lbs. per 100 gals. water for Gypsy Moth control and 1 lb. per 100 gals. water for Tent Caterpillar control.
	Douglas Fir Tussock Moth Larvae Gypsy Moth Larvae* Webworms	⅔ lb.	As the insects begin to appear.	
	Scales (Crawlers)	⅔ lb.	As crawlers begin to appear. Repeat applications, at a 2 week or more interval, may be necessary where there is continuous crawler production.	

USE PRECAUTIONS:

- UPI does not recommend application to Huckleberry, Balm of Gilead, Cottonwood, Lombardy Poplar and Viburnum suspensum.
- Nursery crops. Before treating large plantings, spray only a few plants and observe two weeks for phytotoxicity.
- Do not apply more than 1 ⅓ lbs./A per 100 gals. of water.

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ORNAMENTAL TREES AND SHRUBS (Continued)

PLANTS	INSECTS	AMOUNT ACEPHATE WSP PER ACRE (lb. Product)	TIME OF APPLICATION	USE INSTRUCTIONS
Trees and Shrubs (except Flowering Crabapple and Douglas Fir, see below)	Ponderosa Pine Needle Miner	⅔ lb.	Time of application is important. Consult your Farm Advisor or County Extension Agent.	Apply the specified amount of ACEPHATE 75 WSP in 100 gals. water with a hydraulic sprayer
	Grasshoppers	⅔ lb.	As the grasshoppers begin to appear.	
	California Oakworm Cankerworms (Spring and Fall)	⅓ to ⅔ lb.	As the insects begin to appear. Use the higher amount when the larger larvae are present.	
	Nantucket Pine Tip Moth Larvae	1 lb.	Time of application is important. Consult your Farm Advisor or County Extension Agent. Repeat applications will be required for subsequent generations.	
	Root Weevil Adults	1 lb.	Apply when first feeding damage occurs. Repeat applications at four week intervals until the first heavy frost may be necessary for complete foliage protection.	
	Box Elder Bugs Sawflies Budworms Leafhoppers	1 lb.	As the insects begin to appear.	
	Japanese Beetle	1 ⅓ lbs.	As the Japanese Beetles begin to appear. Repeat applications, at 2 week intervals, may be necessary.	
	Elm Leaf Beetle (larvae)	1 ⅓ lbs.	As the larvae begin to appear. ACEPHATE 75 WSP will not prevent Elm Leaf Beetle eggs from hatching.	

USE PRECAUTIONS:

- UPI does not recommend application to Huckleberry, Balm of Gilead, Cottonwood, Lombardy Poplar and Viburnum suspensum.
- Nursery crops. Before treating large plantings, spray only a few plants and observe two weeks for phytotoxicity.
- Do not apply more than 1 ⅓ lbs./A per 100 gals. of water.

ORNAMENTAL TREES AND SHRUBS (Continued)

PLANTS	INSECTS	AMOUNT ACEPHATE WSP PER ACRE (lb. Product)	TIME OF APPLICATION	USE INSTRUCTIONS
Douglas Fir Christmas Trees	Douglas Fir Needle Midge	⅔ lb.	Application should be made no more than 2 weeks prior to bud burst. For additional pest management information, consult your county extension service.	Apply the specified amount of ACEPHATE 75 WSP in not less than 2 gals. of spray per acre by air or in 100 gals. of spray per acre by ground.
Flowering Crabapples	Aphids Tent Caterpillars Leafrollers	⅓ lb.	As the insects begin to appear.	Apply the specified amount of ACEPHATE 75 WSP in 100 gals. water with a hydraulic sprayer.

USE PRECAUTIONS:

- Do not apply more often than 3 times in a growing season at a 4 week interval.
- Caution: Phytotoxicity has occurred on the following Crabapple varieties: Hops, Ichonoski, Malus floribunda, Pink Perfection, Red Wine and Snow Cloud.
- Do not apply more than 1 ⅓ lbs./A per 100 gals. of water

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MOUND TREATMENT OF FIRE ANTS IN TURFGRASS

Do not allow livestock to graze treated areas. Do not feed treated grass to livestock.

PLANTS	INSECTS	APPLICATION RATE	TIME OF APPLICATION	USE INSTRUCTIONS
Turfgrass and Non-Crop Areas	Imported Fire Ants	Mound Treatment — Drench Method: Mix ⅓ lb. in 20 gals. of water. Apply 1 gal. of mix to each mound area by sprinkling the mound until it is wet and treat a four (4) foot diameter circle around the mound.	For best results apply the material in the early morning or late afternoon when the ants are most active. Applications made under prolonged hot and dry conditions may be ineffective due to the location of the ants deep within the nest.	Apply the specified amount of ACEPHATE 75 WSP as directed. Grass in treated area may be injured. Do not treat mound more than once per season.

USE PRECAUTIONS:

- Do not apply more than 4 lbs./A to Sod Farms and 5 ⅓ lbs./A to Golf Courses.

OUTDOOR AND PERIMETER SPRAY
Excluding residential turf

LOCATION	INSECTS	AMOUNT ACEPHATE WSP	TIME OF APPLICATION	USE INSTRUCTIONS
Outdoor and perimeter area	Wasps	⅓ lb./3.3 gals. (1 packet in 3.3 gals. water)	Treat early or late in the day as wasps are generally less active during these times.	Apply as a spot treatment to the nest, nest entrance, and surrounding areas where the wasps alight.
	Ants (Excluding fire, harvester, carpenter, and pharaoh ants) Crickets Cockroaches Earwigs Pillbugs	⅓ lb./3.3 gals. (1 packet in 3.3 gals. water)	As the insects appear.	Apply to a band of soil 6 to 10 feet adjacent to the structure and to a height of 2 to 3 feet on the foundation where pests may be active or may find entrance. Also apply as a residual spray or with a paint brush to surfaces of buildings, window frames, shutters, entry-ways, screens, eaves patios, garages, carports, around garbage areas and other areas where these pests congregate.

The use of low-pressure handwand equipment for perimeter or wasp treatments is prohibited.

OUTDOOR FLORAL CROPS AND GROUND COVERS

PLANTS	INSECTS	AMOUNT ACEPHATE WSP PER ACRE PER 100 GALS. (lb. Product)	TIME OF APPLICATION	USE INSTRUCTIONS
Chrysanthemums Daisies Dahlias Easter Lily Gladioli Gyposophila Pachysandra Peony Roses Sedum Statice Strawflower Yarrow Zinnia	Aphids Thrips Lygus	⅔ lbs.	As insects begin to appear. Repeat applications may be necessary.	Apply the specified amount of ACEPHATE 75 WSP in 100 gals. water with a hydraulic sprayer as a full coverage spray. Multiple applications may cause slight tip burn or marginal leaf necrosis on some varieties. Test on a few plants to determine varietal susceptibility. Repeat at 3 day intervals for application rates up to 0.5 lb./A and 7 day intervals for rates greater than 0.5 lb./A. Do not apply more than 1 ⅓ lbs./A per 100 gals. of water and do not exceed 1 lb./A for cut flowers.
Roses Boston Ivy	Japanese Beetles	1 ⅓ lbs.	As the Japanese Beetles begin to appear. Repeat applications at 2 week intervals may be necessary.	

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COMMERCIAL GREENHOUSE FLORAL AND FOLIAGE CROPS
Not for use in residential greenhouses

PLANTS	INSECTS	AMOUNT ACEPHATE WSP PER ACRE PER 100 GALS. (lb. Product)	TIME OF APPLICATION	USE INSTRUCTIONS
Roses	Leafrollers	⅔ to 1 lb.	As leafrollers begin to appear. Use the higher amount when large larvae are present.	Apply the specified amount of ACEPHATE 75 WSP in 100 gals. water with a hydraulic sprayer as a full coverage spray. Do not apply more than 1 lb./A for cut flowers.
Foliage Plants Orchids Anthuriums Cacti Poinsettia	Aphids	⅓ lb.	As aphids begin to appear.	Apply the specified amount of ACEPHATE 75 WSP in 100 gals. water with a hydraulic sprayer as a full coverage spray. The addition of a wetting agent may be required on difficult to wet foliage. Caution: Phytotoxicity has occurred on the following foliage plants: *Bletchum gibbum, Cissus antarctica, Ficus triangularis, Fittonia verschaffeltii, Maranta leuconeura kerchoveana, Plectranthus lutes, Plectranthus australis, Polypodium aureus, Polystichum, Pteris ensiformis, Tolmiea menziesii.* Before treating large plantings spray only a few plants and observe 2 weeks for varietal phytotoxicity.
	Mealybugs Thrips Whiteflies	⅔ lb.	As the insects begin to appear. A repeat application, at a 2 week interval, may be necessary for control of mealybugs and whiteflies.	
	Scales (Crawlers)	⅔ lb.	As crawlers begin to appear. Repeat applications, at a 2 week or more interval; may be necessary, where there is continuous crawler production.	

COMMERCIAL GREENHOUSE FLORAL AND FOLIAGE CROPS (Continued)

PLANTS	INSECTS	AMOUNT ACEPHATE WSP PER ACRE PER 100 GALS. (lb. Product)	TIME OF APPLICATION	USE INSTRUCTIONS
Foliage Plants Orchids Anthuriums Cacti Poinsettia	Sweetpotato/ Silverleaf Whiteflies (Except CA)	⅓ lb. plus TAME® 2.4 EC Spray 10 ⅔ fl. oz. (0.2 lb. a.i.)	Apply when insects first appear. If a population is well established, make one application of the tank mix and follow 5 to 7 days later with TAME alone at 16 fl. oz./100 gals. See TAME label for instructions.	For Sweetpotato/Silverleaf Whitefly control, apply the specified amount of ACEPHATE 75 WSP plus TAME® 2.4 EC Spray as a tank mix at a volume necessary to obtain good coverage. Follow the TAME® label for specific instructions on the alternation of TAME® plus ACEPHATE 75 WSP and TAME® alone and the rotation instruction to avoid potential resistance. Do not apply more than 1 lb./A for cut flowers.
Roses Carnations Chrysanthemums	Aphids Thrips	⅔ lb.	As aphids begin to appear As thrips begin to appear or at the tight flower bud stage. Repeat applications may be necessary.	Apply the specified amount of ACEPHATE 75 WSP in 100 gals. water with a hydraulic sprayer as a full coverage spray. Do not apply more than 1 lb./A for cut flowers.

USE PRECAUTIONS:

- Application to Carnations and Chrysanthemum more often than once every 28 days may result in flower damage.
- Caution: Phytotoxicity has occurred on the following Chrysanthemum varieties: Albatross. Bonnie Jean, Dixie, Garland. Gent, Iceberg, Pride, Showoff. Statesman, Tally Ho, Westward Ho, and Wild Honey. Before treating large Chrysanthemum plantings, spray only a few plants and observe two weeks for varietal phytotoxicity.
- UPI does not recommend application to chrysanthemums and roses with open flowers.
- Do not apply under conditions involving possible drift to food, forage or other plantings that might be damaged or the crops thereof rendered unfit for sale, use or consumption.

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STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Keep pesticide in original container. Do not put concentrated or dilute into food or drink containers. Store in cool, dry place. Protect from excessive heat. Do not contaminate food or foodstuffs. Do not store or transport near feed or food.

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

CONTAINER DISPOSAL: Do not reuse the outer bag. Dispose of outer bag in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

IMPORTANT INFORMATION
READ BEFORE USING PRODUCT

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product reflect the opinion of experts based on field use and tests, and must be followed carefully. 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 manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of United Phosphorus, Inc. or Seller. Handling, storage, and use of the product by Buyer or User are beyond the control of United Phosphorus, Inc. and Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold United Phosphorus, Inc. and Seller harmless for any claims relating to such factors.

To the extent consistent with applicable law, United Phosphorus, 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, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or United Phosphorus, Inc., and Buyer and User assume the risk of any such use. To the extent consistent with applicable law, UNITED PHOSPHORUS, INC. MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent consistent with applicable law, United Phosphorus, Inc. or Seller shall not be liable for any incidental, consequential or special damages resulting from the use or handling of this product and **THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF UNITED PHOSPHORUS, INC. AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF UNITED PHOSPHORUS, INC. OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

United Phosphorus, Inc. and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by the duly authorized representative of United Phosphorus, Inc.

AMMO® – Reg. TM of FMC Agri Chemical Group for cypermethrin insecticide.

ASANA® – Reg. TM of E.I. DuPont de Nemours & Co., Inc. for esfenvalerate insecticide.

BAYTHROID® – Reg. TM of Miles, Inc. for cyfluthrin synthetic pyrethroid.

CAPTURE ® – Reg. TM of FMC Agri Chemical Group for bifenthrin insecticide-miticide.

DANITOL® – Reg. TM of Sumitomo Chemical Company Ltd. for fenpropathrin Insecticide-miticide.

KARATE® – Reg. TM of Zeneca Ag Products U.K. for lambdacyhalothrin insecticide.

LORSBAN® – Reg. TM of Dow Chemical Company for chlorpyrifos insecticide.

SCOUT® – Reg. TM of Hoechst-Roussel Agri-Vet Co. for tralomethrin pyrethroid insecticide.

TAME® – Reg. TM of Valent USA Corp. for fenpropathrin Insecticide-miticide.

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Rev. 2/7/08

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Acephate 90 WSP®

Soluble Powder Insecticide

IN WATER SOLUBLE BAGS

ACTIVE INGREDIENT	By Wt.
Acephate (O, S-Dimethyl acetylphosphoramidothioate)	90%
OTHER INGREDIENTS	10%
TOTAL	100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

Contains an organophosphate that inhibits cholinesterase.

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 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 by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment information, contact the Rocky Mountain Poison Control Center at 1-866-673-6671.

NOTE TO PHYSICIAN

Acephate is a cholinesterase inhibitor. Blood cholinesterase measurements may be useful to monitor exposure but treatment-related decisions may be needed before the results of the blood tests are available. If signs of cholinesterase inhibition appear, atropine is antidotal. 2-PAM may also be used in conjunction with atropine but should not be used alone.

For Chemical Emergency Assistance (Spill, Leak, Fire or Accident), Call CHEMTREC 1-800-424-9300

EPA Reg. No. 70506-2
EPA Est. No. 65387-AR-002

Net Contents: 2.5 lbs.

United Phosphorus, Inc.
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PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS
CAUTION

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes and clothing.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are butyl, nitrile, and neoprene. If you want more options, follow the instructions for category A on an EPA chemical-resistance category selection chart.

Mixers, loaders, applicators and other handlers using engineering controls must wear:

- long-sleeved shirt and long pants
- chemical resistant gloves for all mixers and loaders, and for applicators using hand-held application equipment
- socks and shoes.

In addition, applicators using low pressure hand wand application equipment must wear:

- a NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH-approved respirator with any N, R, P, or HE filter.

See engineering controls for additional requirements.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENGINEERING CONTROLS

Water-soluble packages when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must:

- wear the personal protective equipment required above for mixers/loaders, and
- be provided, must have immediately available, and must use in an emergency, such as a broken package, spill, or equipment breakdown, the following PPE: coveralls, chemical-resistant footwear and a NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH-approved respirator with any N, R, P, or HE filter.

Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)].

The use of human flaggers is prohibited.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing/PPE 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 birds.

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 cleaning equipment or disposing of equipment washwaters.

Exposed treated seed may be hazardous to birds and other wildlife. Dispose of all excess treated seed and seed packaging by burial away from bodies of water.

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 while bees are actively visiting the treatment area.

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.

For use on turf, use limited to sod farms and golf courses, except when applying to mound or spot treatment for fire ant and harvester ant control.

Not for indoor residential use. For greenhouse use, use is limited to commercial greenhouses for use on ornamental, floral and foliage plants, and tobacco (floatbed application).

Do not apply with low pressure handwand except for control of fire ants as a mound treatment and when used on ornamental trees, shrubs, and floral plants grown for non-agricultural or non-commercial use.

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 until restricted-entry interval (REI) of 24 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 made of any waterproof material, shoes plus socks.

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 enter or allow others to enter treated areas until sprays have dried.

GENERAL INFORMATION

ACEPHATE 90 WSP is an insecticide which controls a wide range of important pests in selected crops and in non-crop areas. The active ingredient is acephate, a water-soluble insecticide readily absorbed by plant roots and foliage to give systemic control of feeding insects. Insect pests are generally controlled more effectively by ACEPHATE 90 WSP through ingestion than by contact. Application of ACEPHATE 90 WSP to maintain control should be repeated only as directed.

FAILURE TO FOLLOW THE DIRECTION FOR USE AND PRECAUTIONS ON THIS LABEL MAY RESULT IN POOR INSECT CONTROL, CROP INJURY, AND/OR ILLEGAL RESIDUES.

TANK MIXES

NOTICE: Tank mixing of this product with any other product which is not specifically and expressly authorized by the label shall be at the exclusive risk of the use, applicator, and/or application advisor. Read and follow the entire label of each product to be used in the tank mix with this product.

CHEMIGATION

Apply only to cranberries with sprinkler irrigation systems and do not use any other type of irrigation systems. Do not apply this product through chemigation to any other crop.

SPRAY DRIFT

A variety of factors including weather conditions, (e.g., wind direction, wind speed, temperature, relative humidity) and method of application (e.g., ground aerial, airblast, chemigation) can influence pesticide drift. The applicator and grower must evaluate all factors and make appropriate adjustments when applying this product.

Observe the following precautions to minimize drift:

- All aerial, ground and air-assisted/airblast application equipment must be properly maintained and calibrated using water as carrier. Do not apply this product as an ultralow volume (ULV) spray except as specified in the instructions for use on non-crop wasteland. Do not apply in any carrier other than water.
- Use the largest droplet size consistent with good pest control. Small droplets are more prone to spray drift and can be minimized by appropriate nozzle selection, by orienting nozzles away from the air stream as much as possible, and by avoiding excessive spray boom pressure.
- Do not apply at wind speeds greater than 10 mph at the application site.
- Make applications when wind velocity favors on-target product deposition (approximately 3 to 10 mph).
- Apply as close to target plants as practical to obtain a good spray pattern for adequate coverage.

For Aerial Applications:

- Do not apply at heights greater than 10 feet (consistent with flight safety).
- The spray boom should be mounted on the aircraft so as to minimize drift caused by wing tip vortices.
- The minimum practical boom length should be used and must not exceed 75% of wing span or rotor diameter.

For Ground Applications:

- Do not apply at heights greater than 4 feet.

For Airblast Applications:

- Direct spray above foliage and turn off outward pointing nozzles at row ends and outer rows.

WATER SOLUBLE PACKAGES

The enclosed pouches, or packages, are water-soluble. **Do not** allow pouches to become wet prior to adding to the spray tank. **Do not** handle pouches with wet hands or wet gloves. **Do not** remove water-soluble pouches from overwrap except to add directly to the spray tank. Refer to the Table of Equivalents to calculate the number of packages to use. Always reseal overwrap bag to protect remaining unused pouches.

PREPARATION OF SPRAY SOLUTION

To prepare spray solution, drop the unopened packet(s) of ACEPHATE 90 WSP into a spray tank containing at least one-half of the total quantity of water required. Add remaining water directed toward the water-soluble pouch with the agitator running until the spray volume is reached. Do not add any liquid fertilizers, micronutrients or adjuvants to the spray solution until the ACEPHATE 90 WSP has completely dissolved. ACEPHATE 90 WSP should completely dissolve in approximately 15 minutes. Dissolution rate may be slowed by cold water, lack of agitation, or water containing high concentrations of boron or sulfur. Application of ACEPHATE 90 WSP to maintain control should be repeated only as directed.

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WATER SOLUBLE PACKAGING DIRECTIONS
TABLE OF EQUIVALENTS

AMOUNT OF ACEPHATE 90 WSP PER ACRE	ACRES TREATED BY A 5 LB. PACKAGE (TWO 2.5 LB. WATER-SOLUBLE POUCHES)	ACRES TREATED BY ONE 2.5 LB. WATER-SOLUBLE POUCH
0.08 lb.	62.5	31
2.5 oz.	32	16
3.2 oz.	25	12.5
3.25 oz.	24.6	12.3
0.25 lb.	20	10
0.28 lb.	17.8	8.9
0.4 lb.	12.5	6
0.5 lb.	10	5
0.56 lb.	8.9	4.5
0.8 lb.	6.25	3.1
1.0 lb.	5	2.5
1.1 lbs.	4.5	2.3
2.2 lbs.	2.3	1.1
2.75 lbs.	1.8	0.9
3.4 lbs.	0.7	0.4
4.3 lbs.	1.2	0.6
5.5 lbs.	1	0.5

CROP USE DIRECTIONS

BEANS AND LIMA BEANS —Dry and Succulent Forms—

PESTS CONTROLLED	AMOUNT OF ACEPHATE 90 WSP PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS	MINIMUM SPRAY INTERVAL (DAYS)	DAYS TO HARVEST
Fleahoppers Grasshoppers	0.28 to 0.56 lb. (4.4 to 8.9 oz.)	Apply when eggs or insects first appear. Use the higher rates for severe insect infestations. **Ground Application:** Apply in 20 to 100 gallons per acre by conventional ground equipment to ensure thorough coverage of the target crop. **Aerial Application:** Make applications of ACEPHATE 90 WSP Insecticide in a minimum of 2 gallons per acre. Use sufficient carrier volume to provide thorough, uniform coverage.	Do not apply more than 2.2 lbs./A (2 lbs. a.i./A per crop cycle. Do not feed treated vines to livestock.	3 (for application rates at 8.9 oz. or less) 7 (for application rates greater than 8.9 oz.)	14 (snap beans or dry beans) 1 (lima beans, succulent form)
Aphids (excluding, Black Bean Aphid) Bean Leaf Beetle Bean Leafroller Cabbage Looper Cutworms Green Cloverworm Leafhoppers Mexican Bean Beetle Plant bugs (Lygus) Soybean Looper Thrips Whitefly (Except Sweetpotato & Silverleaf Whitefly)	0.56 to 1.1 lbs. (8.9 to 17.6 oz.)				
Armyworms (excluding Beet Armyworm) Corn Earworm European Corn Borer	0.83 to 1.1 lbs. (13.3 to 17.6 oz.)				

BRUSSELS SPROUTS & CAULIFLOWER

PESTS CONTROLLED	AMOUNT OF ACEPHATE 90 WSP PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS	MINIMUM SPRAY INTERVAL (DAYS)	DAYS TO HARVEST
Green Peach Aphid	0.56 to 1.1 lbs. (8.9 to 17.6 oz.)	Apply when eggs or insects first appear. Use the higher rates when heavy infestations of aphids are present. Repeat application as necessary to maintain control. **Ground Application:** Apply in 25 to 150 gallons per acre by conventional ground equipment to ensure thorough coverage of the target crop. **Aerial Application:** Make applications of ACEPHATE 90 WSP Insecticide in a minimum of 5 gallons per acre. Use sufficient carrier volume to provide thorough, uniform coverage. **This insect has demonstrated an ability to develop resistance to various classes of insecticides. Consult your local Agricultural Extension Service for current recommended control practices for this insect.	Do not apply more than 2.2 lbs./A (2 lbs. a.i./A) per crop cycle. Do not feed trimmings to livestock or allow animals to graze in treated areas.	3 (for application rates at 8.9 oz. or less) 7 (for application rates greater than 8.9 oz.)	14
Cabbage Looper Imported Cabbage Worm	1.1 lbs. (17.6 oz.)				
Diamondback Moth Larvae**					

CELERY

PESTS CONTROLLED	AMOUNT OF ACEPHATE 90 WSP PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS	MINIMUM SPRAY INTERVAL (DAYS)	DAYS TO HARVEST
Green Peach Aphid	0.56 to 1.1 lbs. (8.9 to 17.6 oz.)	Apply when eggs or insects first appear. Use the higher rates when heavy infestations of aphids are present. Repeat application as necessary to maintain control. **Ground Application:** Apply in 50 to 100 gallons per acre by conventional ground equipment to ensure thorough coverage of the target crop. **Aerial Application:** Make applications of ACEPHATE 90 WSP Insecticide in a minimum of 5 gallons per acre. Use sufficient carrier volume to provide thorough, uniform coverage.	Do not apply more than 2.2 lbs./A (2 lbs. a.i./A) per crop cycle. All celery must be trimmed (tops removed) before shipment for use. Do not use trimmed tops for food or feed.	3 (for application rates at 8.9 oz. or less) 7 (for application rates greater than 8.9 oz.)	21
Cabbage Looper Fall Armyworms	1.1 lbs. (17.6 oz.)				

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COTTON

RESTRICTIONS APPLICABLE TO ALL USES ON COTTON:

Do not use treated seed for food or feed purposes or process for oil.

Do not feed gin trash or treated forage to livestock.

Do not allow livestock to graze on treated areas.

Do not apply more than 4.44 lbs. of ACEPHATE 90 WSP per acre (4.0 lbs. a.i./A) per crop cycle. This includes all uses of acephate on cotton; i.e. in-furrow sprays, foliar applications, and seed treatment applications.

When applied by air, do not apply more than 1.1 lbs. of ACEPHATE 90 WSP per acre (1 lb. a.i./A) in California and Arizona. Do not apply more than 0.83 lb. of ACEPHATE 90 WSP per acre (0.75 lb. a.i./A) for all other areas of the United States.

RESISTANCE MANAGEMENT

Cotton pest control programs, especially those for control of Silverleaf/Sweetpotato Whitefly populations, should employ a properly designed resistance management strategy. Such resistance management strategies include mixture or rotation of alternative classes of chemistry including organophosphates, carbamates, pyrethroids or insect growth regulators. Consult your state or area agricultural extension service for local resistance management strategies and advice on alternative insecticides.

COTTON IN-FURROW TREATMENT

PESTS CONTROLLED	AMOUNT OF ACEPHATE 90 WSP PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS
Aphids* Thrips Black (Greasy) Cutworm (Except CA) * Excluding Cotton Aphids in AZ & CA	0.56 to 1.1 lbs. (8.9 to 17.6 oz.) **NOTE:** for the Blacklands of Texas use 1.1 lbs./A (17.6 oz.) ACEPHATE 90 WSP	Apply ACEPHATE 90 WSP in 3 to 5 gals. of water per acre as an in-furrow spray at planting. Use flat-fan nozzles for this application, and align nozzles to ensure good spray deposition into the seed furrow. Cone type nozzles may not provide a spray pattern that ensures maximum spray deposition in the seed furrow, and should be avoided. Spray systems that employ metal or plastic tubing for delivery of spray solution into the seed furrow should have tubing securely fastened to the furrow opener and should be checked frequently to insure that the tubing is properly positioned to deposit spray solution into the seed furrow. ACEPHATE 90 WSP can be mixed with fungicides that are sprayed in-furrow for disease control.	Do not apply more than 4.4 lbs. of ACEPHATE 90 WSP per acre (4.0 lbs. a.i./A) per crop cycle. This includes all uses of ACEPHATE 90 WSP in commercial seed-treatment, in-furrow spray, and foliar applications.

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COMMERCIALLY TREATED COTTONSEED —FOR USE BY COMMERCIAL SEED TREATERS ONLY—

PESTS CONTROLLED	AMOUNT ACEPHATE 90 WSP PER 100 LBS. COTTONSEED	EFFECTIVENESS OF ACEPHATE 90 WSP	APPLICATION INSTRUCTIONS	RESTRICTIONS
Cotton Aphids Thrips	0.44 lb. (7.1 oz.) [Use one 2.5 lbs. water soluble pouch for 570 lbs. cotton seed]	ACEPHATE 90 WSP provides effective reduction of thrips and cotton aphids for up to three weeks after planting.	Apply ACEPHATE 90 WSP as a separate treatment using enough water to give adequate coverage of the seed. ACEPHATE 90 WSP dissolves in water within 15 minutes with a minimum of agitation. ACEPHATE 90 WSP can be mixed in the slurry tank with most of the fungicide seed treatments commonly used. Observe all precautions and limitations on labeling of all products used in mixtures.	Do not apply more than 4.4 lbs. of ACEPHATE 90 WSP per acre (4.0 lbs. a.i./A) per crop cycle. This includes all uses of ACEPHATE 90 WSP in commercial seed-treatment, in-furrow spray, and foliar applications. Do not use treated seed for food or feed purposes or process for oil. This formulation does not contain a dye. Compliance with the Federal Seed Act and 21 CFR Chapter 1 Section 2.5 requires that all seeds treated with this product must be colored to distinguish from and prevent subsequent inadvertent use as food for man or feed for animals. Treated seeds must not be used for, or mixed with food for animal feed, or processed for oil. Seeds treated with ACEPHATE 90 WSP may be considered adulterated under state and federal laws if sold or shipped as food or feedstuffs. Seeds commercially treated with ACEPHATE 90 WSP must be labeled as follows: "TREATED SEED; DO NOT USE FOR FOOD, FEED OR OIL."
Black (Greasy) Cutworm		ACEPHATE 90 WSP provides reduction of Black (greasy) cutworm from planting through the 3rd to 4th leaf stage of development. When planting into fields where large cutworms are present, (5th instar and larger), economic damage may occur.		

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COTTON FOLIAR APPLICATION

PESTS CONTROLLED	AMOUNT OF ACEPHATE 90 WSP PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS	MINIMUM SPRAY INTERVAL (DAYS)	DAYS TO HARVEST
Thrips (including Western Flower Thrips)	3.2 oz.	**Ground and Air Application:** Apply in water at 3 to 10 gals. spray per acre by air (minimum 5 gals. per acre in CA and AZ) or 10 to 25 gals. spray per acre by ground. Use sufficient carrier volume to provide thorough, uniform coverage. Apply when eggs or insects first appear. Repeat as necessary to maintain control.* **Lygus** – Use the higher rate for Lygus adults that have migrated into cotton. **Cotton Aphid** – This insect may develop resistance to various classes of insecticides. Consult your local Agricultural Extension Service for current control recommendations. **Armyworms & Cabbage Looper** – Apply when eggs first appear. **Bollworm and Tobacco Budworm** – Early season light infestation use 0.56 lb. per acre. Mid and late season moderate to severe infestations use 0.83 to 1.1 lbs. per acre for moderate to severe infestations. Apply when eggs first appear. Moths of budworm larvae are controlled when they come in direct contact with spray particles during application. Moth kill is most likely to occur when application is made late in the evenings during periods of peak activity. **DEADHATCH®:** Control of emerging larvae by consumption of treated egg casings. **Pink Bollworm** – Apply when insects first appear. **Cutworms** – Ground application is recommended. Aerial applications are less effective, but may be used. Apply in water at 3 to 10 gals. spray per acre by air (minimum 5 gals. per acre in CA and AZ) or 10 to 25 gals. spray per acre by ground. Control is most effective when ground application is made in the evenings and sprays are directed toward the base and lower portion of plant. Apply when insects first appear or damage is first noted and repeat application as necessary to maintain control.*	**Aerial Application: Do not apply ACEPHATE 90 WSP at more than 1.1 lbs./A (1.0 lb. a.i./A) in CA and AZ and not more than 0.83 lb./A (0.75 lb. a.i./A) in all other areas of the U.S.** Do not feed gin trash or treated forage to livestock. Do not allow animals to graze on treated areas. Do not apply more than 4.4 lbs. of ACEPHATE 90 WSP per acre (4.0 lbs. a.i./A) per crop cycle. This includes all uses of ACEPHATE 90 WSP in commercial seed-treatment, in-furrow spray, and foliar applications.	3 (for application rates at 0.56 lb. or less) 7 (for application rates greater than 0.56 lb.)	21
Plant Bugs (Lygus)	0.28 to 1.1 lbs. 0.56 to 1.1 lbs. (CA and AZ)				
Fleahopper	0.28 lb.				
Cotton Aphid (excluding AZ and CA)	0.56 to 1.1 lbs.				
Whitefly (excluding Sweetpotato/ Silverleaf Whitefly)	0.56 to 1.1 lbs.				
Armyworms (excluding Beet Armyworm) Cabbage Looper	1.1 lbs.				
Bollworm Tobacco Budworm Adults Larvae Eggs (DEADHATCH®)	0.56 to 1.1 lbs. (East of Rockies) 1.1 lbs. (CA & AZ)				
Cutworms Stinkbugs	0.83 lb.				
Pink Bollworm (AZ & CA)	1.1 lbs.				

COTTON TANK MIXES

GENERAL USE PRECAUTIONS:

Do not use treated seed for food or feed purposes or process for oil.

Do not feed gin trash or treated forage to livestock.

Do not allow livestock to graze on treated acres.

Do not apply more than 4.44 lbs. of ACEPHATE 90 WSP per acre (4.0 lbs. a.i./A) per crop cycle. This includes all uses of acephate on cotton; i.e. in-furrow sprays, foliar applications, and seed treatment applications.

When applied by air, do not apply more than 1.1 lbs. of ACEPHATE 90 WSP per acre (1 lb. a.i./A) in California and Arizona. Do not apply more than 0.83 lb. of ACEPHATE 90 WSP per acre (0.75 lb. a.i./A) for all other areas of the United States.

Always read and follow all label directions when using any pesticide alone or in tank mix combinations. Observe all restrictions and precautions that appear on all product labels. The most restrictive labeling applies when using a tank mix.

RESISTANCE MANAGEMENT

Cotton pest control programs, especially those for control of Sweetpotato/Silverleaf Whitefly populations, should employ a properly designed resistance management strategy. Such resistance management strategies include mixture or rotation of alternative classes of chemistry including organophosphates, carbamates, pyrethroids or insect growth regulators. Consult your state or area agricultural extension service for local resistance management strategies and advice on alternative insecticides.

PESTS CONTROLLED	AMOUNT ACEPHATE 90 WSP + CHLORPYRIFOS 4E PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS	MINIMUM SPRAY INTERVAL (DAYS)	DAYS TO HARVEST
Armyworms (excluding Beet Armyworm) Bollworms Cabbage Looper Cotton Aphid Cutworms** Fleahopper Grasshoppers Pink Bollworm Plant Bugs (Lygus, Mirids) Salt Marsh Caterpillar Thrips Tobacco Budworm Whitefly (excluding Sweetpotato/ Silverleaf Whitefly)	0.28 to 1.1 lbs. (4.4 to 17.6 oz.) ACEPHATE 90 WSP + 1 to 2 pts. CHLORPYRIFOS 4E	Apply when insects first appear or when damage is first noted and repeat application as necessary to maintain control.* Observe all applicable directions, restrictions and precautions on the EPA registered label for CHLORPYRIFOS 4 E. **By Ground:** Ground application is recommended. Apply in 10 to 25 gals. of spray per acre. Control is most effective when ground application is made in the evenings and sprays are directed toward the base and lower portion of plant. **By Air:** Aerial applications are less effective, but may be used. Apply in 3 to 10 gals. spray per acre (minimum 5 gals. spray per acre in CA). ****Cutworms:** Use 0.83 lb. per acre of ACEPHATE 90 WSP.	**Aerial Application: Do not apply ACEPHATE 90 WSP at more than 1.1 lbs./A (1.0 lb. a.i./A) in CA and AZ and not more than 0.83 lb./A (0.75 lb. a.i./A) in other areas of the U.S.** Do not feed gin trash or treated forage to livestock. Do not allow livestock to graze on treated areas. * Do not apply more than 4.4 lbs. of ACEPHATE 90 WSP per acre (4.0 lbs. a.i./A) per crop cycle. This includes all uses of ACEPHATE 90 WSP in commercial seed-treatment, in-furrow spray, and foliar applications.	3 (for application rates at 0.56 lb. or less) 7 (for application rates greater than 0.56 lb.)	21
Sweetpotato/ Silverleaf Whitefly	0.56 to 1.1 lbs. (8.9 to 17.6 oz.) ACEPHATE 90 WSP + 10 2/3 to 16 fl. oz. DANITOL® 2.4 EC	Apply when insects first appear or when damage is first noted. Repeat applications may be needed to maintain control.* Apply in water at 3 to 10 gals. spray per acre by air (minimum 5 gals. per acre in CA) or 10 to 25 gals. spray per acre by ground. Observe all applicable directions, restrictions and precautions on the EPA registered label for DANITOL® 2.4 EC Spray.			

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COTTON TANK MIXES WITH PYRETHROIDS

GENERAL USE PRECAUTIONS:

Do not use treated seed for food or feed purposes or process for oil.

Do not feed gin trash or treated forage to livestock.

Do not allow livestock to graze on treated acres.

Do not apply more than 4.44 lbs. of ACEPHATE 90 WSP per acre (4.0 lbs. a.i./A) per crop cycle. This includes all uses of acephate on cotton; i.e. in-furrow sprays, foliar applications, and seed treatment applications.

When applied by air, do not apply more than 1.1 lbs. of ACEPHATE 90 WSP per acre (1 lb. a.i./A) in California and Arizona. Do not apply more than 0.83 lb. of ACEPHATE 90 WSP per acre (0.75 lb. a.i./A) for all other areas of the United States.

Synthetic Pyrethroids should be used within the guidelines of state and/or regional resistance management programs and recommendations. Always read and follow all label directions when using any pesticide alone or in tank mix combinations. Observe all restrictions and precautions that appear on all product labels. The most restrictive labeling applies when using a tank mix.

RESISTANCE MANAGEMENT

Cotton pest control programs, especially those for control of Sweetpotato/Silverleaf Whitefly populations, should employ a properly designed resistance management strategy. Such resistance management strategies include mixture or rotation of alternative classes of chemistry including organophosphates, carbamates, pyrethroids or insect growth regulators. Consult your state or area agricultural extension service for local resistance management strategies and advice on alternative insecticides.

PESTS CONTROLLED	ACEPHATE 90 WSP AND TANK MIX PARTNER	AMOUNT OF ACEPHATE 90 WSP + TANK MIX PARTNER PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS	MINIMUM SPRAY INTERVAL (DAYS)	DAYS TO HARVEST
Aphids Bollworm Cabbage Looper Cotton Leaf Perforator Cutworms** Fall Armyworm Fleahoppers Pink Bollworm (AZ & CA) Plantbugs Stinkbugs** Sweetpotato/ Silverleaf Whitefly Thrips Tobacco Budworm Whitefly	ACEPHATE 90 WSP + one of the following:	0.56 to 1.1 lbs. per acre + one of the following:	Begin applications when eggs or insects appear and repeat application as needed to maintain control.* **By Ground:** Ground application is recommended. Control is most effective when ground applications are made in the evenings and sprays are directed toward the base and lower portion of plant. Apply in water at 10 to 25 gals. spray per acre by ground. **By Air:** Aerial applications are less effective, but may be used. Apply in water at 3 to 5 gals. spray per acre by air (minimum 5 gals. per acre in CA). ****Stinkbugs and Cutworms:** Use 0.83 lb. per acre of ACEPHATE 90 WSP.	**Aerial Application: Do not apply ACEPHATE 90 WSP at more than 1.1 lbs./A (1.0 lb. a.i./A) in CA and AZ and not more than 0.83 lb./A (0.75 lb. a.i./A) in other areas of the U.S.** Do not feed gin trash or treated forage to livestock. Do not allow livestock to graze on treated areas. * Do not apply more than 4.4 lbs. (4.0 lbs. a.i./A) of ACEPHATE 90 WSP per acre per crop cycle. This includes all uses of ACEPHATE 90 WSP in commercial seed-treatment, in-furrow spray, and foliar applications.	3 (for application rates at 0.56 lb. or less) 7 (for application rates greater than 0.56 lb.)	21 For use with SCOUT X-TRA, allow at least 28 days to elapse between final application and harvest.
	Cypermethrin 2.5 EC	Refer to the Cypermethrin 2.5 EC approved label for use instructions.				
	ASANA® XL	Refer to the ASANA® XL approved label for use instructions.				
	BAYTHROID® 2 EC	Refer to the BAYTHROID® 2 EC approved label for use instructions.				
	Bifenthrin 2 EC	Refer to the Bifenthrin 2 EC approved label for use instructions.				
	Lambda-Cyhalothrin 1 EC (Except CA)	Refer to the Lambda-Cyhalothrin 1 EC approved label for use instructions.				
	SCOUT® X-TRA (Except CA)	Refer to the SCOUT® X-TRA approved label for use instructions.				

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CRANBERRY

Ground Application: Apply with conventional ground equipment in sufficient water to ensure thorough coverage of the target crop.

Aerial Application: Make aerial applications in a minimum of 2 gallons per acre. Use sufficient carrier volume to provide thorough, uniform coverage.

Chemigation Application: This product may only be applied through sprinkler irrigation systems including center pivot, lateral move, end tow, side (wheel) roll, travelers, big gun, solid set, or hand move. Do not apply this product through any other type of irrigation system. Constant agitation must be maintained in the chemical supply tank during the entire period of insecticide application. Inject the product with a positive displacement pump into the main line ahead of a right turn to ensure adequate mixing. Application of more than label-recommended quantities of irrigation water per acre may result in decreased product performance by removing the chemical from the zone of effectiveness. Crop injury, lack of effectiveness, or illegal pesticide residues in the crop may result from non-uniform distribution of treated water.

GENERAL PRECAUTIONS FOR APPLICATIONS THROUGH CHEMIGATION SYSTEMS

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 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.
- 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 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.
- Do not apply when wind speed favors drift beyond the area intended for treatment.
- If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers, or other experts.
- **Solid Set System:** Apply specified dosage for the entire length of the irrigation period or for a 30 to 60 minute period at the end of a regular irrigation set or as a 30 to 60 minute injection as a separate application not associated with a regular irrigation. Allow time for all lines to flush the pesticide through all nozzles before turning off irrigation water. To ensure the lines are flushed and free of remaining pesticide, a dye indicator may be injected into the lines to mark the end of the application period. See Note below.
- **Center Pivot Systems:** Inject the specified dosage per acre continuously for one complete revolution of the system. See Note below.

NOTE: Constant agitation must be maintained in the chemical supply tank during the entire period of insecticide application. Inject the product with a positive displacement pump into the main line ahead of a right turn to ensure adequate mixing.

Application of more than label-recommended quantities of irrigation water per acre may result in decreased product performance by removing the chemical from the zone of effectiveness.

PESTS CONTROLLED	AMOUNT OF ACEPHATE 90 WSP PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS	MINIMUM SPRAY INTERVAL (DAYS)	DAYS TO HARVEST
Cranberry Blossomworm Cranberry Cutworm Gypsy Moth False Armyworm Fireworms Spanworms Sparganothis	1.1 lbs. (17.6 oz.)	Apply in water by air, ground or with sprinklers when insects first appear. Use a minimum of 2 gals. spray per acre by air. Use a sufficient amount of water to give thorough coverage with ground or sprinkler equipment.	Limit to one application per growing season. Do not apply more than 1.1 lbs./A (1.0 lb. a.i./A) per season. Do not apply from start of bloom until all berries set.	7	90

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HEAD LETTUCE —Crisphead Type Only—

PESTS CONTROLLED	AMOUNT OF ACEPHATE 90 WSP PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS	MINIMUM SPRAY INTERVAL (DAYS)	DAYS TO HARVEST
Aster Leafhopper Green Peach Aphid	0.56 to 1.1 lbs. (8.9 to 17.6 oz.)	**Ground Application:** Apply in 10 to 60 gallons per acre by conventional ground equipment to ensure thorough coverage of the target crop. **Aerial Application:** Make aerial applications in minimum of 5 gallons per acre. Use sufficient carrier volume to provide thorough, uniform coverage. Repeat application as necessary to maintain control.*	* Do not apply more than 2.2 lbs./A (2 lbs. a.i./A) per crop cycle. Do not feed trimmings to livestock or allow animals to graze on treated areas. For use on spring, summer, and early fall crops in all areas; winter crops in Florida and Texas; late fall crops in Arizona; and winter crops in Arizona and California. Do not apply after first head begins to form in crops which germinate from mid-September through November in desert areas of AZ & CA.	3 (for application rates at 8.9 oz. or less) 7 (for application rates greater than 8.9 oz.)	21
Armyworm (excluding Beet Armyworm) Cabbage Looper	1.1 lbs. (17.6 oz.)				

NON-BEARING CITRUS

PESTS CONTROLLED	AMOUNT OF ACEPHATE 90 WSP PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS	MINIMUM SPRAY INTERVAL (DAYS)	DAYS TO HARVEST
Aphids Grasshoppers Katydid Mealybugs Orangedog Plant bugs Thrips Whiteflies (except Sweetpotato & Silverleaf Whitefly)	0.56 lb. (8.9 oz.)	Apply when eggs or insects first appear. Apply as necessary to maintain control. Use the high rate when a heavy infestation is present. **Ground Application:** Apply in 100 to 200 gallons per acre by conventional ground equipment to ensure thorough coverage of the target crop. Spray individual juvenile or non-bearing trees for coverage with total application not to exceed specified rate in lbs. per acre. Length of residual activity will depend upon spray coverage and the amount of moisture following application.	Do not graze livestock in treated areas.	7	365
Citrus Blackfly	0.56 to 0.83 lb. (8.9 to 13.3 oz.)				
Ants (excluding fire, harvester, carpenter, and pharaoh)	0.83 lb. (13.3 oz.)				

PEANUTS

PESTS CONTROLLED	AMOUNT OF ACEPHATE 90 WSP PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS	MINIMUM SPRAY INTERVAL (DAYS)	DAYS TO HARVEST
Grasshoppers	0.28 to 0.56 lb. (4.4 to 8.9 oz.)	Apply when eggs or insects first appear. Repeat application as necessary to maintain control.* **Ground Application:** Apply in 10 to 50 gallons per acre by conventional ground equipment to ensure thorough coverage. **Aerial Application:** Make aerial applications in 5 to 10 gallons per acre. Use sufficient carrier volume to provide thorough, uniform coverage. ACEPHATE 90 WSP can be tank-mixed with registered at-cracking and early post-emergence peanut herbicides, as long as the labels of those products do not prohibit tank mixes. The most restrictive of label limitations and precautions must be observed. Do not exceed any of the label dosage rates. The physical compatibility can be tested by pouring the recommended proportions of each chemical with the same proportion of water as will be present in the chemical supply tank into a suitable container. Mix thoroughly and allow to stand for five minutes. If the combination remains mixed, or can be remixed readily, the mixture is considered physically compatible. If included, add wettable powder or dry flowable formulations and disperse these first, then add liquid pesticides. If any separation is observed and it cannot be readily remixed, the combination should not be used. Tank mixes should be agitated continuously and should be applied as soon as prepared. Do not allow combinations to remain in the chemical supply tank or irrigation lines for prolonged periods.	* Do not apply more than 4.4 lbs./A (4 lbs. a.i./A) per crop cycle. This includes all uses of ACEPHATE 90 WSP on peanuts as a foliar spray in addition to the peanut planter box seed treatment use. Do not feed treated forage or hay to livestock or allow animals to graze on treated areas.	3 (for application rates at 0.56 lb. or less) 7 (for application rates greater than 0.56 lb.)	14 (from final application to digging or lifting of peanuts)
Thrips	0.42 to 0.83 lb. (6.7 to 13.3 oz.)				
Corn Earworm Fall Armyworm Leafhoppers Loopers Velvetbean Caterpillar	0.83 to 1.1 lbs. (13.3 to 17.6 oz.)				

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PEPPERMINT AND SPEARMINT

PESTS CONTROLLED	AMOUNT OF ACEPHATE 90 WSP PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS	MINIMUM SPRAY INTERVAL (DAYS)	DAYS TO HARVEST
Alfalfa Looper Aphids Cutworms	1.1 lbs. (17.6 oz.)	Apply when eggs or insects first appear. Make one repeat application, if necessary, to maintain control. **Ground Application:** Apply in 20 to 100 gallons per acre by conventional ground equipment to ensure thorough coverage of the target crop. **Aerial Application:** Make aerial applications in minimum of 5 to 10 gallons per acre. Use sufficient carrier volume to provide thorough, uniform coverage.	Do not apply more than 2.2 lbs./A (2 lbs. a.i./A) per crop cycle. Do not graze treated areas. Do not use spent hay for feed for dairy animals.	7	14
Strawberry Root Weevil Adult Black Vine Weevil Adult	1.1 lbs. (17.6 oz.)	**Ground Application:** Apply in 40 to 100 gallons per acre by conventional ground equipment to ensure thorough coverage of the target crop. Good spray coverage and canopy spray penetration is critical for control. Increase spray volume and pressure with tall or dense mint canopy. Apply after adult emergence is complete but prior to egg laying. Apply at dusk or during the night on a warm still evening. A second application may be necessary to reduce heavy infestations.	Do not apply more than 2.2 lbs./A (2 lbs. a.i./A) per crop cycle. Do not graze treated areas. Do not use spent hay for feed for dairy animals.	10	14

BELL PEPPERS

PESTS CONTROLLED	AMOUNT OF ACEPHATE 90 WSP PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS	MINIMUM SPRAY INTERVAL (DAYS)	DAYS TO HARVEST
Grasshoppers	0.28 to 0.56 lb. (4.4 to 8.9 oz.)	Apply when eggs or insects first appear. Repeat as necessary to maintain insect-pest populations below economically damaging numbers.* **Ground Application:** Apply in 25 to 150 gallons per acre by conventional ground equipment to ensure thorough coverage. **Aerial Application:** Make aerial applications in minimum of 3 gallons per acre (minimum of 5 gals./A in CA). Use sufficient carrier volume to provide thorough, uniform coverage.	* Do not apply more than 2.2 lbs./A (2 lbs. a.i./A) per crop cycle.	7	7
Cabbage Looper Green Peach Aphid Tobacco Hornworm	0.56 to 1.1 lbs. (8.9 to 17.6 oz.)				

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NON-BELL PEPPERS (For use only in Midwestern states, Eastern states, and Puerto Rico)

PESTS CONTROLLED	AMOUNT OF ACEPHATE 90 WSP PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS	MINIMUM SPRAY INTERVAL (DAYS)	DAYS TO HARVEST
Aphids	0.56 lb. (8.9 oz.)	**Ground Application:** Apply in 40 to 150 gallons per acre by conventional ground equipment to ensure thorough coverage. Repeat at 7 to 10 day spray intervals as necessary.*	* Do not apply more than 1.1 lbs./A (1.0 lb. a.i./A) per crop cycle.	7	7

SOYBEANS

PESTS CONTROLLED	AMOUNT OF ACEPHATE 90 WSP PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS	MINIMUM SPRAY INTERVAL (DAYS)	PRE-HARVEST INTERVAL, DAYS (PHI)
Grasshopper Thrips	0.28 to 0.56 lb. (4.4 to 8.9 oz.)	Apply when eggs or insects first appear. Repeat as necessary to maintain insect-pest populations below economically damaging numbers.* **Ground Application:** Apply in 10 to 50 gallons per acre by conventional ground equipment to ensure thorough coverage. **Aerial Application:** Make aerial applications in 5 to 10 gallons per acre (minimum of 5 gals./A in CA). Use sufficient carrier volume to provide thorough, uniform coverage.	* Do not apply more than 1.67 lbs./A (1.5 lbs. a.i./A) per crop cycle. Do not graze or cut vines for hay or forage.	3 (for application rates at 8.9 oz. or less) 7 (for application rates greater than 8.9 oz.)	14
Potato Leafhopper Stinkbugs	0.56 to 1.1 lbs. (8.9 to 17.6 oz.)				
Armyworm (except Beet) Bean Leaf Beetle Cabbage Looper Green Cloverworm Mexican Bean Beetle Soybean Aphid Threecornered Alfalfa Hopper Velvetbean Caterpillar	0.83 to 1.1 lbs. (13.3 to 17.6 oz.)				

TOBACCO

TOBACCO TRANSPLANT WATER APPLICATION

PESTS CONTROLLED	AMOUNT OF ACEPHATE 90 WSP PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS
Cutworms Flea Beetle Green Peach Aphid Potato Tuberworm Tobacco Aphid Tobacco Thrips	0.83 lb. (13.3 oz.)	ACEPHATE 90 WSP provides control of early season insect pressures for approximately 3 to 4 weeks after transplanting. For later season control of these insects, apply a foliar spray of ACEPHATE 90 WSP. Apply in a minimum of 100 gals. of transplant water per acre. ACEPHATE 90 WSP can be pre-mixed in water to form a slurry solution prior to adding to the transplant water tank. Make transplant water applications using mechanical transplant equipment only to ensure that the insecticide/water mix is applied directly to the soil along with the transplanted plants.	Do not apply more than 4.4 lbs./A (4 lbs. a.i./A) per crop cycle. This includes all uses of ACEPHATE 90 WSP including transplant water, plant bed, soil, foliar and float bed. Do not apply more than 0.83 lb. ACEPHATE 90 WSP per acre as a transplant water application as some phytotoxicity may occur.

US EPA ARCHIVE DOCUMENT

TOBACCO *continued*

TOBACCO FOLIAR APPLICATION

PESTS CONTROLLED	AMOUNT OF ACEPHATE 90 WSP PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS	MINIMUM SPRAY INTERVAL (DAYS)	DAYS TO HARVEST
Grasshoppers	0.28 to 0.56 lb. (4.4 to 8.9 oz.)	**Ground Application:** Apply in 10 to 50 gallons per acre by conventional ground equipment to ensure thorough coverage. **Aerial Application:** Make aerial applications in minimum of 3 gallons per acre. Use sufficient carrier volume to provide thorough, uniform coverage.	Do not apply more than 4.4 lbs./A (4 lbs. a.i./A) per crop cycle. This includes all uses of ACEPHATE 90 WSP including transplant water, plant bed, soil, foliar and float bed.	3 (for application rates at 8.9 oz. or less) 7 (for application rates greater than 8.9 oz.)	3
Green Peach Aphid Flea Beetle Tobacco Hornworm Tobacco Thrips	0.56 lb. (8.9 oz.)				
Stink bugs Tobacco Aphid Vegetable Weevils	0.56 to 0.83 lb. (8.9 to 13.2 oz.)				
Budworm Cabbage Looper Cutworm Japanese Beetle	0.83 lb. (13.2 oz.)				

TOBACCO PLANT BED APPLICATION

PESTS CONTROLLED	APPLICATION INSTRUCTIONS	RESTRICTIONS
Cutworm Flea Beetle Green Peach Aphid Tobacco Aphid	Apply to foliage at the equivalent of 0.83 lb./A (0.75 lb. a.i./A) ACEPHATE 90 WSP in 3 gallons of water for every 3,000 square feet of bed. Apply evenly to ensure thorough coverage.	Do not apply more than 4.4 lbs./A (4 lbs. a.i./A) per crop cycle. This includes all uses of ACEPHATE 90 WSP including transplant water, plant bed, soil, foliar and float bed.

NON-CROP AREAS

FIELD BORDERS, FENCEROWS, ROADSIDES, DITCHBANKS, AND BORROW PITS

PESTS CONTROLLED	AMOUNT OF ACEPHATE 90 WSP PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS
Grasshoppers	0.28 lb. (4.4 oz.)	**Ground Application:** Apply in 10 to 20 gallons per acre by conventional ground equipment to ensure thorough coverage. **Aerial Application:** Make aerial applications in minimum of 1 to 5 gallons per acre (minimum 5 gallons/A in CA). Use sufficient carrier volume to provide thorough, uniform coverage. Make applications early to mid-season. Use the higher volumes when spraying dense foliage. An approved drift retardant may be added to aid in controlling drift and reducing evaporation of aerial sprays.	Do not graze livestock or feed vegetation cut from treated areas to livestock.

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NON-CROP AREAS *continued*

WASTELAND

PESTS CONTROLLED	AMOUNT OF ACEPHATE 90 WSP PER ACRE	APPLICATION INSTRUCTIONS	RESTRICTIONS
Black Grass Bugs Grasshoppers Mormon Crickets	0.11 to 0.14 lb. (1.7 to 2.2 oz.)	**Ground Application:** Apply in 10 to 20 gallons per acre by conventional ground equipment to ensure thorough coverage. **Aerial Application:** Make aerial applications in minimum of 1/2 gallon per acre (minimum 5 gallons/acre in CA). Use sufficient carrier volume to provide thorough, uniform coverage. Use the higher volumes when spraying dense foliage. An approved drift retardant may be added to aid in controlling drift and reducing evaporation of aerial sprays.	Do not make more than one application per season. Do not graze livestock or feed vegetation cut from treated areas to livestock.

SPECIALTY USES

CROP TOLERANCE

ACEPHATE 90 WSP Insecticide is generally not phytotoxic to most greenhouse or field grown plants or turf. However, it is impossible to test all plant varieties and cultural conditions. Before treating large plantings, apply to a representative group of plants and observe for two weeks to assure that a particular variety, grow under current conditions is not sensitive to ACEPHATE 90 WSP. Use on turfgrass is limited to sod farms and golf courses, except when applying by mound or spot treatment for fire ant and harvester ant control.

The following have been found to be sensitive to ACEPHATE 90 WSP:

Trees: Balm of Gilead, Cottonwood, Lombardy Poplar or Viburnum suspensum and Crabapple varieties, Ichonoski, Malusfioribunda, Pink Perfection, Red Wine and Snow Cloud.

Plants: Bletchum gibbum, Cissus antarctica, Ficus triangularis, Fittonia verschaffeltii, Maranta leuconeura kerchovena, Pachystachya lutea, Plectranthus australis, Polypodium aureus, Polystichum, Pteris ensiformis, Tolmiea menziesii.

Chrysanthemum Varieties: Albatross, Bonnie Jean, Dixie, Garland, Gem, Iceberg, Pride, Showoff, Statesman, Tally Ho, Westward Ho and Wild Honey. Application to chrysanthemums and roses with open flowers will cause injury to the flowers.

Application to Huckleberry, Balm of Gilead, Cottonwood, Lombardy Poplar and Viburnum suspensum may cause injury to the plants.

Nursery crops. Before treating large plantings, spray only a few plants and observe two weeks for phytotoxicity.

TABLE OF EQUIVALENTS FOR 0.28 LB. POUCH

RATE OF ACEPHATE 90 WSP PER 100 GALS. WATER	NUMBER OF 0.28 LB. POUCHES PER 100 GALS. OF WATER
0.28 lb. (4.4 oz.)	1
0.56 (8.9 oz.)	2
0.83 (13.3 oz.)	3
1.1 lbs. (17.7 oz.)	4

RATES OF ACEPHATE 90 WSP		TREATMENT AREA PER 0.28 LB. POUCH	
LB. PER ACRE	OZ. PER 1,000 SQ. FT.	ACRES	SQ. FT.
1.1	0.4	0.255	11,115
2.3	0.8	0.127	5,515
3.2	1.2	0.085	3,676
3.4	1.3	0.076	3,384
4.3	1.6	0.068	2,756
5.5	2.0	0.051	2,206

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CONTAINER GROWN ORNAMENTAL NURSERY STOCK

PLANTS	PESTS CONTROLLED	AMOUNT ACEPHATE 90 WSP PER 100 GALS.	APPLICATION TIMING	APPLICATION INSTRUCTIONS
Arborvitae Azalea Camellia Rhododendron Roses Viburnum Yew	Black Vine Weevil Strawberry Root Weevil	0.83 lb. (13.3 oz.)	Application should be made by mid-September for greenhouse stock and by mid-October for outdoor stock. Consult your local county extension agent for information on the identification and control of root weevils on ornamentals.	Apply the specified amount ACEPHATE 90 WSP Spray per 100 gals. of solution so as to thoroughly drench the root system. Make repeat applications at 3 day intervals for application rates at 8.9 oz. or less and at 7 day intervals for application rates greater than 8.9 oz. Do not apply more than 0.83 lb./acre (0.75 lb. a.i./A).
	Ants (excluding fire, harvester, carpenter, and pharaoh)		Apply as needed to control the pest.	

ORNAMENTAL TREES AND SHRUBS

PLANTS	PESTS CONTROLLED	AMOUNT ACEPHATE 90 WSP PER 100 GALS.	APPLICATION TIMING	APPLICATION INSTRUCTIONS
Trees and Shrubs (except Flowering Crabapple, and Douglas Fir, see below)	Aphids Bagworms Birch Leafminer Tent Caterpillar* Lace Bugs Leafrollers	0.28 lb. (4.4 oz.)	As the insects begin to appear. Make repeat applications at 3 day intervals for application rates at 8.9 oz. or less and at 7 day intervals for application rates greater than 8.9 oz.	Apply the specified amount of ACEPHATE 90 WSP in 100 gals. water with a hydraulic sprayer. The addition of a suitable sticker improves control of Gypsy Moth larvae. Application to Huckleberry, Balm of Gilead, Cottonwood, Lombardy Poplar and Viburnum suspensum may cause injury to the plants. Nursery crops: Before treating large plantings, spray only a few plants and observe two weeks for phytotoxicity. * Use a mist blower application. Adjust rates to 1.1 lbs. per 100 gals. water for Gypsy Moth control and 0.83 lb. per 100 gals. water for Tent Caterpillar control.
	Douglas Fir Tussock Moth Larvae Gypsy Moth Larvae* Webworms	0.56 lb. (8.9 oz.)	As the insects begin to appear. Make repeat applications at 3 day intervals for application rates at 8.9 oz. or less and at 7 day intervals for application rates greater than 8.9 oz.	
	Scales (Crawlers)		As crawlers begin to appear. Repeat applications, at a 2-week or more interval, may be necessary where there is continuous crawler infestation.	
	Ponderosa Pine Needle Miner	0.56 lb. (8.9 oz.)	Time of application is important. Consult your Farm Advisor or County Extension Agent.	Apply the specified amount of ACEPHATE 90WSP in 100 gals. Water with a hydraulic sprayer to ensure a full coverage spray. Except where noted, make repeat applications at 3 day intervals for application rates at 8.9 oz. or less and at 7 day intervals for application rates greater than 8.9 oz. For all listed ornamental trees and shrubs, application rates must not exceed 1.1 lbs./acre (1.0 lb. a.i./A) ACEPHATE 90 WSP per 100 gals.
	Grasshoppers		As the grasshoppers begin to appear.	
	California Oakworm Cankerworms (Spring and Fall)	0.28 to 0.56 lb. (4.4 to 89 oz.)	As the insects begin to appear. Use the higher amount when the larger larvae are present.	

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ORNAMENTAL TREES AND SHRUBS *continued*

PLANTS	PESTS CONTROLLED	AMOUNT ACEPHATE 90 WSP PER 100 GALS.	APPLICATION TIMING	APPLICATION INSTRUCTIONS
Trees and Shrubs (except Flowering Crabapple, and Douglas Fir, see below)	Nantucket Pine Tip Moth Larvae	0.83 lb. (13.3 oz.)	Time of application is important. Consult your Farm Advisor or County Extension Agent. Repeat applications will be required for subsequent generations.	Apply the specified amount of ACEPHATE 90 WSP in 100 gals. Water with a hydraulic sprayer to ensure a full coverage spray. Except where noted, make repeat applications at 3 day intervals for application rates at 8.9 oz. or less and at 7 day intervals for application rates greater than 8.9 oz. For all listed ornamental trees and shrubs, application rates must not exceed 1.1 lbs./acre (1.0 lb. a.i./A) ACEPHATE 90 WSP per 100 gals.
	Root Weevil Adults		Apply when first feeding damage occurs. Repeat applications at four week intervals until the first heavy frost may be necessary for complete foliage protection.	
	Box Elder Bugs Sawflies Budworms Leafhoppers		As the insects begin to appear.	
	Japanese Beetle	1.1 lbs. (17.6 oz.)	As the Japanese Beetles begin to appear. Repeat applications at 2 week intervals may be necessary.	
	Elm Leaf Beetle (larvae)		As the larvae begin to appear. ACEPHATE 90 WSP will not prevent Elm Leaf Beetle eggs from hatching.	
Douglas Fir Christmas Trees	Douglas Fir Needle Midge	0.56 lb. (8.9 oz.) (equivalent to 0.56 lb. per acre)	Application should be made no more than 2 weeks prior to bud burst. For additional pest management information, consult your County Extension Service.	Apply the specified amount of ACEPHATE 90 WSP in not less than 2 gals. of spray per acre by air or in 100 gals. of spray per acre by ground. Do not make more than one application per season.
Flowering Crabapples	Aphids Tent Caterpillars Leafrollers	0.28 lb. (4.4 oz.)	As the insects begin to appear.	Apply the specified amount of ACEPHATE 90 WSP in 100 gals. water with a hydraulic sprayer. Do not apply more than 3 times in a growing season at 4 week intervals. Caution: Phytotoxicity has occurred on the following Crabapple varieties: Hops, Ichonoski, Malusfloribunda, Pink Perfection, Red Wine and Snow Cloud.

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OUTDOOR FLORAL CROPS AND GROUND COVERS

PLANTS	PESTS CONTROLLED	AMOUNT ACEPHATE 90 WSP PER 100 GALS.	APPLICATION TIMING	APPLICATION INSTRUCTIONS	RESTRICTIONS
Chrysanthemums Daisies Dahlias Easter Lily Gladioli Gyposophila Pachysandra Pansy Peony Roses Sedum Statice Strawflower Yarrow Zinnia	Aphids Thrips Lygus	0.56 lb. (8.9 oz.)	As insects begin to appear. Repeat applications at 14 day intervals may be necessary.	Apply the specified amount of ACEPHATE 90 WSP in 100 gals. water with a hydraulic sprayer as a full coverage spray. Multiple applications may cause slight tip burn or marginal leaf necrosis on some varieties. Test on a few plants to determine varietal susceptibility.	If flowers are to be cut, do not apply more than 0.83 lb./acre (0.75 lb. a.i./A) ACEPHATE 90 WSP per 100 gals. For all other ornamental flowers and plants, application rates must not exceed 1.1 lbs./acre (1.0 lb. a.i./A) ACEPHATE 90 WSP per 100 gals.
Roses Boston Ivy	Japanese Beetles	0.83 to 1.1 lbs. (13.3 to 17.7 oz.)	As the Japanese Beetles begin to appear. Repeat applications at 2 week intervals may be necessary.		

COMMERCIAL GREENHOUSE FLORAL AND FOLIAGE PLANTS

PLANTS	PESTS CONTROLLED	AMOUNT ACEPHATE 90 WSP PER 100 GALS.	APPLICATION TIMING	APPLICATION INSTRUCTIONS	RESTRICTIONS
Roses	Leafrollers	0.56 to 0.83 lb. (8.9 to 13.3 oz.)	As leafrollers begin to appear. Use the higher amount when large larvae are present.	Apply the specified amount of ACEPHATE 90 WSP in 100 gals. water with a hydraulic sprayer as a full coverage spray.	Do not apply more than 0.83 lb./acre (0.75 lb. a.i./A).
Foliage Plants Orchids Anthuriums Cacti Poinsettia	Aphids	0.28 lb. (4.4 oz.)	As aphids begin to appear.	Apply the specified amount of ACEPHATE 90 WSP in 100 gals. water with a hydraulic sprayer as a full coverage spray. The addition of a wetting agent may be required on difficult to wet foliage. Caution: Phytotoxicity has occurred on the following foliage plants: Bletchum gibbum, Cissus antarctica, Ficus triangularis, Fittonia verschaffeltii, Maranta leuconeura kerchoveana, Pachystachya lutea, Plectranthus australis, Polypodium aureus, Polystichum, Pteris ensiformis, Tolmiea menziesii. Before treating large plantings spray only a few plants and observe 2 weeks for varietal phytotoxicity. Application of ACEPHATE 90 WSP on Poinsettias after bract formation may result in phytotoxicity on certain varieties.	
	Mealybugs Thrips Whiteflies	0.56 lb. (8.9 oz.)	As the insects begin to appear. A repeat application, at a 2 week interval, may be necessary for control of mealybugs and whiteflies.		
	Scales (Crawlers)		As crawlers begin to appear. Repeat applications at a 2 week or more interval may be necessary where there is continuous crawler infestation.		

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COMMERCIAL GREENHOUSE FLORAL AND FOLIAGE PLANTS *continued*

PLANTS	PESTS CONTROLLED	AMOUNT ACEPHATE 90 WSP PER 100 GALS.	APPLICATION TIMING	APPLICATION INSTRUCTIONS	RESTRICTIONS
Foliage Plants Orchids Anthuriums Cacti Poinsettia	Sweetpotato/ Silverleaf Whiteflies (Except CA)	0.56 lb. (8.9 oz.) plus TAME® 2.4 EC Spray 10 2/3 fl. oz. (0.2 lb. a.i.)	Apply when insects first appear. If a population is well established, make one application of the tank mix and follow 5 to 7 days later with TAME alone at 16 fl. oz./ 100 gals. See TAME label for instructions.	For Sweetpotato/Silverleaf whitefly control, apply the specified amount of ACEPHATE 90 WSP plus TAME 2.4 EC Spray as a tank mix at a volume necessary to obtain good coverage. Follow the TAME label for specific instructions on the alternation of TAME plus ACEPHATE 90 WSP and TAME alone and the rotation instruction to avoid potential resistance.	Do not apply more than 0.83 lb./acre (0.75 lb. a.i./A).
Roses Carnations Chrysanthemum	Aphids Thrips	0.56 lb. (8.9 oz.)	As aphids begin to appear. As thrips begin to appear or at the tight flower bud stage. Repeat applications to roses may be necessary at two week intervals.	Apply the specified amount of ACEPHATE 90 WSP in 100 gals. water with a hydrauiic sprayer as a full coverage spray. UPI recommends that application to Carnations and Chrysanthemum not be made more often than once every 28 days. Caution: Phytotoxicity has occurred on the following Chrysanthemum varieties: Albatross, Bonnie Jean, Dixie, Garland, Gent, Iceberg, Pride, Showoff, Statesman, Tally Ho, Westward Ho, and Wild Honey. Before treating large Chrysanthemum plantings, spray only a few plants and observe two weeks for varietal phytotoxicity. Application to chrysanthemums and roses with open flowers will cause injury to the flowers. Do not apply under conditions involving possible drift to food, forage or other plantings that might be damaged or the crops thereof rendered unfit for sale, use or consumption.	

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COMMERCIAL TURFGRASS: SOD FARMS AND GOLF COURSES ONLY

Do not allow livestock to graze treated areas. Do not feed treated grass to livestock. Use is limited to sod farms and golf courses, except when applying by mound or spot treatment for fire ant and harvester ant control. Aerial applications to turf are prohibited.

PESTS CONTROLLED	AMOUNT ACEPHATE 90 WSP PER 1,000 SQ. FT. GOLF COURSES	AMOUNT ACEPHATE 90 WSP PER 1,000 SQ. FT. SOD FARM TURF	APPLICATION TIMING	APPLICATION INSTRUCTIONS	MINIMUM SPRAY INTERVAL (DAYS)	DAYS TO HARVEST
Fall Armyworm Yellow Striped Armyworm Southern Armyworm	0.4 to 1 oz. (1.1 to 2.7 lbs. per acre)	0.4 to 1 oz. (1.1 to 2.7 lbs. per acre)	Apply when the insects first appear. A repeat application may be needed.	Apply the specified amount of ACEPHATE 90 WSP per 1,000 sq. ft. Use a minimum of 5 gals. water per 1,000 sq. ft. to obtain good coverage.	14	3 (Sod farm turf)
Cutworm	1 to 1.6 oz. (2.7 to 4.3 lbs. per acre)	1 to 1.2 oz. (2.7 to 3.2 lbs. per acre)				
Chinch bugs	1 to 1.6 oz. (2.7 to 4.3 lbs. per acre)	1 to 1.2 oz. (2.7 to 3.2 lbs. per acre)	Apply as needed for adult population knock-down. A repeat application may be needed.	Apply the specified amount of ACEPHATE 90 WSP per 1,000 sq. ft. Use 1 to 15 gals. water per 1,000 sq. ft. to obtain good coverage. For heavy infestations, use the higher dosage rate.	10	
Leafhopper	0.8 oz. (2.3 lbs. per acre)	0.8 oz. (2.3 lbs. per acre)	As the leafhoppers begin to appear. A repeat application may be needed.		7	
Sod Webworm (Crambus spp.)	0.4 to 0.8 oz. (1.1 to 2.3 lbs. per acre)	0.4 to 0.8 oz. (1.1 to 2.3 lbs. per acre)	As the webworms begin to appear. A repeat application may be needed.			
Mole Crickets (Except CA) Spittlebug (Except CA)	0.8 to 1.6 oz. (2.3 to 4.3 lbs. per acre)	0.8 to 1.2 oz. (2.3 to 3.2 lbs. per acre)	As insects begin to appear. More than one application may be required throughout the growing season for knockdown of existing populations. Apply during late afternoon or early evening hours and after an irrigation. Do not irrigate after application. **See footnote 1.**			
Greenbug (Schizaphis graminum) Grasshoppers	0.4 oz. (1.1 lbs. per acre)	0.4 oz. (1.1 lbs. per acre)	Apply when the insects first appear. A repeat application may be needed.	Apply the specified amount of ACEPHATE 90 WSP per 1,000 sq. ft. Use 4 gals. water per 1,000 sq. ft. to obtain good coverage. Do not mow turfgrass for at least 24 hours after application.		
Black Turfgrass Ataenius (Except CA)	1.3 to 1.6 oz. (3.4 to 4.3 lbs. per acre)	1.2 oz. (3.2 lbs. per acre)		Apply the specified amount of ACEPHATE 90 WSP per 1,000 sq. ft. Use a minimum of 5 gals. water per 1,000 sq. ft. Irrigate lightly (no more than 0.5 inches) after application. Use the higher rate for severe infestations.		

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COMMERCIAL TURFGRASS: SOD FARMS AND GOLF COURSES ONLY *continued*

PESTS CONTROLLED	AMOUNT ACEPHATE 90 WSP PER 1,000 SQ. FT. GOLF COURSES	AMOUNT ACEPHATE 90 WSP PER 1,000 SQ. FT. SOD FARM TURF	APPLICATION TIMING	APPLICATION INSTRUCTIONS	MINIMUM SPRAY INTERVAL (DAYS)	DAYS TO HARVEST
Dichondra on Golf Courses and Sod Farms: Cutworm Flea Beetle Southern Armyworm Yellow Striped Armyworm	0.83 to 1.6 oz. (2.3 to 4.3 lbs. per acre)	0.83 to 1.2 oz. (2.3 to 3.2 lbs. per acre)	Apply when the insects first appear. A repeat application may be needed.	Apply the specified amount of ACEPHATE 90 WSP per 1,000 sq. ft. Use a minimum of 15 gals. water per 1,000 sq. ft. to obtain good coverage.	14	3 (sod farm turf)

Footnote 1: The use of a lemon fragrance substance in the spray mix may enhance control by acting as a flushing agent and thus provide increased mole cricket contact with ACEPHATE 90 WSP. The following lemon-scented products have been shown to be effective flushing agents: Lemon Joy, Lemon Palmolive, and Mighty Myrt Products Manufacture- Base Pure Lemon Fragrance. The use rate for these lemon-scented products is 2 teaspoons per gallon of water for small total mix volumes or 6 fl. oz. per 50 gals. of water for large mix volumes.

OUTDOOR AND PERIMETER SPRAY EXCLUDING RESIDENTIAL TURF

LOCATION	PESTS CONTROLLED	AMOUNT ACEPHATE 90 WSP	APPLICATION TIMING	APPLICATION INSTRUCTIONS
Outdoor and perimeter area excluding residential turf	Wasps	1.3 oz. (0.08 lb.) Equivalent to 1 packet (0.28 lb.) in 3.5 gallons water	Treat early or late in the day as wasps are generally less active during these times.	Apply the specified amount of ACEPHATE 90 WSP per gallon of water used. Apply as a spot treatment to the nest, nest entrance, and surrounding areas where the wasps alight.
	Ants (excluding fire, harvester, carpenter, and pharaoh ants) Crickets Cockroaches Earwigs Pillbugs		As the insects appear.	Apply specified amount of ACEPHATE 90 WSP per gallon of water used. Apply to a band of soil 6 to 10 feet adjacent to the structure and to a height of 2 to 3 feet on the foundation where pests may be active or may find entrance. Also apply as a residual spray or with a paint brush to surfaces of buildings, window frames, shutters, entryways, screens, eaves, patios, garages, carports, around garbage areas and other areas where these pests congregate.

NON-BEARING CITRUS - SOIL MOUND DRENCHES

PESTS CONTROLLED	AMOUNT ACEPHATE 90 WSP	APPLICATION INSTRUCTIONS	RESTRICTIONS
Ants (excluding carpenter and pharaoh)	Drench method: Mix 1 lb. in 100 gals. of water.	Apply 1 gal. of mix to each mound area by sprinkling the mound until it is wet and treat a four (4) foot diameter circle around the mound. Repeat application as necessary to maintain control.	Do not graze treated areas. Do not harvest citrus for one year after treatment.

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OUTDOOR AND PERIMETER SPRAY EXCLUDING RESIDENTIAL TURF *continued*

TOBACCO GREENHOUSE (FLOATBED) APPLICATION

PESTS CONTROLLED	AMOUNT ACEPHATE 90 WSP	APPLICATION INSTRUCTIONS	RESTRICTIONS
Cutworm Flea Beetle Green Peach Aphid Tobacco Aphid	0.83 lb./A (13.3 oz.)	Apply to foliage at the equivalent of 0.83 lb./A (0.75 lb. a.i./A) ACEPHATE 90 WSP in 3 gallons of water for every 3,000 square feet of bed. Apply evenly to ensure thorough coverage.	Do not apply more than 4.4 lbs./A (4 lbs. a.i./A) per crop cycle. This includes all uses of ACEPHATE 90 WSP including transplant water, plant bed, soil, foliar and float bed. Floatbed water should be disposed of in the transplanted field in either transplant water or as a foliar spray.

TOBACCO SOIL APPLICATION

PESTS CONTROLLED	AMOUNT ACEPHATE 90 WSP	APPLICATION INSTRUCTIONS	RESTRICTIONS
Fire Ants & Harvester Ants	Drench method: Mix 1 lb. in 100 gals. of water.	When insects first appear. Apply 1 gal. of mix to each mound area by sprinkling the mound until it is wet and treat a four (4) foot diameter circle around the mound.	Do not apply more than 4.4 lbs./A (4 lbs. a.i./A) per season. This includes the use of ACEPHATE in transplant water, plant bed, soil, float bed (greenhouse), and foliar applications. Allow at least 3 days to elapse between final application and harvest. Treat a maximum of 13 mounds per acre. Do not treat more than once per season.

CRAPE MYRTLE

PESTS CONTROLLED	AMOUNT ACEPHATE 90 WSP	APPLICATION TIMING	APPLICATION INSTRUCTIONS
Aphids	2.0 lbs. in 20 oz. water Equivalent to 7 packets (each 0.28 lb.) in 20 oz. water	As aphids begin to appear.	Remove the loose bark from the trunk areas to be treated. Completely paint a band around each trunk to a width twice its diameter. Paint on to trunks within a zone 6 to 12 inches above the ground and below the point where branching begins. For multi-trunk plants, be certain to treat all trunks. For either single or multi-trunk plants, application should be made as low as possible within the recommenced treatment zone.

MOUND TREATMENT OF FIRE ANTS AND HARVESTER ANTS IN TURFGRASS

PLANTS	PESTS CONTROLLED	AMOUNT ACEPHATE 90 WSP	APPLICATION TIMING	APPLICATION INSTRUCTIONS
Turfgrass Residential, Recreational and Commercial Turf	Imported Fire Ants and Harvester Ants	Drench method: Mix 1 lb. in 100 gals. of water.	When insects first appear.	Apply 1 gal. of mix to each mound area by sprinkling the mound until it is wet and treat a four (4) foot diameter circle around the mound. Grass in treated area may be injured. Do not allow livestock to graze treated areas. Do not feed treated grass to livestock. Do not treat mound more than once per season. For Sod Farms: allow at least 3 days to elapse between last application and harvesting sod.

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STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Keep pesticide in original container. Do not put concentrated or dilute product into food or drink containers. Store in a cool, dry place. Protect from excessive heat. Do not contaminate food or feedstuffs. Do not store or transport near feed or food.

PESTICIDE DISPOSAL: 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 the outer bag. Dispose of outer bag in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

IMPORTANT INFORMATION
READ BEFORE USING PRODUCT

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product reflect the opinion of experts based on field use and tests and must be followed carefully. 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 manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of United Phosphorus, Inc. or Seller. Handling, storage, and use of the product by Buyer or User are beyond the control of United Phosphorus, Inc. and Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold United Phosphorus, Inc. and Seller harmless for any claims relating to such factors.

To the extent consistent with applicable law, United Phosphorus, 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, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or United Phosphorus, Inc., and Buyer and User assume the risk of any such use. To the extent consistent with applicable law, UNITED PHOSPHORUS, INC. MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent consistent with applicable law, United Phosphorus, Inc. or Seller shall not be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF UNITED PHOSPHORUS, INC. AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF UNITED PHOSPHORUS, INC. OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

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ASANA® -- Reg. TM of E.I. duPont de Nemours & Co., Inc. for esfenvalerate insecticide.
BAYTHROID® -- Reg. TM of Bayer Crop Protection for cyfluthrin synthetic pyrethroid.
CAPTURE® -- Reg. TM of FMC Corporation for bifenthrin insecticide-miticide.
DANITOL® -- Reg. TM of Sumitomo Chemical Company Ltd. for fenpropathrin insecticide-miticide.
KARATE® -- Reg. TM of Syngenta Crop Protection, Inc. for lambdacyhalothrin insecticide.
SCOUT® X-TRA -- Reg. TM of Hoechst-Roussel Agri for tralomethrin pyrethroid insecticide.
TAME® -- Reg. TM of Valent U.S.A. Corporation.

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Bayer CropScience

SEVIN® 80 Solupak

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. 264-316 **E.P.A. Est. No. 264-MO-02**

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.)

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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)

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.

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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® 80 Solupak 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

Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If bag is burned, stay out of smoke.

GENERAL CAUTIONS AND RESTRICTIONS

SEVIN® 80 Solupak 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 water soluble paks from the container except for immediate use. Use the entire contents of a water soluble pak, do not break open to use partial contents of a water soluble pak.

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® 80 Solupak into the mixing tank. Allow all the water soluble paks to dissolve and completely disperse. Depending upon the water temperature and the

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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® 80 Solupak, 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® 80 SOLUPAK 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® 80 Solupak 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® 80 Solupak, and then the remaining volume of water. (Suspension concentrations using the appropriate dosage per acre recommended on this label of SEVIN® 80 Solupak, 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® 80 Solupak into the irrigation water line so as to deliver the desired rate per acre. The suspension of SEVIN® 80 Solupak 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® 80 Solupak 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

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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.

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ASPARAGUS

CROP	PEST	POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	SPECIFIC DIRECTIONS
Broccoli Brussel Sprouts Cauliflower Cabbage Chinese Cabbage Collards Kale Kohlrabi Mustard Greens	Flea beetles Harlequin bug Leafhoppers	5/8 to 1 1/4	2.0 to 1.0	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 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.

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CEREAL GRAIN CROPS

FIELD CORN AND POPCORN

CROP	PEST	POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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.

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GRAIN SORGHUM

CROP	PEST	POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	SPECIFIC DIRECTIONS
Grain Sorghum	Armyworm, Chinch bugs, Corn earworm, Fall armyworm, Stink bugs, 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® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	SPECIFIC DIRECTIONS
Rice	Armyworm, Chinch bugs, Fall armyworm, Leafhoppers, Stink bugs	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.

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SWEET CORN

CROP	PEST	POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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.

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WHEAT AND PROSO MILLET

CROP	PEST	POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	SPECIFIC DIRECTIONS
Wheat Proso Millet	Flea beetles	5/8 to 1 1/4	2.0 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 are 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® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	SPECIFIC DIRECTIONS
Cucurbit Vegetables: Cucumbers Melons Pumpkins Squash	Pickleworm Melonworm	5/8 to 1 1/4	2.0 to 1.0	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 1/4	1.0	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 7 1/2 pounds per acre per crop.
- Observe plant response precautions.

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FLAX

CROP	PEST	POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	SPECIFIC DIRECTIONS
Alfalfa, Clovers, and Birdsfoot Trefoil	Blister beetles Mexican bean beetle	5/8 to 1 1/4	2.0 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 5/8	1.0 to 0.77	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.

US EPA ARCHIVE DOCUMENT

PASTURE AND GRASSES GROWN FOR SEED

CROP	PEST	POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	SPECIFIC DIRECTIONS
Rangeland	Black grass bug Grasshoppers Mormon cricket Range caterpillar Range crane fly	5/8 to 1 1/4	2.0 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.

US EPA ARCHIVE DOCUMENT

FRUITING VEGETABLES

CROP	PEST	POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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	5/8 to 1 1/4	2.0 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® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	SPECIFIC DIRECTIONS
Leafy vegetables:	Flea beetles Harlequin bug Leafhoppers	5/8 to 1 1/4	2.0 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.

US EPA ARCHIVE DOCUMENT

LEGUME VEGETABLES

CROP	PEST		POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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	5/8 to 1 1/4	2.0 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		5/8 to 1 7/8	2.0 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.

US EPA ARCHIVE DOCUMENT

NONCROPLAND

CROP	PEST	POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	SPECIFIC DIRECTIONS
Conservation Reserve Program Acreage Set-Aside Program Acreage Wasteland Rights-of-Way Hedgerows Ditchbanks Roadsides	Black grass bug	1/3 to 5/8	3.7 to 2.0	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	5/8 to 1 1/4	2.0 to 1.0	
	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® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	SPECIFIC DIRECTIONS
Okra	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.

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

US EPA ARCHIVE DOCUMENT

PEANUTS

CROP	PEST	POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	SPECIFIC DIRECTIONS
Peanuts	Blister beetles Mexican bean beetle	5/8 to 1 1/4	2.0 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® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	SPECIFIC DIRECTIONS
Prickly Pear Cactus	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.

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

US EPA ARCHIVE DOCUMENT

ROOT AND TUBER CROPS

ROOT AND TUBER CROPS EXCEPT SUGAR BEETS AND SWEET POTATOES

CROP	PEST	POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	SPECIFIC DIRECTIONS
Root and Tuber Crops:	Flea beetles Leafhoppers	5/8 to 1 1/4	2.0 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® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	SPECIFIC DIRECTIONS
Sugar beets	Armyworm Beet leaf beetle Fall armyworm Flea beetles Leafhoppers Webworms	1 1/4 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.

US EPA ARCHIVE DOCUMENT

SWEET POTATOES

CROP	PEST		POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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.

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SUNFLOWERS

CROP	PEST	POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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 0.5	**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.

US EPA ARCHIVE DOCUMENT

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® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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 0.06	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® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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.

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POME FRUITS

CROP	PEST		POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	SPECIFIC DIRECTIONS
Pome Fruits: apples, pears, loquats, crabapples, oriental pears	White apple leafhopper		5/8 to 1 7/8	2.0 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. 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 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	

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POME FRUITS
(continued)

CROP	PEST	POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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 5/8 pounds per 100 gal. of spray mixture. For difficult to thin varieties: apply 5/8 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® 80 Solupak 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.

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STONE FRUITS

CROP	PEST	POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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.

US EPA ARCHIVE DOCUMENT

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® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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.

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TREE NUTS

CROP	PEST	POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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.

US EPA ARCHIVE DOCUMENT

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® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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	1.4 to 1.0	

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FORESTED AREAS AND RANGELAND TREES, CONTINUED

CROP	PEST	POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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.

US EPA ARCHIVE DOCUMENT

CONTROL OF SPECIFIC PESTS ACROSS MULTIPLE SITES
GRASSHOPPERS

CROP	PEST	POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	SPECIFIC DIRECTIONS
All crops on this label	Grasshoppers	5/8 to 1 7/8*	2.0 to 0.67	Apply 5/8 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® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	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.

US EPA ARCHIVE DOCUMENT

IMPORTED FIRE ANTS

CROP/SITE	PEST	POUNDS OF SEVIN® 80 Solupak PER VOLUME OF WATER	AREA TREATED per SEVIN® 80 Solupak	SPECIFIC DIRECTIONS
Pastures Rangeland Forested Areas 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.

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ADULT MOSQUITO CONTROL

Apply in sufficient gallonage for thorough coverage.

CROP	PEST	POUNDS OF SEVIN® 80 Solupak PER ACRE	ACRES TREATED per SEVIN® 80 Solupak	SPECIFIC DIRECTIONS
Pastures Rangeland Forested Lands Wastelands	Mosquitoes (adults)	1/3 to 1 1/4*	3.75 to 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 5/8 pounds per 100 gallons in mistblowers, 5/8 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.

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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: TO THE EXTENT ALLOWED BY LAW, 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: 4 x (1.25 lb) Water Soluble Paks

SEVIN is the registered trademark of Bayer.

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)

07/19/06

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Pesticide Product MSDS

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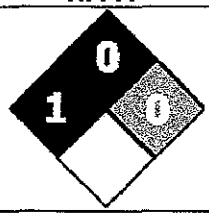
Material Safety Data Sheet

United Phosphorus, Inc.

NFPA	PPE
	 

Issued Date 12-Apr-2007 **Revision Date** **Revision Number:** 0

12U-101 - Acephate 75 WSP

1. PRODUCT AND COMPANY IDENTIFICATION

UPI
630 Freedom Business Center
Suite 402
King of Prussia,PA 19406

Emergency Telephone Number
Chemtrec: (800) 424-9300 (24hrs) or (703) 527-3887
Medical: Rocky Mountain Poison Control Center
(866) 767-5089 (24hrs)

Company Information	Contact Information	Phone Number	Available Hrs
UPI	Customer Service	1-800-438-6071	8:00 am to 5:00 pm EST
	R&D Technical Service	610-878-6100	8:00 am - 5:00 pm (EST)

Product Name	Acephate 75 WSP
EPA Reg #	70506-1
Recommended Use	insecticide
Product Code	12U-101

2. HAZARDS IDENTIFICATION

Emergency Overview
Irritating to eyes
Harmful if swallowed

CAUTION
Appearance Fine,, White. **Physical State** Powder. Highly hydroscopic. **Odor** Rotten. Cabbage.

Potential Health Effects

Eyes	Moderately irritating to the eyes.
Skin	Prolonged or repeated contact may cause irritation, redness and rash..
Inhalation	Harmful by inhalation. Mist or dust concentrations may be harmful or irritating if inhaled. Signs and symptoms of respiratory tract irritation may include nasal discharge, sore throat, pulmonary edema and difficulty breathing. .
Ingestion	Harmful if swallowed. Signs and symptoms which may occur within 12 hours following overexposure include headache, dizziness, weakness, pinpoint pupils, blurred vision, excessive salivation and nasal discharge, abdominal cramps, nausea and vomiting..

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients Name

Chemical Name	CAS-No	Weight %	OSHA PEL
Acephate	30560-19-1	75	N/A

4. FIRST AID MEASURES

Eye Contact
Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.
Call a poision control center or doctor for treatment advice.

Skin Contact
Take off contaminated clothing.
Rinse skin immediately with plenty of water for 15-20 minutes.
Call poison control center or doctor for treatment advice.

Inhalation
Move person to fresh air.
If person is not breathing, call 911 or an ambulance, then give artifical respiration.
Call a physician or Poison Control Centre immediately

Ingestion
Call a physician or Poison Control Centre immediately
Have person sip a glass of water if able to swallow
Never give anything by mouth to an unconscious person
Do not induce vomiting unless told to do so by a poison control center or doctor

Notes to Physician
Cholinesterase inhibitor. Atropine is antidotal. PAM may alos be used in conjunction with atropine but should not be used alone.

5. FIRE-FIGHTING MEASURES

Flammable Explosive Properties

Flash Point Not available
Autoignition Temperature Not available

Flammability Limits in Air Not available

Extnguishing Media Foam Carbon dioxide (CO2) Water spray

Fire/Explosion Hazard Contain run-off from fire.

Hazardous Combustion Products Carbon dioxide (CO2), Sulfur oxides, Oxides of nitrogen, Oxides of phosphorous.

NFPA **Health** 1 **Flammability** 0 **Instability** 0

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Avoid contact with the skin and the eyes. Ensure adequate ventilation. Take precautionary measures against static discharges.

Environmental Precautions Consult a regulatory specialist to determine appropriate state or local reporting

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requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinenet environmental permits.. Do not flush into surface water or sanitary sewer system. Do not allow material to contaminate ground water system.

Methods for Clean-up Sweep up and shovel into suitable containers for disposal. Reduce dust spreading with water spray, collect rinsate..

7. HANDLING AND STORAGE

Handling Keep out of reach of children. Wear personal protective equipment. Avoid contact with skin and eyes. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation. Wash thoroughly after handling. . Remove and wash contaminated clothing before re-use. Empty containers may contain hazardous residues.

Storage Keep away from direct sunlight. Keep containers tightly closed in a cool, well-ventilated place.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines

Engineering Controls Investigate engineering techniques to reduce exposures. Local mechanical exhaust ventilation is preferred. Consult ACGIH ventilation manual or NFPA Standard 91 for design of exhaust systems. .

Personal Protective Equipment

Eye/face Protection Use eye protection to avoid eye contact. . Where there is potential for eye contact have eye flushing equipment available..

Skin Protection Chemical resistant gloves. Chemical resistant protective clothing.

Respiratory Protection Where airborne exposure is likely, use NIOSH approved respiratory protection equipment appropriate to the material and/or its components. Full facepiece equipment is recommended and, if used, replaces need for face shield and/or chemical goggles. If exposures cannot be kept at a minimum with engineering controls, consult respirator manufacturer to determine appropriate type equipment for given application. Observe respirator use limitations specified by NIOSH or the manufacturer. For emergency and other conditions where there may be a potential for significant exposure, use an approved full face positive-pressure, self-contained breathing apparatus. Respiratory protection programs must comply with 29 CFR 1910.134. .

General Hygiene Considerations
Do not eat, drink or smoke when using this product. Wash hands and face before breaks and immediately after handling the product. Remove and wash contaminated clothing before re-use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Fine, White	**Odor**	Rotten Cabbage
Physical State	Powder Highly hydroscopic	**pH**	approx. (1% solution)4
Boiling Point/Range	Not available	**Melting Point/Range**	90 °C / 195°F
Specific Gravity	Not available	**Solubility**	Soluble
Evaporation Rate	Not available	**Vapor Pressure**	1.7 X 10-6 mmHG @24 C (acephate)
Vapor Density	Not available	**VOC Content**	Not available
Viscosity	Not available	**Molecular Weight**	183.2
Bulk Density	25-30 lbs/ft3	**Percent Solids**	Not available
Percent Volatiles	Not available		

10. STABILITY AND REACTIVITY

Stability Stable under recommended storage conditions

Conditions to Avoid Extreme temperatures. Excess moisture.

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Incompatible Materials	Alkaline.
Hazardous Decomposition Products	Oxides of sulfur. Oxides of nitrogen. Oxides of phosphorous.
Possibility of Hazardous Polymerization	Hazardous polymerisation does not occur

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Product Information

Acephate 75 SP
Eye irritation - minimal effects clearing within 24 hrs
Skin irritation - non-irritating (rabbit)
Dermal toxicity - LD50 5050 mg/kg (rat)
Oral toxicity - LD50 3129 mg/kg (rat)
Inhalation tox - 4 hr LC50 >2,3 mg/L (rat)
Sensitization - negative (guinea pig)

Chronic Toxicity

Carcinogenicity

Acephate - High doses of Acephate technical have produced cancer in mice but there is no evidence thatt Acephate technical causes cancer in humans. EPA has classified Acephate as a Group C possible human carcinogen based on the cancer produced in female mice. This product is not listed as a carcinogen by the National Toxicology Program (NTP), the International Agency for Rearch of Cancer (IARC) or the Occupational Safety and Health Administration (OSHA). .

12. ECOLOGICAL INFORMATION

Ecotoxicity

Acephate- This pesticide is toxic to birds. Do not apply directly to water, to areas where surface water is present. Cover or soil incorporate spills. 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 drift to blooming crops or weeds if bees are visiting the treatment area. Oral LD50 for bees is 1.2 ug/bee.

Fish and avian toxicity:
96 hr LC50 Rainbow trout - >1,000 ug/L
96 hr LC50 Bluegill - >2,000 ug/L
Oral LD50 Mallar duck - 350 mg/kg
Oral LD50 Pheasant - 140 mg/kg

In addition, Acephate technical in the diet causes adverse effects on reproduction in mallard ducks (NOEL >5ppm but <20ppm) and in Bobwhite quail (NOEL >20ppm and <80ppm). Acephate SP -
Bluegill - 2050 ppm
Black Bass - 1725 ppm
Catfish - 2230 ppm
Crayfish - 750 ppm
Mosquito fish - 6000 ppm

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method	Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If the wastes cannot be disposed of by use or 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. . Dispose of in accordance with all applicable federal, state, and local laws and regulations. .
Contaminated Packaging	Empty containers may container hazardous residues. Containers should be handled as instructed by following all container disposal directions .

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14. TRANSPORT INFORMATION

DOT	Not regulated
ICAO	Not regulated
IATA	Not regulated
IMDG/IMO	Not regulated

15. REGULATORY INFORMATION

International Inventories

Acephate

EINECS/ELINCS	Listed
CHINA	Listed
KECL	Listed

USA

Federal Regulations

SARA 313
SARA 313

Chemical Name	CAS-No	Weight %
Acephate	30560-19-1	75

SARA 311/312 Hazardous Categorization

Chronic Health Hazard	Yes
Acute Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act

Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs) (see 40 CFR 61)
This product does not contain any HAPs.

CERCLA
RCRA
Pesticide Information

State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals.

State Right-to-Know
International Regulations
Mexico - Grade Not available

Canada

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all the information required by the CPR.

WHMIS Hazard Class
Not determined

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16. OTHER INFORMATION

Revision Date

Revision Summary
Add to new MSDS system

UPI, Inc. believes that the information and recommendations container herein (including data and statements) are accurate as of the date hereof. NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY, OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IS MADE CONCERNING THE INFORMATION PROVIDED HEREIN. The information provided herein relates only to the specific product designated and may not be valid where such product is used in combination with other materials or in any process. Further, since the conditions and methods of use are beyond the control of UPI, Inc. UPI, Inc. expressly disclaims any and all liability as to any results obtained or arising from any use of the product or reliance on such information.

End of MSDS

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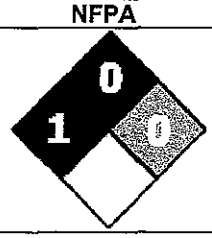
Material Safety Data Sheet

United Phosphorus, Inc.

NFPA	PPE
	

Issued Date 12-Apr-2007 **Revision Date** **Revision Number:** 0

12U-103 - Acephate 90 SP Insecticide
Acephate 90 WSP Insecticide

1. PRODUCT AND COMPANY IDENTIFICATION

UPI
630 Freedom Business Center
Suite 402
King of Prussia,PA 19406

Emergency Telephone Number
Chemtrec: (800) 424-9300 (24hrs) or (703) 527-3887
Medical: Rocky Mountain Poison Control Center
(866) 767-5089 (24hrs)

Company Information	Contact Information	Phone Number	Available Hrs
UPI	Customer Service	1-800-438-6071	8:00 am to 5:00 pm EST
	R&D Technical Service	610-878-6100	8:00 am - 5:00 pm (EST)

Product Name	Acephate 90 SP Insecticide Acephate 90 WSP Insecticide
EPA Reg #	70506-2
Recommended Use	insecticide
Product Code	12U-103

2. HAZARDS IDENTIFICATION

Emergency Overview
Irritating to eyes
Harmful if swallowed

CAUTION

Appearance Fine,, White. **Physical State** Powder. Highly hydroscopic. **Odor** Rotten. Cabbage.

Potential Health Effects

Eyes	Moderately irritating to the eyes.
Skin	Prolonged or repeated contact may cause irritation, redness and rash..
Inhalation	Harmful by inhalation. Mist or dust concentrations may be harmful or irritating if inhaled. Signs and symptoms of respiratory tract irritation may include nasal discharge, sore throat, pulmonary edema and difficulty breathing. .
Ingestion	Harmful if swallowed. Signs and symptoms which may occur within 12 hours following overexposure include headache, dizziness, weakness, pinpoint pupils, blurred vision,

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excessive salivation and nasal discharge, abdominal cramps, nausea and vomiting..

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients Name

Chemical Name	CAS-No	Weight %	OSHA PEL
Acephate	30560-19-1	90	N/A

4. FIRST AID MEASURES

Eye Contact
Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.
Call a poision control center or doctor for treatment advice.

Skin Contact
Take off contaminated clothing.
Rinse skin immediately with plenty of water for 15-20 minutes.
Call poison control center or doctor for treatment advice.

Inhalation
Move person to fresh air.
If person is not breathing, call 911 or an ambulance, then give artifical respiration.
Call a physician or Poison Control Centre immediately

Ingestion
Call a physician or Poison Control Centre immediately
Have person sip a glass of water if able to swallow
Never give anything by mouth to an unconscious person
Do not induce vomiting unless told to do so by a poison control center or doctor

Notes to Physician
Cholinesterase inhibitor. Atropine is antidotal. PAM may alos be used in conjunction with atropine but should not be used alone.

5. FIRE-FIGHTING MEASURES

Flammable Explosive Properties

Flash Point Not available
Autoignition Temperature Not available

Flammability Limits in Air Not available

Extnguishing Media Foam Carbon dioxide (CO2) Water spray

Fire/Explosion Hazard Contain run-off from fire.

Hazardous Combustion Products Carbon dioxide (CO2), Sulfur oxides, Oxides of nitrogen, Oxides of phosphorous.

NFPA **Health** 1 **Flammability** 0 **Instability** 0

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Avoid contact with the skin and the eyes. Ensure adequate ventilation. Take precautionary measures against static discharges.

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Environmental Precautions Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinenet environmental permits.. Do not flush into surface water or sanitary sewer system. Do not allow material to contaminate ground water system.

Methods for Clean-up Sweep up and shovel into suitable containers for disposal. Reduce dust spreading with water spray, collect rinsate..

7. HANDLING AND STORAGE

Handling Keep out of reach of children. Wear personal protective equipment. Avoid contact with skin and eyes. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation. Wash thoroughly after handling. . Remove and wash contaminated clothing before re-use. Empty containers may contain hazardous residues.

Storage Keep away from direct sunlight. Keep containers tightly closed in a cool, well-ventilated place.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines

Engineering Controls Investigate engineering techniques to reduce exposures. Local mechanical exhaust ventilation is preferred. Consult ACGIH ventilation manual or NFPA Standard 91 for design of exhaust systems. .

Personal Protective Equipment

Eye/face Protection Use eye protection to avoid eye contact. . Where there is potential for eye contact have eye flushing equipment available..

Skin Protection Chemical resistant gloves. Chemical resistant protective clothing.

Respiratory Protection Where airborne exposure is likely, use NIOSH approved respiratory protection equipment appropriate to the material and/or its components. Full facepiece equipment is recommended and, if used, replaces need for face shield and/or chemical goggles. If exposures cannot be kept at a minimum with engineering controls, consult respirator manufacturer to determine appropriate type equipment for given application. Observe respirator use limitations specified by NIOSH or the manufacturer. For emergency and other conditions where there may be a potential for significant exposure, use an approved full face positive-pressure, self-contained breathing apparatus. Respiratory protection programs must comply with 29 CFR 1910.134. .

General Hygiene Considerations
Do not eat, drink or smoke when using this product. Wash hands and face before breaks and immediately after handling the product. Remove and wash contaminated clothing before re-use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Fine, White	**Odor**	Rotten Cabbage
Physical State	Powder Highly hydroscopic	**pH**	approx. (1% solution)4
Boiling Point/Range	Not available	**Melting Point/Range**	Not available 90 °C / 195°F
Specific Gravity	Not available	**Solubility**	Soluble
Evaporation Rate	Not available	**Vapor Pressure**	1.7 X 10-6 mmHG @24 C (acephate)
Vapor Density	Not available	**VOC Content**	Not available
Viscosity	Not available	**Molecular Weight**	No data available
Bulk Density	25-30 lb/ft3	**Percent Solids**	Not available
Percent Volatiles	Not available		

10. STABILITY AND REACTIVITY

Stability Stable under recommended storage conditions

Conditions to Avoid Extreme temperatures. Excess moisture.

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Incompatible Materials	Alkaline.
Hazardous Decomposition Products	Oxides of sulfur. Oxides of nitrogen. Oxides of phosphorous.
Possibility of Hazardous Polymerization	Hazardous polymerisation does not occur

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Product Information

Acephate 90
Eye irritation: Moderate irritation (rabbit)
Skin irritation: Not irritating (rabbit)
Dermal toxicity : LD50 (rat) >10 g/kg
Oral toxicity: LD50 (female rat) 1030 mg/kg
Inhalation toxicity: 4 hr LC50 (Rat, acephate tech) >60 mg/L
Skin sensitization: Negative (guinea pig)

Chronic Toxicity

Carcinogenicity

Acephate - High doses of Acephate technical have produced cancer in mice but there is no evidence thatt Acephate technical causes cancer in humans. EPA has classified Acephate as a Group C possible human carcinogen based on the cancer produced in female mice. This product is not listed as a carcinogen by the National Toxicology Program (NTP), the International Agency for Rearch of Cancer (IARC) or the Occupational Safety and Health Administration (OSHA). .

12. ECOLOGICAL INFORMATION

Ecotoxicity

Acephate- This pesticide is toxic to birds. Do not apply directly to water, to areas where surface water is present. Cover or soil incorporate spills. 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 drift to blooming crops or weeds if bees are visiting the treatment area. Oral LD50 for bees is 1.2 ug/bee.

Fish and avian toxicity:
96 hr LC50 Rainbow trout - >1,000 ug/L
96 hr LC50 Bluegill - >2,000 ug/L
Oral LD50 Mallar duck - 350 mg/kg
Oral LD50 Pheasant - 140 mg/kg

In addition, Acephate technical in the diet causes adverse effects on reproduction in mallard ducks (NOEL >5ppm but <20ppm) and in Bobwhite quail (NOEL >20ppm and <80ppm). Acephate SP -
Bluegill - 2050 ppm
Black Bass - 1725 ppm
Catfish - 2230 ppm
Crayfish - 750 ppm
Mosquito fish - 6000 ppm

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method	Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If the wastes cannot be disposed of by use or 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. . Dispose of in accordance with all applicable federal, state, and local laws and regulations. .
Contaminated Packaging	Empty containers may container hazardous residues. Containers should be handled as instructed by following all container disposal directions .

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14. TRANSPORT INFORMATION

DOT	Not regulated
ICAO	Not regulated
IATA	Not regulated
IMDG/IMO	Not regulated

15. REGULATORY INFORMATION

International Inventories

Acephate

EINECS/ELINCS	Listed
CHINA	Listed
KECL	Listed

USA

Federal Regulations

SARA 313
SARA 313

Chemical Name	CAS-No	Weight %
Acephate	30560-19-1	90

SARA 311/312 Hazardous Categorization

Chronic Health Hazard	Yes
Acute Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act

Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs) (see 40 CFR 61)
This product does not contain any HAPs.

CERCLA
RCRA
Pesticide Information

State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals.

State Right-to-Know
International Regulations
Mexico - Grade Not available

Canada

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all the information required by the CPR.

WHMIS Hazard Class
Not determined

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16. OTHER INFORMATION

Revision Date

Revision Summary
Add to new MSDS system

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End of MSDS

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Bayer CropScience

Material Safety Data Sheet

SEVIN® BRAND 80 SOLUPAK

MSDS Number: 102000004247
MSDS Version 2.0
Revision Date: 08/03/2006

SECTION 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Product Name SEVIN® BRAND 80 SOLUPAK
MSDS Number 102000004247
EPA Registration No. 264-316

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	80.00
Synthetic amorphous silica	112926-00-8	12.00
Quartz (Silica, Crystalline)	14808-60-7	0.05

SECTION 3. HAZARDS IDENTIFICATION

NOTE: Please refer to Section 11 for detailed toxicological information.

Emergency Overview Warning! Hazard to humans and domestic animals. May be fatal if swallowed. Harmful if inhaled or absorbed through skin. Harmful if gets in eyes. Do not breathe dust or spray mist. Do not get in eyes, on skin, or on clothing. Keep out of reach of children and animals. Highly toxic to bees.

Physical State solid powder fine

Odor phenolic

Appearance white to slightly yellow

Routes of Exposure Inhalation, Ingestion, Skin contact, Eye contact

Immediate Effects

Eye Causes redness, irritation, tearing.

Skin Harmful if absorbed through skin. May produce symptoms similar to those from ingestion.

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Ingestion	May be fatal 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. 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

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	Wash off with soap and water. Take off contaminated clothing and shoes immediately. Call a physician or poison control center immediately.
Ingestion	Do not leave victim unattended. Call a physician or poison control center immediately. Rinse out mouth and give water in small sips to drink. Never give anything by mouth to an unconscious person. DO NOT induce vomiting unless directed to do so by a physician or poison control center.
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	Local: Temporary blurred vision due to contraction of the pupils (miosis) following contact with the eyes. Systemic: bradycardia low blood pressure salivation bronchial hypersecretion nausea vomiting diarrhoea

sweating
muscular fasciculation
spasm
breathing difficulties
respiratory paralysis
somnolence
coma
respiratory failure
hypothermia
convulsions

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 not applicable

Fire and Explosion Hazards In the event of fire the following can be released:
carbon monoxide (CO)
nitrogen oxides (NOx)

Accumulation of fine dust may entail the risk of a dust explosion in the presence of air.

Suitable Extinguishing Media foam, dry powder, carbon dioxide (CO_2)

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Fire Fighting Instructions	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. 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. 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. Use breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Methods for Cleaning Up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Pick up and fill the product into a tightly closed container. When picked up, treat material as prescribed in Ch. 13. "Disposal considerations". Use approved industrial vacuum cleaner for removal. Avoid dust formation. Decontaminate tools and equipment following cleanup. Clean contaminated surface thoroughly.
Additional Advice	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. Spills may be reportable to the National Response Center (800-424-8802) and to state and/or local agencies. Do not allow to enter soil, waterways or waste water canal.

SECTION 7. HANDLING AND STORAGE

Handling Procedures	Wear suitable gloves and eye/face protection. Smoking, eating and drinking should be prohibited in the application area. Avoid contact with skin and eyes. Do not ingest. Avoid breathing dust.
Storing Procedures	Keep out of reach of children and animals. Store in original container. Keep in a dry, cool place. Keep away from food, drink and animal feedingstuffs.
Work/Hygienic Procedures	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. Contaminated work clothing should not be allowed out of the workplace. In addition, based upon the specific hazard of this product: Shower and change into street clothes before leaving the work site.
Min/Max Storage Temperatures	Do not transport or store below 0 °C / 32 °F Thirty (30) day average not to exceed 100ºF.

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SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

General Protection

Cholinesterase activity of the worker should be supervised.

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.

Engineering Controls

Provide appropriate exhaust ventilation at places where dust is formed.

Eye/Face Protection

Safety glasses with side-shields

An emergency eye wash must be readily accessible to the work area.

Hand Protection

Chemical-resistant gloves made of waterproof material such as neoprene, butyl rubber, barrier laminate or nitrile rubber

Body Protection

Wear long-sleeved shirt and long pants and shoes plus socks.

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.

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	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
Synthetic amorphous silica	112926-00-8	ACGIH	TWA	10 mg/m3
		OSHA Z1A	TWA	6 mg/m3
		NIOSH	REL	6 mg/m3
		OSHA Z1	PEL	5 mg/m3
		Form of Exposure		Respirable fraction.
		OSHA Z1	PEL	15 mg/m3
		Form of Exposure		Total dust.
		Z3	TWA	15 millions of particles per

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				cubic foot of air
		Form of Exposure		Respirable fraction.
		Z3	TWA	50 millions of particles per cubic foot of air
		Form of Exposure		Total dust.
		Z3	TWA	5 mg/m3
		Form of Exposure		Respirable fraction.
		Z3	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.
		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	10 mg/m3
		Form of Exposure		Total dust.
		Z3	TWA	20 millions of particles per cubic foot of air
		Z3	TWA	0.8 mg/m3
		Remarks		The value is calculated from a specified equation using a value of 100%. Lower values of % will give higher exposure limits. See regulation for specific equation.
Quartz (Silica, Crystalline)	14808-60-7	ACGIH	TWA	0.05 mg/m3
		Form of Exposure		Respirable fraction.
		ACGIH NIC	TWA	0.025 mg/m3
		Form of Exposure		Respirable fraction.
		NIOSH	REL	0.05 mg/m3
		Form of Exposure		Respirable dust.
		OSHA Z1A	TWA	0.1 mg/m3
		Form of Exposure		Respirable dust.
		Z3	TWA	2.4 millions of particles per cubic foot of air
		Form of Exposure		Respirable.
		Remarks		The value is calculated from a specified equation using a value of 100%. Lower values of % will give higher exposure limits. See regulation for specific equation.

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Z3		TWA	0.1 mg/m3
	Form of Exposure		Respirable.
	Remarks		The value is calculated from a specified equation using a value of 100%. Lower values of % will give higher exposure limits. See regulation for specific equation.
Z3		TWA	0.3 mg/m3
	Form of Exposure		Total dust.
	Remarks		The value is calculated from a specified equation using a value of 100%. Lower values of % will give higher exposure limits. See regulation for specific equation.
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.
OSHA Z1		PEL	5 mg/m3
	Form of Exposure		Respirable fraction.
OSHA Z1		PEL	15 mg/m3
	Form of Exposure		Total dust.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	white to slightly yellow
Physical State	solid powder fine
Odor	phenolic
pH	4 - 6.5 (10 %) suspension in water
Density	0.3 g/l loose
Bulk Density	18.0 lbs/cu.ft.
Water solubility	dispersible
Decomposition Temperature	175 - 190 °C Exothermic decomposition.

SECTION 10. STABILITY AND REACTIVITY

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Chemical Stability	Stable under recommended storage conditions.
Conditions to Avoid	Exposure to extreme heat. Exposure to open flame.
Incompatibility	strong acids bases
Hazardous Decomposition Products	Thermal decomposition nitrogen oxides (NOx) Carbon oxides methyl isocyanate (trace; no adverse effects expected)
Hazardous Reactions	None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity data has been bridged from similar formulations containing the same or a slightly higher percentage of the active ingredient, carbaryl. The non-acute information pertains to technical-grade carbaryl.

Acute Oral Toxicity	male rat: LD50: 406 mg/kg female rat: LD50: 203 mg/kg
Acute Dermal Toxicity	male/female rat: LD50: > 5,000 mg/kg
Acute Inhalation Toxicity	male/female rat: LC50: > 4.9 mg/l Exposure time: 4 h male/female rat: LC50: > 19.6 mg/l Exposure time: 1 h Extrapolated from the 4 hr LC50.
Skin Irritation	rabbit: No skin irritation.
Eye Irritation	rabbit: Mild eye irritation.
Sensitization	guinea pig: Non-sensitizing.
Chronic Toxicity	Reversible cholinesterase inhibition occurred in chronic toxicity studies in rats and dogs. The principal organs affected in rats from long-term exposure to high-doses of carbaryl included the urinary bladder, thyroid, kidneys and liver.

Assessment Carcinogenicity

Carbaryl has been shown to cause tumors in laboratory animals in lifetime feeding studies.

ACGIH

Carbaryl	63-25-2	Group A4

NTP
None.

IARC

Carbaryl	63-25-2	Overall evaluation: 3

OSHA
None.

Reproductive & Developmental Toxicity	REPRODUCTION: Carbaryl was not a reproductive toxicant in a two-generation study in rats. 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	A battery of in vitro and in vivo mutagenicity studies have been conducted on carbaryl. Collectively, these studies indicate that carbaryl poses only a slight mutagenic risk.

SECTION 12. ECOLOGICAL INFORMATION

Toxicity to Fish	Rainbow trout (Oncorhynchus mykiss) LC50: 3.3 mg/l Exposure time: 96 h Information refers to the main component.
Toxicity to Aquatic Plants	Navicula pelliculosa (diatom algae) EC50: 0.61 mg/l Exposure time: 120 h Information refers to the main component.
Acute Toxicity to Aquatic Invertebrates	Water flea (Daphnia magna) EC50: 0.0164 mg/l Exposure time: 48 h Information refers to the main component. Water flea (Daphnia magna) NOEC: 5.6 mg/l Information refers to the main component.
Toxicity to other organisms	Mallard duck LC50: > 5,000 mg/kg Exposure time: 8 d

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The value mentioned relates to the active ingredient.
Dietary concentrations.

Bobwhite quail
LC50: > 5,000 mg/kg
Exposure time: 8 d
The value mentioned relates to the active ingredient.

Environmental Precautions

Extremely toxic to aquatic and estuarine invertebrates. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark outside of a treated rice field. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent sites. Do not contaminate surface or ground water by cleaning equipment or disposal of wastes, including equipment wash water.

Highly toxic to bees. 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

In accordance with current regulations may be taken to waste disposal site or incineration plant, after consultation with site operator and/or with the responsible authority.

Container Disposal

Empty residue into application equipment. Dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

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

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SECTION 14. TRANSPORT INFORMATION

DOT CLASSIICATION:
NON-BULK
Not regulated for transportation in packages smaller than 125 pounds. Packages of 125 pounds or more are regulated as:
Environmentally Hazardous Substances, Solid, N.O.S. (Carbaryl) // 9 // UN3077 // PG III // RQ(Carbaryl)

BULK:
Environmentally Hazardous Substances, Solid, N.O.S. (Carbaryl) // 9 // UN3077 // PG III // RQ(Carbaryl) // Marine Pollutant

FREIGHT CLASSIFICATION:
Insecticides or Fungicides, N.O.I., other than poison

SECTION 15. REGULATORY INFORMATION

EPA Registration No. 264-316

US Federal Regulations

TSCA list

Carbaryl	63-25-2	

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

Canadian Regulations

Canadian Domestic Substance List
None.

Environmental

CERCLA

Carbaryl	63-25-2	100 lbs

Clean Water Section 307 Priority Pollutants
None.

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Safe Drinking Water Act Maximum Contaminant Levels
None.

International Regulations

European Inventory of Existing Commercial Substances (EINECS)

Carbaryl	63-25-2

SECTION 16. OTHER INFORMATION

NFPA 704 (National Fire Protection Association):
Health - 3 Flammability - 1 Reactivity - 1 Others - none
0 = minimal hazard, 1 = slight hazard, 2 = moderate hazard, 3 = severe hazard, 4 = extreme hazard

Reason to Revise: Update to Section 11. Toxicologcal Information; Section 14. Transportation Information.

Revision Date: 08/03/2006

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Researcher CVs

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Curriculum Vitae

Eric Dean Bruce

21 Oak Knoll Ct.
Walnut Creek, CA 94596
925-939-4987 (office)
925-708-5538 (mobile)
eybruce@pacbell.net

Education:

University of California, Davis, California
B.S. Degree with Honors in Environmental Toxicology, 1980

Course work included toxicology, pharmacology, pharmacokinetics, biochemistry, physiology, and chemistry with extensive laboratory courses in sampling and analysis of environmental contaminants, mammalian toxicology, and instrumental analysis.

Oregon State University, Corvallis, Oregon
Graduate studies in Pharmacology and Toxicology, 1981 to 1982

Graduate research involved monitoring the half-life of aminopyrine *in vivo* in rats as a measure of hepatic metabolic activity. This assay was used to test the efficacy of several agents believed to prevent the alcohol-induced inhibition of the liver's drug metabolizing ability.

Continuing Education:

- Hazard Communication Regulations: Domestic and International
- Risk Assessment: U.C. Davis Extension and Symposium by California Academy of Sciences
- Industrial Hygiene: Chevron Corporation certification.
- Pesticide Exposure Assessment workshop (international)
- Pesticide Handlers Exposure Database Training
- Advanced training in Microsoft Word, Excel, Access, and Powerpoint
- CITI Course in The Protection of Human Research Subjects, Group 1

Work Experience:

1999 to Present: Toxicology Consultant

Provide technical support to pesticide industry, primarily dealing with the generation and interpretation of worker exposure data. Duties include study design, protocol preparation, study conduct (i.e., acting as Study Director or Principal Investigator), analysis of results, report preparation, and creation of generic databases for pesticide manufacturers.

Updated: December, 2008

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Curriculum Vitae

Eric Dean Bruce **-- 2 –**

1991 to 1998: Regulatory Project Manager, Valent U.S.A. Corporation

Managed pesticide registration projects including design of testing programs, monitoring of technical studies, preparation of study reports, summarizing safety data, submitting registration applications to U.S. Environmental Protection Agency (EPA), and negotiating with EPA to ensure registration.

1990 to 1991: Supervisor, Hazard Information, Chevron Corporation

Managed Material Safety Data Sheet (MSDS) generation and maintenance for the corporation. Responsible for ensuring MSDS content meets regulatory requirements, preparing MSDSs using a proprietary computer system, maintaining the computer system, and distributing MSDSs.

1983 to 1990: Senior Toxicology Associate, Chevron Corporation

Performed exposure assessments for environmental contaminants, including Chevron products and slightly radioactive wastes. Coordinated toxicology studies to support exposure assessments for oil and pesticide products in the areas of inhalation toxicity, biochemistry, dermal absorption, and metabolism. Prepared and reviewed technical reports prior to submission to regulatory agencies. All studies were conducted under U.S. Good Laboratory Practices (GLP) Standards.

1981 to 1983: Laboratory Technician, Chevron Chemical Company

Performed quality control assays for organic and inorganic fertilizer products, wastes, and research samples for elemental composition. Duties included record keeping, reporting of results, reagent preparation, and equipment maintenance.

Updated: December, 2008

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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.

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PAR**AG**ON 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 Instituite, 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

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Access Research and Consulting, Inc.	**Curriculum Vitae** Page 1 of 3
	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.

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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

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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.

26 Jun 06

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

Reviewed 13 Nov 07. bdl 13 Nov 07

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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.

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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

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RANDY J. THOMPSON
12 OAKSHIRE COURT
ST. PETERS, MO 63376
RThompson2002@Charter.Net
RESIDENCE: (636) 447-2790
CELLULAR: (314) 277-0679

SUMMARY

A results-oriented market research director with a hands-on practical approach to the integration and management of market information and communication activities delivering added value and competitive advantage. Fifteen years agency experience working across a wide range of roles including qualitative and quantitative project management, proprietary and small to very large-scale syndicated research, and sales to Fortune 500 clients. Thirteen years of industry experience as a research project leader for two global crop protection companies bringing several products to near-commercial or commercial status. BS and MS in the Biological Sciences; MBA in Finance and Management.

BUSINESS EXPERIENCE

DOANE MARKETING RESEARCH, INC, St. Louis, MO **1992–2007**

Director, Market Analysis and Development 1999–2007

Responsible for managing ad hoc syndicated marketing research and proprietary client research studies including complex questionnaire and statistical designs.

- Project Director for a new multiclient pesticide transactional sales database. During the first year of production, approximately 1.5 million transactions from 2,000 businesses were collected, summarized, and reported to subscribing clients.
- Director of ad hoc syndicated marketing research studies. Led internal meetings for generating ideas, assigned responsbilities for researching ideas, wrote client prospectuses, and managed projects.
- Quantitative research experience includes multivariate analysis techniques such as factor analysis, cluster analysis, and perceptual mapping; conjoint techniques including discrete choice pricing models; and various forecasting models.
- Qualitative research experience includes in-person and telephone one-on-ones, focus groups, and Delphi procedures.

Manager, Market Analysis and Development 1994–1999

Responsible for creating and producing new multiclient marketing research studies and conducting proprietary client research studies in the areas of product registration, non-crop chemical usage, and biotechnology. For three of these years, 20% of my time was devoted to client sales.

- Responsible for sales to five major chemical manufacturers who had previously conducted no to very little business with Doane. Sales quota was $228,000 in 1995, $462,000 in 1996, and $680,000 in 1997. I exceeded my sales quota by 114% in 1995 and by 73% in 1996. In 1997 my sales fell 12% below quota; however, 1997 was a year of client reorganization and retraction with Doane's overall division sales falling 31% below the forecasted annual budget.
- Produced numerous qualitative and quantitative proposals for client projects resulting in an 80% acceptance level. Two sequential projects for one client were worth over $750,000 of additional business. Managed all accepted proposals including questionnaire and sample design, data collection, coding, data entry, programming, and analysis and production of final reports.

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Project Director 1992–1994

Responsible for overall production of PROFILE™, an annual on-farm pesticide usage tracking database that is viewed globally as the industry standard. All efforts on this project significantly increased our clients' satisfaction with this product.

- During my first eight months at Doane, produced this 17,000 respondent, six month long survey on-time for our client base even after my immediate supervisor, the general manager of the project, suddenly resigned from the company one month into the survey.
- Wrote two annual executive reports on PROFILE™, which were additions to the user-friendly database typically provided. The first, a five year trend analysis, and the second, a two year comparison, were almost 300 pages each and reported on all pesticide usage for over 50 crops. These two reports were the only ones ever written for this product and were well received by clients.
- Completely rewrote this product's User's Manual, which resulted in a significant increase in customer satisfaction.
- Conducted a thorough review of this project's massive code lists. Reorganized brand / product relations, standardized pest and chemical names to approved standards, added Latin binomials to all pest names, and updated all product use rates and prices.

MONSANTO AGRICULTURE COMPANY, St. Louis, MO 1980–1991

Project Leader for Rice, Turf, and Post -Burndown Herbicide Discovery

Responsible for conducting advanced greenhouse and field trials for discovering new commercial candidates in these selected target markets.

- Discovered and conducted the initial development of a proprietary upland seeded rice herbicide with a market potential of $120M. Received a Monsanto Achievement Award for this important discovery.
- Conducted an end-user market survey that determined market penetration and established an acceptable price level for Monsanto's new direct seeded rice herbicide. This survey strengthened the decision to commercialize this product.
- Discovered DIMENSION® turf herbicide. The annual revenue of this product was projected at $75M. A Monsanto Achivement Award was received for this outstanding contribution. A patent was also received for this discovery.
- Conducted a turf market survey that greatly influenced upper management's decision to commercialize DIMENSION®.
- Discovered two lead field candidates for the Asian transplant rice market. Was also the department's liason with Monsanto's Japanese Research Station.
- Discovered two new areas of post-burndown proprietary chemistry that had extremely high unit activity and were the driving force for this project.
- Co-chaired a 12 person committee that successfully developed a coaching curriculum for use by Monsanto Agriculture's Human Resource training department. This course enhanced coaching and counseling skills for all levels of Monsanto employees.
- Assisted in the development of an electronic field data collection system and database. This system was used by research and product development departments and provided uniform and rapid data collection and retrieval.
- In just two years of an employee recognition program's existence, received over 15 Rapid Recognition Awards for designing field equipment, defining attributes for a field data collection database, and for presenting technical results at department meetings and field tours.

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DIAMOND SHAMROCK CORPORATION, Painesville, OH **1977–1980**

Project Leader, Herbicide Discovery

Responsible for all phases of greenhouse and field evaluation of new chemistry. Discovered and conducted early field development of two promising commercial candidates.

EDUCATION

Southern Illinois University at Edwardsville 1988
M.B.A., Major in Finance, Minor in Management (GPA: 4.80/5.00)

Cornell University 1978
M.S., Major in Vegetable Crops, Minor in Plant Physiology (GPA: 3.43/4.00)

Washington State University 1975
B.S., Fruit and Vegetable Culture (GPA: 3.81/4.00)

Company sponsored: Sawtooth Software Conjoint Analysis Workshop, SAS on-line training, Sales Management Workshop, Time Management, Effective Coaching, Team Management, Evelyn Wood Speed Reading, and Dale Carnegie Speaking

COMPUTER SKILLS

Thoroughly computer literate with most software especially Microsoft Word, Access, Excel, PowerPoint, Publisher, and Outlook; Arc GIS; Adobe PageMaker and Acrobat Writer. Familiar with SAS, C#, and SQL Server.

PATENTS / DISCLOSURES

- "Herbicides for Turf Use"
- "Synergistic Herbicide Mixtures Containing Pyridine Dicarboxylate Derivatives"

PUBLIC SPEECHES

- “Impact of Genetically Engineered Crops on the Marketplace,” 1996 Virginia Ag-Chemicals & Soil Fertility Association
- “1994 Survey Results of Weeds and of Products Used in Midwest Corn and Soybeans,” 1994 North Central Weed Science Society Convention

PERSONAL

Member of Beta Gamma Sigma and former Financial Secretary and Treasurer of the Harvester Council of the Knights of Columbus.

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Curriculum Vitae

RICHARD C. HONEYCUTT, PH.D.

Environmental Field Scientist (Exposure Assessment)/ Consultant/Biochemist

Richard C. Honeycutt. Ph.D.
220-1 Swing Road
Greensboro, NC 27409
(336) 294-5559
E-Mail: herac@aol.com

EXPERIENCE:

Founder and President of the Hazard Evaluation and Regulatory Affairs Company, Inc. (H.E.A.R.C., Inc.) from 1990 to present. Responsible for designing, planning executing and reporting field research in the exposure assessment of agrochemicals to humans (farmers) and exposure to the environment as required for registration of agrochemicals by the Environmental Protection Agency. Developed protocols, located field sites, performed surveys; directed field scientist research staff in execution of the field phase of agricultural worker exposure and reentry studies; dislodgeable residue studies; environmental soil/field dissipation studies and magnitude of residue studies with pesticides. Represented Agrochemical Company on the Agricultural Handlers Exposure Task Force (AHETF), Agricultural Reentry Task Force (ARTF), and consulted with agribusiness companies for the purpose of managing research projects and writing reports to be submitted to EPA on exposure assessment of agrochemicals. Over 100 exposure related research projects completed and data submitted to EPA for twenty or more agrochemical companies.

Senior Environmental Specialist at Ciba-Geigy Corporation (Syngenta) from 1980 to 1990. Planned, coordinated, and managed numerous in-house and contracted research studies in environmental chemistry and environmental toxicology to register products with EPA. Such studies included environmental fate of pesticides, groundwater research, mixer-loader/applicator and reentry exposure assessment, avian and fish ecotoxicology. Prepared, submitted and rebutted environmental impact statement submissions to EPA.

Senior Metabolism Chemist at Ciba-Geigy Corporation from 1976-1980. Planned, managed and executed laboratory research in pesticide metabolism to meet registration requirements for EPA. Developed protocols, isolated, and identified metabolic pathways for pesticides in plants, animals and soil.

Senior Chemist at Rohm and Haas Company, Philadelphia, PA from 1973-1976. Planned and managed metabolism and residue analysis studies required for registration of pesticide products.

Research Fellow at the Radiation Biology Laboratory at the Smithsonian Institution, Washington, DC. From 1971-1973. Performed research in photosynthesis and plant ribosomal protein synthesis.

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CURRICULUM VITAE: RICHARD C. HONEYCUTT, PH.D.

EDUCATION:

Ph.D., Purdue University (1971), W. Lafayette, IN, Biochemistry
A.B., Anderson University (1967), Anderson Indiana, Chemistry/Biology/Math, Cum Laude
High School Diploma (1963), Newport News High School, Newport News, VA

SPECIAL COURSES OR TRAINING

NIH Ethics Course: Protecting Human Research Participants (2008)
Farm Family Exposure Study-Methods for Calling, Recruiting, Documentation, Questionnaires - University of Minnesota, School of Public Health (2000)
Good Laboratory Practice Standards Courses (1989, 1996, 2006)
Technical and Professional Society Symposia 1973 to Present (e.g. ACS, ICOH, SETAC)
Persuasion Skills (1986)
Product Innovation (1982)
Management Accounting (1981)
Developing More Effective Supervisors (1980)
Kepner Tregoe Problem Analysis (1979)
Managing People (1978)

AWARDS:

Smithsonian Fellow (1972); NIH Fellow (1968-1971); Phi Lambda Upsilon (1970); Freshman Chemistry Award (1964); Sigma Zeta (Science); Kappa Mu Epsilon (Math); Phi Eta Sigma (academic); Alpha Chi (academic);

ACS Division of Agrochemicals Fellow Award (1985): Special Award from Ciba-Geigy for environmental research on Tilt Fungicide (1988); American Chemical Society (ACS) National Tour Speaker (1989 to present).

PROFESSIONAL AFFILIATIONS AND MEMBERSHIPS:
American Chemical Society (1973 to present)
American Chemical Society: Division of Agrochemicals and Division of Environmental Chemistry; IUPAC (present)
Division of Agrochemicals of the American Chemical society, Chair (1999-2000)
Central North Carolina Section of ACS: Chair (1990); Councilor (1992-1999)
International Commission of Occupational Health (1986-1990)
Society of Environmental Toxicology and Chemistry (1980-1998)
Greensboro, NC Chamber of Commerce (1987-1989)
ACS Committee on Environmental Improvement (1990-2000)
Associate Member American Crop Protection Association (1997-1999)
International Society of Exposure Analysis (2000-2001)

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CURRICULUM VITAE: RICHARD C. HONEYCUTT, PH.D.

SELECTED PUBLICATIONS:

Baker B.A., Alexander B.H., Mandel J.S., Acquavella J., Honeycutt R., Chapman P., "Farm Family Exposure Study: Methods and Recruitment Practices for a Biomonitoring Study of Pesticide Exposure", J Expo. Ana. Environ. Epidemiol. 15:491-499, 2005.

Mandel J.S., Alexander B.H., Baker B.A., Acquavella J.F., Chapman P., Honeycutt R., "Biomonitoring for Farm Families in the Farm Family Exposure Study", Scand J Work Environ Health 31,Suppl 1:98-104, 2005.

R.C. Honeycutt, "Field Methods for Performing Farm Worker Exposure and Re-entry Studies", Handbook of Residue Analytical Methods for Agrochemicals, Editor, Philip Lee, John Wiley & Sons, Ltd, 2003.

R.C. Honeycutt and E.W. Day, Editors, Worker Exposure to Agrochemicals, Methods for Monitoring and Assessment, CRC Press, LLC, Boca Raton, FL, 2000.

R.C. Honeycutt, M. Honeycutt, M. DeGeare, E.W. Day, Jr., B. Houtman, B. Chen, B.A. Shurdut, R.J. Nolan, J.R. Vaccaro, P. Murphy, and M.J. Bartels, "Use of Simultaneous Biological Monitoring and Dermal Dosimetery Techniques to Determine the Exposure of Chlorpyrifos to Applicators and Re-entry Workers", R.C. Honeycutt and E.W. Day, Editors, Worker Exposure to Agrochemicals, Methods for Monitoring and Assessment, CRC Press, LLC, Boca Raton, FL, 2000.

R.C. Honeycutt, "Mechanics and Field Operation for a Successful Terrestrial Field Dissipation Study", Invited presentation, 220th ACS Meeting, August 20, 2000.

R.C. Honeycutt and D.J. Schabacker, Editors, Mechanisms of Pesticide Movement into Ground Water, Lewis Publishers. (1994).

R.C. Honeycutt, Editor, Regulation of Pesticides, Science, Law and the Media. Government Institutes, Inc. (1988).

H.M. Lebaron, R.O. Mumma, and R.C. Honeycutt, Editors, Biotechnology in Agricultural Chemistry, ACS Symposium Series 334, American Chemical Society (1987)

R.C. Honeycutt, "NACA Overview on Assessment of Mixer-loader-applicator Exposure to Pesticides (Dermal exposure, patch test, biological monitoring, generic exposure database)", Toxicology Letters , Edited by E.A.H. van Heemstra-Lequin and N.J. van Sittert, Elsevier-Amsterdam (1986).

R. Honeycutt, "Field Worker Exposure: The Usefulness of Estimates Based on Generic Data", Dermal Exposure Related to Pesticide Use; Discussion of Risk Assessment, Edited by Richard C. Honeycutt, Gunter Zweig, and Nancy N. Ragsdale, ACS Symposium Series 273, The American Chemical Society, Washington, DC, 1985.

Krause A. ; Hancock W. G., Minard R. D., Freyer A. J., Honeycutt R. C., Lebaron H. M., Paulson D. L. Shu-yen Liu, Bollag J.M., "Microbial Transformation of the Herbicide Metolachlor by a Soil Actinomycete", Journal of Agricultural and Food Chemistry, Vol. 33, pp. 584-589 (1985).

Fifty additional publications by R.C. Honeycutt as well as one hundred fourteen unpublished research reports authored by R.C. Honeycutt are listed in a booklet available upon request.

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Curriculum Vitae
Vicky Standart

4605 NW Normandy Lane
Kansas City, MO 64116
vstandart@earthlink.net

(816)453-9806 (work & home)
(816)585-5791(cell)

Education: B.A. – Major in Spanish & Minor in German – May 1971 – Central Missouri State University, Warrensburg, MO
M.A. - Spanish Language & Literature – May 1974 – El Instituto Tecnológico y de Estudios Superiores de Monterrey, Monterrey, México
M.S. – Industrial Hygiene/Safety – May 1983 – Central Missouri State University, Warrensburg, MO

Certification: Comprehensive Practice of Industrial Hygiene (CIH) (Ret) (1993-2006)

Other Training: Human Participations Protection Education for Research Teams - NIH

Work Experience:

Dec. 06-present **Consultant**

Agricultural Handler Exposure Task Force - Prepare and review various documents related to its field research program; make presentations to committees; participate in special assignments and projects.

Jan. 03-Nov. 06 **Product Safety Consultant**

Bayer CropScience (BCS)
17745 South Metcalf Avenue
Stilwell, KS 66085

1) Conduct ongoing risk assessments from generic data on BCS developmental compounds to determine potential need for occupational or consumer mixer/loader-applicator studies or dislodgeable foliar residue (DFR) studies.

2) Review Re-registration Eligibility Documents (RED's & IRED's) as they pertain to occupational or consumer risk assessments; when necessary, develop strategy to address issues potentially jeopardizing re-registration of products.

3) Interact with Study Directors in the coordination of GLP mixer/loader-applicator studies, reentry studies and DFR studies. Prepare subsequent risk assessments for submission to regulatory authorities.

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Curriculum Vitae
Vicky Standart

June 87-Dec.02 **Industrial Hygienist/Product Safety Representative**

Bayer CropScience
8400 Hawthorn Road
Kansas City, MO 64120

1) Coordinate preparation and conduct of mixer/loader-applicator and reentry exposure studies, including protocol preparation, monitoring of workers, sample collection and shipping and subsequent report writing. Serve occasionally as Study Director.

2) Conduct product risk assessments (developmental or registered) for submission to state and/or federal authorities. The basis for assessments is generic exposure data (generally from PHED) or data generated from proprietary studies.

3) Coordinate preparation and distribution of product MSDSs, including writing sections specific to ingredient information, signs & symptoms of exposure, first aid and PPE.

4) Serve as contact person between BCS and contracted Poison Control Center, and follow up on allegations of human exposure incidents when necessary.

Sep. 74-May 87 **Bilingual Administrative Assistant**

Mobay Corporation (later Miles, Inc.)
8400 Hawthorn Road
Kansas City, MO 64120

1) Provide general administrative support in a technically-oriented environment.

June 72–Aug. 74 **Translator**

Chemagro
8400 Hawthorn Road
Kansas City, MO 64120

1) Translate technical documents, including toxicology and DFR reports and analytical methods, from German to English.

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Curriculum Vitae
Vicky Standart

Special Assignments:

Jan. 02
To Nov.06 Served as Technical Committee Chairperson of the Agricultural Exposure Task Force. Worked with Task Force Manager in establishing meeting agendas, assigning tasks, approval of contracts and invoices. Led meeting discussions and made various presentations as appropriate.

Mar. 99
& Feb.00 Representing Bayer AG, participated in an international project in Costa Rica. The goal of the project was to establish worker transfer coefficients for various work tasks in bananas. As part of the study team, learned various aspects of banana culture to develop a plan to maximize data development within a given budget and to prepare a GLP study protocol. Work also included the monitoring of banana workers performing various activities and participating in the preparation of the final report.

Feb. 97 At the request of Bayer de Mexico, served as bilingual observer and advisor during training of workers in Sinaloa in the safe use and handling of pesticides. The Safe Use and Handling Initiative was a cooperative effort undertaken by pesticide registrants in Mexico to train workers throughout the country.

The following is a partial list of exposure studies in which I had a role, including coordination, conduct and/or oversight:

Approximate year	Type of study
1987	MLA & reentry – termite treatment
1988	MLA – ground spray in wheat
1988	MLA – airblast in grapes
1988	MLA - residential (crack & crevice, trigger, etc)
1989	Seed treatment in canola
1989	Planting of canola
1990	Reentry – termite treatment
1990	Seed treatment of small grains
1991	Reentry in apple
1992	MLA – ground boom & aerial in cotton
1992	Reentry in cotton
2003	Reentry in corn
2004	Reentry in apple, nuts
2004	MLA – airblast in apple
2006	Seed treatment of potato

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Researcher HRP Training Certifications

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Printed 12/10/2008

CITI Collaborative Institutional Training Initiative

Additional Groups in the Course for The Protection of Human Subjects Curriculum Completion Report
Printed on Wednesday, December 10, 2008

Learner: Eric Bruce (username: ericbruce)
Institution: Independent Investigational Review Board, Inc.(IIRBI)
Contact Information 21 Oak Knoll Ct.
Walnut Creek, CA 94596 USA
Phone: 925-708-5538
Email: eybruce@pacbell.net

Study Coordinators/Key Research Staff (Biomedical):

Stage 1. Study Coor -BioMed BASIC Passed on 12/10/08 (Ref # 1796663)

Required Modules	Date Completed	Score
Belmont Report and CITI Course Introduction	05/12/08	3/3 (100%)
History and Ethical Principles	12/09/08	5/7 (71%)
Basic Institutional Review Board (IRB) Regulations and Review Process	12/10/08	5/5 (100%)
Informed Consent	12/10/08	4/4 (100%)
Genetic Research in Human Populations	12/10/08	2/2 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	12/10/08	4/4 (100%)
Vulnerable Subjects - Research Involving Minors	12/10/08	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero	12/10/08	3/3 (100%)
International Research	12/10/08	1/1 (100%)
Group Harms: Research With Culturally or Medically Vulnerable Groups	12/10/08	3/3 (100%)
FDA-Regulated Research	12/10/08	5/5 (100%)
HIPAA and Human Subjects Research	12/10/08	2/2 (100%)
Hot Topics	12/10/08	no quiz
Conflicts of Interest in Research Involving Human Subjects	12/10/08	1/2 (50%)
Independent Investigational Review Board, Inc. (IIRBI)	12/10/08	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

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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

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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

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

CR# 243945

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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

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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

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CITI Collaborative Institutional Training Initiative

Course In The Protection of Human Subjects Curriculum Completion Report
Printed on Wednesday, December 10, 2008

Learner: Randy Thompson (username: Randy2002)
Institution: Independent Investigational Review Board, Inc.(IIRBI)
Contact Information 12 Oakshire Ct
St. Peters, MO 63376 USA
Phone: 636-447-2790
Email: rthompson2002@charter.net

IIRB Project Leader:

Stage 1. IIRB Project Basic Passed on 12/10/08 (Ref # 2357387)

Required Modules	Date Completed	Score
Belmont Report and CITI Course Introduction	12/10/08	3/3 (100%)
History and Ethical Principles	12/10/08	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process	12/10/08	5/5 (100%)
Informed Consent	12/10/08	4/4 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	12/10/08	4/4 (100%)
International Research	12/10/08	1/1 (100%)
FDA-Regulated Research	12/10/08	4/5 (80%)
HIPAA and Human Subjects Research	12/10/08	2/2 (100%)
Hot Topics	12/10/08	no quiz
Conflicts of Interest in Research Involving Human Subjects	12/10/08	2/2 (100%)
Independent Investigational Review Board, Inc. (IIRBI)	12/10/08	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

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Certificate for Richard Carl Honeycutt

Certificate of Completion

The NIH Office of Human Subjects Research certifies that **Richard Honeycutt** successfully completed the National Institutes of Health Web-based training course “Protecting Human Research Participants”.

Date: 05/13/2008

Certification Number: 34912

US EPA ARCHIVE DOCUMENT

Completion Certificate

This is to certify that

Vicky Standart

has completed the **Human Participants Protection Education for Research Teams** online course, sponsored by the National Institutes of Health (NIH), on 12/26/2007.

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/

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SOPs Referenced in the AHE120 Protocol

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The follow Agricultural Handler Exposure Task Force Standard Operating Procedures are referenced in upcoming worker exposure study protocols. The most recent versions are provided in this file. Some of these SOPs have been reviewed and revised by the AHETF and may be in draft form at this time. Any changes to the final versions will be updated by the AHETF Quality Assurance Unit.

Versions as December 08, 2008:

1.B Ethics Training
1.F Potential Referable Findings [FIFRA 6(a)(2)]

2.C Protocol Amendments and Deviations

6.B Access to Archived Data
6.D Confidential Worker Info

8.A WBD Sampling
8.B Hand Washes
8.C Face/Neck Wipes
8.D OVS Tubes
8.E Field Forts
8.F Sample IDs
8.G Worker Clothing Acceptability
8.K Sample Quality

9.J Analytical Design and Statistics

10.C Worker and Study Observations
10.E Worker Sample Collection Sequence
10.G Air Pump Calibration

11.A Ethics Requirements
11.B Worker Recruitment
11.C Worker Health Status
11.D Pregnancy Testing
11.E Pesticide Safety Precautions
11.F Adverse Events Reporting for IRBs
11.G Heat Illness
11.H Emergency Procedures
11.I Language Requirements
11.J Consent of Participants
11.K Listing Growers
11.M Recruiting Growers or Commercial Applicators

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Personnel Responsibilities

Chapter 1: Administration
AHETF-I.B.4.

Effective Date : **DRAFT**

APPROVAL_____	DATE_____
APPROVAL_____	DATE_____
Last Revision Date: August 31, 2008	Previous Version Number: 1.B.3

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 update the ethical training criteria for researchers in Section 7.1 and to update the appropriate training course web links in Section 7.2.

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.

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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.

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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.

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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 interact with study participants must undergo ethics training. Training must be completed prior to participation in an AHETF study and researchers must complete recertification training at least every three (3) years.

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7.2 The training shall include successful completion of the course from the National Institutes of Health (Protecting Human Research Participants (PHRP)) 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.nih.gov and www.citiprogram.org.

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.

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Potential Referable Findings

Chapter 1: Administration
AHETF-I.F.O.

Effective Date : April 4, 2008

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Signed copies are on file with the AHETF Quality Assurance Unit.

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Last Revision Date: N/a Previous Version Number: N/A

Signed copies are on file with the AHETF Quality Assurance Unit.

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.

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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.

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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)

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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.

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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.

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Procedure for Recruiting Study Participants

Chapter 1: Administration
AHETF-I.H.O.

Effective Date : **DRAFT**

APPROVAL_____	DATE_____
APPROVAL_____	DATE_____
Last Revision Date: N/A	Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines the general procedures for recruiting growers, commercial applicators, and study participants for exposure studies conducted by the Agricultural Handlers Exposure Task Force (AHETF).

2.0 DEFINITIONS

2.1 **Universe List**: A compilation of names from public or private sources of all growers or commercial application services for a given site where an exposure study will be conducted. This list will generally contain at least 75% of the estimated population based on agricultural census information or expert opinion.

2.2 **Master List**: A random sub-sample of the Universe List that is expected to provide a sufficient number of names to recruit from. The Universe List will be sampled such that every member has an equal chance of being placed in the Master List. If the Universe List contains fewer names than desired, it becomes the Master List.

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2.3 **Qualified List**: A list developed from the Master List that, through telephone interviews, includes only growers or commercial applicators that have basic attributes required for an exposure study. This information includes handling of pesticides, growing target crops on desired acreage, and using specific mixing/loading and/or application equipment as defined in individual study protocols. Growers or commercial application services that do not meet the requirements to participate in an AHETF study are eliminated from the list.

2.4 **Potentially Eligible List**: A refined list of potential cooperators derived from the Qualified List. This list is developed after direct contact between the AHETF and potential growers or applicator services to explain the mission of the AHETF and to detail the study to be conducted. This list is presented to the AHETF Study Director for direct contact of the growers or application services to recruit their employees for participation in the AHETF study.

2.5 **Eligible List**: The final list of growers or application services from which an Efficient Configuration of MUs will be determined.

2.6 **Study Participant**: An employee of a grower or application service who has agreed to participate in an AHETF worker exposure study as an applicator, mixer/loader, or mixer/loader/applicator (handler).

2.7 **Monitoring Unit (MU)**: An experimental realization of a single worker handling a particular pesticide under a particular set of circumstances that represent a single workday. MU is also commonly used to refer to a study participant who dons appropriate dosimetry and is monitored for the prescribed work period as well as the resulting exposure measurements from that worker that end up in the AHETF database.

2.8 **Site**: A geographic area where an AHETF exposure study will be conducted. This may be a single county, several adjacent counties, or an entire state. .Within a site, typically five (5) farms or commercial application companies will be chosen to conduct five separate MUs.

2.9 **Ag Census**: Multiple sources for agricultural demographic data that are compiled by outside sources and publicly accessible or available for purchase from third party vendors. Useful information includes the number of farms the size of farms in acres for particular crops and counties.

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2.10 **Efficient Configuration**: The final selection of eligible workers for inclusion in a study that best fits the total number and type of Monitoring Units to be collected at a given site in a cost-effective manner. Generally, this involves identifying five farms or commercial applicators that are near each other and are willing to provide five handlers who will handle various amounts of active ingredient in a short period of time.

3.0 GENERAL PROCEDURE

3.1 The typical scheme for contacting growers or application services, which will lead to recruiting individual handlers to participate in an AHETF study, is shown graphically in Attachment 1-H-1.

3.2 Development of the Universe, Master, and Qualified Lists will be completed as described in SOPs AHETF-11.K or AHETF-11.L.

3.3 The Qualified List will be further refined to the Potentially Eligible List as described in SOP AHETF-11.M.

3.4 The Potentially Eligible List will be presented to the designated AHETF Study Director who will further refine the list by contacting and/or visiting interested growers or application services.

3.5 After contacting growers or application services, the Study Director will have the Eligible List that will be used to select the most appropriate facilities in which to conduct the study according to an Efficient Configuration design.

3.6 Using the Eligible List, the Study Director will conduct individual location visits to confirm the suitability of the facility/operation for the study. During the onsite visit (or a later date) the Study Director will meet with the workers to present an overview of the research, including the risks and benefits of participation in the AHETF study. Typically, a copy of the informed consent form, sample product risk statement, and other appropriate documents are provided to the workers at this recruitment meeting.

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3.7 Individual workers expressing an interest to be study participants may be recruited directly by the Study Director or a designee. Workers will be consented according to SOPs AHETF-11.B, AHETF-11.I, and AHETF-11.J. Participant recruitment may take place prior to or on the day of monitoring. When multiple equivalent handlers are available for a particular MU, one participant will be selected using a simple random technique such as drawing names from a hat or flipping a coin.

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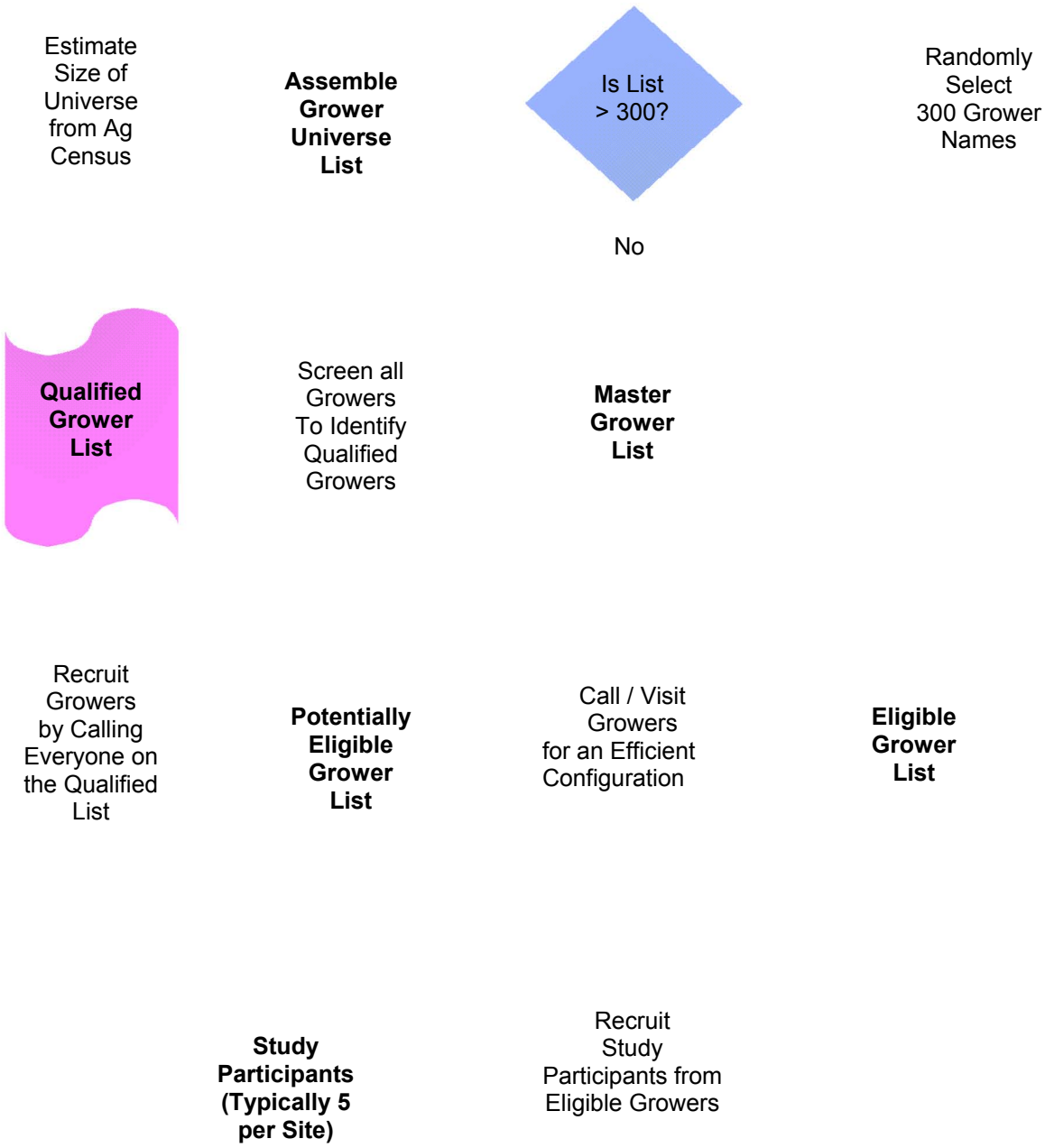
Attachment 1-H-1

Example Process for Recruiting Growers and Study Participants



US EPA ARCHIVE DOCUMENT

Protocol Design and Preparation

Chapter 2: PROTOCOLS
AHETF-2.C.2.

Effective Date : March 3, 2008

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Signed copies are on file with the AHETF Quality Assurance Unit.

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Last Revision Date: January 1, 2006 Previous Version Number: 2.C.1.

Signed copies are on file with the AHETF Quality Assurance Unit.

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.

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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.

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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.

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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)

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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.

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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.

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Access to Archived Data

Chapter 6: ARCHIVES
AHETF-6.B.I.

Effective Date : March 3, 2008

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Signed copies are on file with the AHETF Quality Assurance Unit.

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Last Revision Date: February 1, 2003 Previous Version Number: 6.B.0

Signed copies are on file with the AHETF Quality Assurance Unit.

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.

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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.

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Access to Confidential Worker Information

Chapter 6: ARCHIVES
AHETF-6.D.O.

Effective Date : March 3, 2008

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Signed copies are on file with the AHETF Quality Assurance Unit.

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Last Revision Date: None Previous Version Number: None

Signed copies are on file with the AHETF Quality Assurance Unit.

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)

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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.

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Whole Body Sampling – Inner Dosimeters

Chapter 8: MATRIX SAMPLES

AHETF-8.A.3.

Effective Date : March 3, 2008

This is an approved electronic copy of an AHETF Standard Operating Procedure.

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This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Signed copies are on file with the AHETF Quality Assurance Unit.

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

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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

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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)

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* 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.

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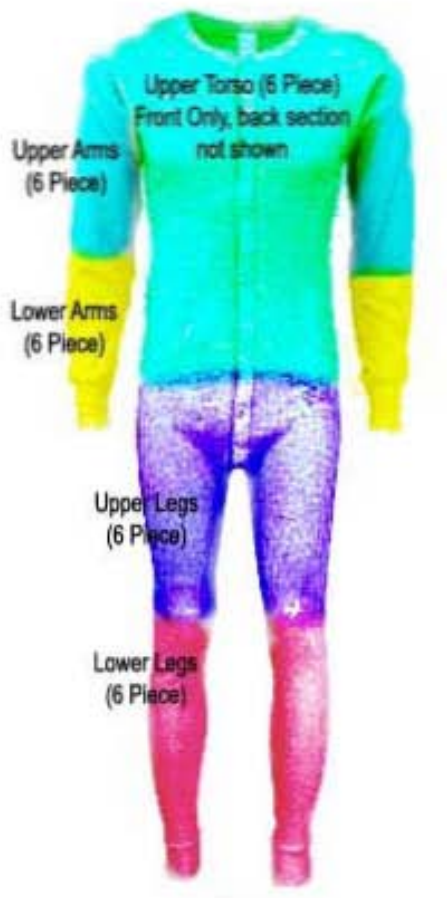
SOP AHETF-8.A.3.

Attachment A

Diagram of Inner Dosimeter



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Hand Wash Samples

Chapter 8: MATRIX SAMPLES
AHETF-8.B.4.

Effective Date : March 3, 2008

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE
Signed copies are on file with the AHETF Quality Assurance Unit.

This is an approved electronic copy of an AHETF Standard Operating Procedure.
APPROVAL DATE

Last Revision Date: January 1, 2006 Previous Version Number: 8.B.3.

Signed copies are on file with the AHETF Quality Assurance Unit.

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)

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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).

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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.

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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.

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Dermal Face/Neck Wipe Samples

Chapter 8: MATRIX SAMPLES
AHETF-8.C.6.

Effective Date : **DRAFT**

APPROVAL_____	DATE_____
APPROVAL_____	DATE_____
Last Revision Date: August 31, 2008	Previous Version Number: 8.C.5.

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 add the steps to follow when the worker is wearing facial Personal Protective Equipment in section 3.3.

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 surfactant 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

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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 surfactant solution (0.01% Aerosol® OT) on the gauze sponge with the syringe or pipette (or other appropriate means of moistening the sponge).

3.3 If the worker is wearing additional Personal Protective Equipment (PPE), such as goggles or a respirator, the worker will remove all PPE before having the face/neck wipe collected.

3.4 Thoroughly wipe the worker's face/neck (front & back) with the moistened sponge.

3.5 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 Face/neck wipe samples will be collected before the workers eat anything and any time the workers would normally wash their face.

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.

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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.

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Collection of Air Samples Using OVS Tubes

Chapter 8: MATRIX SAMPLES

AHETF-8.D.4.

Effective Date : **DRAFT**

APPROVAL_____	DATE_____
APPROVAL_____	DATE_____
Last Revision Date: October 27, 2008	Previous Version Number: 8.D.3.

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 Section 5.1 was revised to add additional hygiene for minimizing cross-contamination of the OVS tubes.

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)

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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.

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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) or replace the batteries. 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

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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 with the original sampling tubing.

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. The sampling pump, tubing and OVS tube must be removed from the worker before any other samples are collected. See SOP AHETF-10.E.

5.0 SAMPLING PROCEDURE

5.1 Upon completion of the monitoring unit, remove the OVS tube from holder, wipe the outside of the OVS tube with a solvent-moistened wipe to remove potential surface residues, then 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.

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Fortification of Matrix Samples

Chapter 8: MATRIX SAMPLES
AHETF-8.E.5.

Effective Date : **DRAFT**

APPROVAL_____	DATE_____
APPROVAL_____	DATE_____
Last Revision Date: April 4, 2008	Previous Version Number: 8.E.4.

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 guidance for Study Directors (SD) to determine when to conduct field fortifications during a cluster (site) location in Section 8.0.

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.

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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.

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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:

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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,

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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.)

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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.

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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

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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.

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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.

8.0 FIELD FORTIFICATIONS GUIDELINES DURING A STUDY

8.1 At least one field fortification set for each surrogate a.i. used on an AHETF exposure study should be prepared and collected at each cluster location (site) described in the protocol. Fortifications do not need to be collected at each individual monitoring unit within a cluster.

8.2 If multiple a.i.'s are used in individual MUs on the same day, it is necessary for only one a.i. to have field fortifications prepared on that day. The SD can choose which surrogate to fortify with, but if one surrogate will only be used once at the cluster, it should have precedence for fortifications that day.

8.3 Additional field fortifications may be prepared at the Study Director's discretion if the following conditions are expected:

a. Different meteorological conditions between study days (*e.g.;* hot, dry, and full sun vs. cool, humid, and cloudy).

b. Significant distances between sites that could provide some environmental differences.

c. One set of field fortifications becomes compromised during the weathering period (*e.g.;* heavy rain, contamination, *etc…*)

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Sample Identification

Chapter 8: MATRIX SAMPLES
AHETF-8.F.5.

Effective Date : August 31, 2008

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APPROVAL DATE

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This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Last Revision Date: March 3, 2008 Previous Version Number: 8.F.4.

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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 include an additional level of air sample fortifications and the option to include more than one active ingredient in section 2.4, and new examples were added to section 2.5.

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.

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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 (alternately, if multiple active ingredients are used in one study, the fortification of the matrices for the different active ingredients will be identified by a sequential number as follows: F1, F2, *etc*., in which the number designates a specific active ingredient. The specific active ingredient associated with the numeric code will be documented in the raw data.

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 number.
Mx - Worker Sample – Mixer/loader only with sequential sample number.

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 sample

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
Cx*	control sample
Lx*	low spike
Mx*	mid spike
Hx*	high spike
Zx**	back-up air spike

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

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*A sequential number will be noted for each control and fortified sample to note worker samples.
**This designation will only be used for the back-up air sample fortifications.

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:	AHE01 – worker - MU 2 - inner dosimeter - lower legs
41-WS-A5-ID-BL:	AHE41 – worker - applicator MU 5 - inner dosimeter - lower body
05-WS-M5-HW-01:	AHE05 – worker– mixer/loader MU 5 - first (or only) hand wash collected
55-WS-05-HW-02:	AHE55 – worker - MU 5 – second hand wash collected
55-WS-03-AR-01:	AHE55 – worker - MU 3 - air sample (first or only sample)
55-WS-09-FW-01:	AHE55 – worker - 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:	AHE11 - Field fort. – First study day - inner dosimeter - second low level
22-F1-03-FW-H1	AHE22 – First AI field fort. – Third study day - face/neck wipe - first high level [this may be the *second* day of fortifications for AHE22]
60-F2-01-AR-Z1	AHE60 – Second AI field fort. – First study day – air sample - first back-up air fortification sample

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Worker Clothing Acceptability Criteria

Chapter 8: MATRIX SAMPLES
AHETF-8.G.2.

Effective Date : September 1, 2003

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APPROVAL DATE

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APPROVAL DATE

Last Revision Date: May 25, 2003 Previous Version Number: 8.G.1.

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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

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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.

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Sample Quality

Chapter 8: MATRIX SAMPLES

AHETF-8.K.O.

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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

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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.

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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

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Analytical Quality Control and Statistics

Chapter 9: DOCUMENTATION

AHETF-9.J.0.

Effective Date: November 1, 2008

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Signed copies are on file with the AHETF Quality Assurance Unit.

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Last Revision Date: N/A Previous Version Number: N/A

Signed copies are on file with the AHETF Quality Assurance Unit.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes quality control calculations and statistical procedures to follow when conducting sample analyses for the Agricultural Handlers Exposure Task Force (AHETF).

2.0 ANALYTICAL QUALITY CONTROL CALCULATIONS

2.1 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.

2.2 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.

2.3 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.

2.3.1. 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 0.98 or greater or all r values must be 0.98 or greater.

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2.3.2. Back calculations of the standard (at or above the LOQ) 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 approximately +/- 15% for all standards but the lowest concentration standard may back calculate to approximately +/-20%. No standard result will be discarded without a scientific reason and not before consultation with the Analytical Monitor.

2.4 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. Analytical methods to follow will be documented in the study protocol.

2.5 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.

2.6 All OVS tubes will be analyzed with front and back sections as separate samples. The front section will consist of the Teflon holding ring, glass fiber filter, the front sorbent material, and the foam divider. The back section will consist of the back sorbent material and the downstream foam plug.

3.0 ANALYTICAL STATISTICAL METHODS

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

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Worker and Study Observations

Chapter 10: FIELD OPERATIONS

AHETF-10.C.4.

Effective Date : August 31, 2008

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Signed copies are on file with the AHETF Quality Assurance Unit.

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Last Revision Date: March 3, 2008 Previous Version Number: 10.C.3.

Signed copies are on file with the AHETF Quality Assurance Unit.

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 add sections 5.2 to clarify the documentation of engineering controls to reduce exposure, Section 6.0 was reorganized and portions re-written, Section 7.0 was added to describe specific information on photographing study activities, and Attachment A was added which contains an observation form.

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. See Attachment A for Worker Observation Form.

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.

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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.

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5.0 EQUIPMENT DETAILS AND OPERATION DOCUMENTATION

5.1 Details of application equipment will be recorded in the field notebook. Application equipment operation will be documented, and calculations recorded, as defined in the study protocol and SOP AHETF-10.D.

5.2 Details regarding any engineering controls in test substance packaging or mixing/loading equipment (*e.g.* dry break systems) will be documented in the raw data.

6.0 WORKER OBSERVATIONS

6.1 Prior to exposure monitoring the AHETF Study Director will review the requirements for observing workers during exposure monitoring for AHETF exposure studies.

6.2 If possible, one researcher will be dedicated to observing one worker during the monitoring period. Each researcher assigned to this task must be familiar with AHETF SOPs for worker observations and have completed appropriate ethics training, which must be documented in their training file. Each observer must use the appropriate forms 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*.

6.3 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.

6.4 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.

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6.5 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.

6.6 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.*).

6.7 Periodically observe 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 by checking the "Pump Running" box. Avoid use of the term "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 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.

6.10 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.

6.11 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.

6.12 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 (*e.g.*, aerial applicators, ground applicators at blind

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side of field). Additional lighting may be employed if the worker's activities occur at night. If the observer needs to take a break, get another researcher to monitor the worker during the observer's absence. Observers will make every effort to minimize interference with the worker's normal activities, such as keeping a reasonable distance from the worker and avoiding unnecessary conversation. Observers should contact the Study Director, PFI or QAU if they observe any activity contrary to the study design, label requirements, or dangerous activities undertaken by the worker. Based on the event, the SD has the discretion to terminate the MU.

6.13 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.

7.0 STUDY PHOTOGRAPHS AND VIDEO RECORDING

7.1 Photographs/videos should be taken of the study site (*e.g.,* crop, site layout, *etc*…); application and/or mixing equipment; and various study activities (*e.g.*, exposure sampling techniques, mixing techniques, test substance application, *etc*…). No photographs/videos should be taken in which a worker can be readily identified. These would include photographs/videos of their faces or any uniquely identifying marks (*e.g*., tattoos, scars, *etc*…). No photographs/videos of the worker dressing or undressing will be taken. If a photograph/video needs to be taken of a worker (e.g., to show a torn shirt sleeve), every effort will be made to capture the image without any identifiable features in the frame.

7.2 Any photographs/videos or photographic files that can be used to readily identify a worker shall be shredded, erased, or deleted and will not be maintained in the raw data file.

7.3 Photographs/videos will be used to show the condition of clothing before and after monitoring, and to provide visual documentation of the study for use by regulatory reviewers. All photographs/videos are the property of the AHETF and will be used to document the research conducted.

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Attachment A
Worker Observation Form

AHETF Study No.: AHE_____

Worker Observation Form Page: 1 of _____

Date of Monitoring: / / Study Day: _____ MU. No.: _____

Pump Start Time: _____

Pump Stop Time: _____ Stopped for: _____

Pump Restart Time: _____

Pump End Time: _____

General Description of Task and Equipment Used

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SOP AHETF-10.C.4.

AHETF Study No.: AHE_____

Worker Observation Form (cont.)

MU. No.: _____ Page: ____of_____

General Description of Task and Equipment Used (cont.)

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AHETF Study No.: AHE_____

Worker Observation Form (cont.)

MU. No.: _____ Page: ____of_____

Time	Observations / Comments	Pump Running?
		□
		□
		□
		□
		□
		□
		□
		□
		□
		□
		□
		□
		□
		□
		□
		□
		□
		□

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Worker Sample Collection Sequence

Chapter 10: FIELD OPERATIONS
AHETF-10.E.2.

Effective Date : March 3, 2008

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Signed copies are on file with the AHETF Quality Assurance Unit.

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Last Revision Date: January 1, 2006 Previous Version Number: 10.E.1

Signed copies are on file with the AHETF Quality Assurance Unit.

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.

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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.

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Personal Air Sampling Pump Calibration

Chapter 10: FIELD OPERATIONS
AHETF-IO.G.I.

Effective Date : April 4, 2008

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Signed copies are on file with the AHETF Quality Assurance Unit.

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Last Revision Date: October 15, 2003 Previous Version Number: 10.G.0

Signed copies are on file with the AHETF Quality Assurance Unit.

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 unit 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)

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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 unit. 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.

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Ethical Requirements for AHETF Studies

Chapter 11: HUMAN SUBJECT MANAGEMENT

AHETF-II.A.I.

Effective Date : August 31, 2008

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

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This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Last Revision Date: April 30, 2008 Previous Version Number: 11.A.0

Signed copies are on file with the AHETF Quality Assurance Unit.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines the ethical requirements necessary to obtain approval from various groups for Agricultural Handlers Exposure Task Force (AHETF) protocols that involve monitoring workers in its field studies. The groups that may be involved in granting permission to work with human subjects include an Institutional Review Board (IRB), U.S. EPA, the Human Studies Review Board (HSRB), the Pest Management Regulatory Agency (PMRA) of Canada when the study is planned for Canada, the California Department of Pesticide Regulation (CDPR) when the study is planned for California, and other state agencies.

1.2 This SOP was revised to change the title. Section 2.1 was clarified to define the "start" of an AHETF study. Section 3.1 was revised to delete the term "interpreter." Section 4.0 was clarified for the proper references to specific rules and regulations. Section 5.4 was added to address amendment review. Section 7.0, re-titled and expanded to include specific EPA review requirements.

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2.0 RESPONSIBILITIES

2.1 Approvals must be obtained from the appropriate groups (see section 1.1) before contacting growers or commercial applicators. Obtaining these approvals is the responsibility of the Study Director (SD) and the study sponsor, AHETF.

3.0 ETHICS TRAINING FOR RESEARCHERS

3.1 The SD, the Principal Field Investigator (PFI), the Task Force Field Study Monitor, the worker observers, and other researchers working on behalf of the AHETF who interact with study participants, will have completed one or more training courses for protection of human subjects. Certificates of completion for the course(s) will be available prior to these individuals participating in the field phase study on behalf of the AHETF. Details on the courses that may be completed are described in SOP AHETF-1.B.

4.0 ADHERENCE TO ETHICAL STANDARDS

4.1 All AHETF field studies involving worker exposure monitoring are designed and conducted in accordance with scientific and ethical criteria set forth in the following ethical codes:

a. U.S. EPA 40 CFR Part 26, Subparts A through L

b. The Belmont Report, Office of the Secretary, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research", The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979 (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm). [Note: this document is not an official policy nor a code of ethical conduct and is mentioned only as reference material.]

5.0 INSTITUTIONAL REVIEW BOARD (IRB)

5.1 All protocols, informed consent forms, and any materials to be distributed to workers must undergo review and approval for ethical compliance by an IRB prior to contacting growers and commercial applicators or enrolling any subjects for studies. The specific IRB used will be documented in the study file.

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5.2 Initial review submissions from AHETF to an IRB typically will include the following:

a. Initial Review Submission Form (latest version from an IRB)

b. Study Protocol (unsigned final draft)

c. Research Subject Information and Consent Form – English (AHETF will request a Spanish version when appropriate)

d. Resumes for Study Director and Principal Field Investigators, including credentials pertaining to ethics training and knowledge of human research

e. Recruitment materials

5.3 The IRB Initial Review Submission Form identifies AHETF as the sponsor and the SD as the Principal Investigator (PI). It should be noted that this designation for the SD is different from the designation used in the AHETF GLP protocols (requirement of 40 CFR, Part 160 for the conduct of EPA GLP studies). It also identifies study site(s) (generally local site coordinator research facilities) and provides details about subject recruitment, consent, and payment. Details of procedures for medical emergencies are outlined in SOP AHETF-11.H.

5.4 Any amendments to the approved study protocol must be reviewed by the IRB and approved before further research can be conducted, unless there is an imminent hazard to the worker. All deviations to the study protocol must be reported to the IRB promptly.

6.0 CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION (CDPR)

6.1 All studies involving worker exposure monitoring to be conducted in California must also have protocols reviewed and approved by the CDPR. This involves science and ethical reviews by the Office of Environmental Health Hazard Assessment (OEHHA) and the Worker Health and Safety Branch (WHS) of CDPR. The SD is responsible for obtaining this approval.

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6.2 Any changes requested by CDPR must be incorporated into the study protocol and/or consent forms which must then be reviewed and approved by the IRB. Only upon receipt of the IRB-approved protocol and consent forms will CDPR grant final approval for the study to be conducted in California.

6.3 In accordance with the California Code of Regulations, at 3 CCR 6710(h), the Study Director shall not make an amendment to the approved protocol that might impact the health of a human participant in California without approval from the Director of the California Department of Pesticide Regulation (CDPR). For amendments where participant health is potentially impacted, the Study Director shall make the request in writing.

7.0 REGULATORY REVIEW FOR AHETF EXPOSURE STUDIES

7.1 Protocols for all worker exposure studies will be submitted to EPA in accordance with EPA's final regulation published at 40 CFR Part 26.1125 that establishes requirements for the protection of subjects in human research. The protocol, informed consent form, IRB materials, and other supporting documents, must be submitted to EPA.

7.2 All non-observational study design documents, as required by the EPA (or other regulating body) will be subject to a public meeting and review by the EPA Human Studies Review Board (HSRB), including a review of the personnel involved with the conduct of a study.

7.3 Any changes to the study design must be approved by an IRB before the research can go forward.

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Recruiting Study Volunteers

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-II.B.4.

Effective Date : **DRAFT**

APPROVAL_____	DATE_____
APPROVAL_____	DATE_____
Last Revision Date: October 10, 2008	Previous Version Number: 11.B.3

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines general procedures for recruiting workers in field studies being conducted by the Agricultural Handlers Exposure Task Force (AHETF). Additional study-specific detail will be included in individual protocols as needed

1.2 The term "designee" used throughout the text refers to any person or persons designated by the Study Director (SD) to perform duties normally done by the SD. This includes, but is not limited to, Principal Field Investigators, bilingual researchers, and sponsor representatives. Any of these researchers may be the person obtaining consent.

1.3 This SOP was revised to clarify the language in Sections 2.1, 4.0, 4.1, 4.2.c, 4.3.c, e, and g to follow language in the study protocols. Section 5.2 was rewritten to standardize the language for inclusion criteria, and section 5.3 was deleted to remove exclusion criteria.

2.0 REQUIRED 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 other Task Force researchers 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.

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3.0 RESEARCH 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 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 (if required), 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 PROCEDURE FOR RECRUITMENT OF POTENTIAL WORKERS

Recruitment of workers typically occurs in two steps. A study-specific recruitment plan will be specified in each study protocol.

4.1 The first step typically involves contacting and selecting growers and/or commercial application companies that can provide the necessary crop/site, equipment, workers, and are willing to use an AHETF surrogate. This will be done by calling from a randomized list of growers in a local area (See SOP AHETF-11.L). Growers that meet the criteria listed above will be placed in a pool of eligible growers. At this time, growers (employers) will be asked for permission to recruit their workers for the research study. 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 step typically involves recruiting workers from a pool of eligible growers and/or commercial applicators identified in the first step. These workers may be the growers themselves, their employees, or employees of commercial applicators. The process is as follows:

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a. Growers and/or commercial applicator companies will have been selected who meet all criteria for eligibility, who are willing to cooperate with AHETF in the monitoring study, and who the SD will have determined are acceptable. The grower or other responsible personnel will have given permission for the SD (or designee) 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 provides a toll-free phone number to accommodate both English and Spanish speakers, or by conducting an on-site visit. Appropriate language flyers (English or Spanish) will be distributed at the discretion of the SD (or designee) or at the request of the employer. Note that growers themselves (if they are qualified handlers) may also be contacted at this time. The SD (or designee) organizes a recruitment meeting with only the interested workers present. This may be done one-on-one or with a group of interested workers. Each interested worker will attend at least one recruitment meeting. Follow-up recruitment meetings will be held at the discretion of the SD (or designee) or at the request of the worker.

c. In cases where the grower or commercial applicator contacted is the owner/operator of the equipment and conducts his/her own applications, the Study Director or designee contacting the grower or commercial applicator may proceed to recruit the owner/operator as an “employee” or worker following section 4.3. In these cases, the Employer Cooperation Statement signed by the owner is not necessary, as there are no employees.

4.3 The recruitment meeting(s) with interested workers will consist of the following (meetings will be held in the preferred language(s) of the attendees):

a. Growers, commercial application company managers, or other personnel to whom employees might report will not attend.

b. Growers and management personnel who express an interest in participating in a study will be invited to a separate recruitment meeting.

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c. The nature of the study and general content of the protocol and Consent Form will be presented. Any recruitment materials used during this recruitment meeting will be approved by the IRB before use.

d. Eligibility criteria will be reviewed with the potential volunteers and all questions will be answered.

e. Informed Consent Forms, an example PRS, and for studies conducted in California the California Experimental Research Subject's Bill of Rights (in their preferred language), will be given to all potential volunteers who attend a recruitment meeting. Workers will be urged to take the copy home for review.

f. Potential volunteers will be given a copy of 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. The copy will be available in English and, if needed, in Spanish.

5.0 INCLUSION CRITERIA FOR STUDY PARTICIPATION

5.1 Potential participants may be farm owners, farm operators, farm employees, contract applicator employees, or commercial applicators, *etc*.

5.2 Although additional eligibility criteria may apply in specific cases, all AHETF study participants must meet these inclusion criteria:

a. Have experience within the past year with the work activity being monitored in the study (including the particular equipment to be used during mixing/loading or application).

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 be exempt from such training.

d. Provide proof of being at least 18 years old with a government-issued photo ID.

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e. Confirm they do not work for a pesticide company or a contractor of the AHETF

f. Consider their general health status to be good and tell researchers they have no medical conditions that affect their ability to participate in the study. See SOP AHETF-11.C for health status determination.

g. Not be pregnant or nursing. (See SOP AHETF-11.D.)

h. Confirm they do not normally wear personal protective equipment that is not required by the label and that might impact the objectives of the study, such as chemical-resistant clothing. Confirm they will follow label directions.

i. Have a private meeting with a researcher to review and discuss the consent form.

j. Understand English or Spanish (see SOP AHETF-11.I for detailed discussion of this topic).

k. Understand and sign the consent form, Product Risk Statement, and if in California, the California Experimental Research Subject's Bill of Rights.

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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: _____

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Worker Health Status

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-II.C.I.

Effective Date : August 31, 2008

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Signed copies are on file with the AHETF Quality Assurance Unit.

This is an approved electronic copy of an AHETF Standard Operating Procedure.

APPROVAL DATE

Last Revision Date: March 3, 2008 Previous Version Number: 11.C.0

Signed copies are on file with the AHETF Quality Assurance Unit.

1.0 PURPOSE AND SCOPE

1.1 The following SOP describes the procedure used 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.

1.2 This SOP was revised to clarify aspects of the consent process referenced in SOP AHETF-11.B in Section 3.2.; Section 3.3 was clarified, and Section 3.4 was added.

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.

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3.2 The worker will be asked during the informed consent process if he/she has any medical condition(s) that could impact his/her ability to participate in the study (refer to SOP AHETF-11.B, Section 5.2.f). 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.

3.3 A worker who fails to meet the inclusion health criteria (see sections 3.1 and 3.2), during the consent process will not be allowed to participate in the study. They will be counted as having been screened for participation, as per IRB guidelines.

3.4 On the scheduled day of participation and after consent has been given, the inclusion health criteria (see sections 3.1 and 3.2) will be verified. If a worker fails the criteria they will be "withdrawn for medical reasons" and that is all that will be documented in the raw data.

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Pregnancy Testing

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-II.D.I.

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Last Revision Date: March 3, 2008 Previous Version Number: 11.D.0

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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, §26.1203) prohibit third parties from conducting research involving intentional exposure to pregnant or nursing women.

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.

1.3 This SOP was revised to clarify the appropriate regulation in Section 1.1, to clarify recruitment procedures outlined in SOP AHETF11.B referenced in Section 2.1, add that a female volunteer may need more than one test in Section 2.2, and to clarify the language in Section 2.5.

2.0 PROCEDURES

2.1 Each female worker will be told during the recruitment and consent processes (refer to SOP AHETF-11.B) that any woman who is pregnant or nursing is ineligible to participate in an AHETF worker exposure study. The female worker will also be told that if she wishes to participate in the study she will be required to take an over-the-counter urine pregnancy

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test and that if the pregnancy text is positive, she will not be allowed to participate in the study nor will she be compensated for her time or inconvenience. The female worker will be informed that no additional remuneration (*i.e*., $80, or the amount specified in the protocol for the inconvenience of participating in the exposure monitoring) will be provided for taking the pregnancy test and then choosing not to 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). All female volunteers will be notified that an additional pregnancy test may be required if there are any delays in the planned start of the study,

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 pregnancy test results will not be revealed to the employer or co-workers.

iii. The pregnancy test results will not be documented.

iv. If a female worker voluntarily withdraws following a pregnancy test, due to any reason, no further documentation will be collected. They will be counted as having been screened for participation, as per IRB guidelines.

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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 participate in the study.

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Pesticide Safety Precautions

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-II.E.I.

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1.0 PURPOSE AND SCOPE

1.1 This SOP describes measures intended to promote pesticide safety which will minimize the risk for illness or injury during participation in an Agricultural Handlers Exposure Task Force (AHETF) worker exposure study. These procedures will be followed during the worker informed consent process and exposure monitoring.

1.2 This SOP was modified as follows: Section 2.1 was clarified to indicate bilingual researchers; Section 3.0 was rewritten to indicate English versions of IRB-reviewed product labels and MSDSs will be available during the monitoring period; provide greater detail explaining Product Risk Statements, and clarify how to address situations when a worker is not in sight of an observer. Section 3.3.c was added to provide suggestions on how to minimize obtrusiveness of observations.

2.0 TRANSLATION

2.1 If needed or requested by the worker, a bilingual researcher (English-Spanish speaking) will be provided during any discussions described below.

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3.0 COMPLIANCE WITH SAFETY REQUIREMENTS

3.1 Product-specific Material Safety Data Sheets (MSDS) and labels will be reviewed by an IRB and will be available on-site during the exposure monitoring period. These documents will be available in English only.

3.2 Pertinent information from the product-specific MSDS and label will be summarized in a Product Risk Statement (PRS). The PRS will be attached to the Informed Consent Form and discussed with the study candidate during the consent meeting. Pertinent information includes: signs and symptoms of acute overexposure, personal protective equipment (PPE) and user safety recommendations. The PRS will be available in English and Spanish. An IRB will review and approve the PRS. A certified Spanish translation will be made of the IRB-approved PRS. Additional information about the PRS can be found in SOP 11.B.

3.3 During the study conduct, researchers will ensure compliance with safety requirements on the product label and with the Worker Protection Standard (WPS). For example, workers will be reminded to use the label-specified PPE and to follow use directions on the label

a. Each worker will be observed by a researcher during the entire monitoring period unless the worker travels out of sight of the observer (*e.g.*,aerial application, driving beyond view in a field).

b. Worker observers will not advise workers on how to perform their work unless a safety issue is involved. If the observer advises a worker about a safety issue and the worker does not comply, the observer will then immediately notify the Study Director and ask the worker to cease any activity.

c. Observers will make every effort to minimize interference with the worker's normal activity, such as keeping a reasonable distance from the worker or avoiding unnecessary conversation.

3.4 The Study Director may stop the worker's participation in the study if he/she is engaging in unsafe work practices such as not using label-specified PPE. The participant will still receive the payment specified in the protocol for his/her inconvenience.

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4.0 ADDITIONAL SAFETY PRECAUTIONS

4.1 AHETF will have an on-site contracted medical professional at each study as an added safety precaution (see AHETF-SOP-11.H for further details).

4.2 AHETF will have a portable on-site eye-wash station at every study in the event that exogenous substances (*e.g.*, dirt, droplets or splashes, *etc.*) get in the eye of study participants, study researchers, or other on-site individuals.

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Adverse Events Reporting for Institutional Review Boards

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-II.F.I.

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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.

1.2 This SOP was revised to remove the tem “investigator” and references to the WIRB.

2.0 PROCEDURES

2.1 The Study Director must familiarize himself with the references cited in this document.

2.2 The Study Director, and/or their designees, are required to report adverse events that meet both of the following criteria:

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 protocol are not unanticipated and do not have to be reported to an IRB),

AND

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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 an IRB.

2.3 If these criteria are not met then the event does not have to be reported to an 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 an 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.

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Identification and Control of Heat Stress

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-II.G.I.

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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

1.2 Section 6.2 was deleted to remove the requirements for Study Directors to have specific first aid or equivalent training.

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.

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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.

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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.

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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 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.

6.3 During the consent process, the Study Director will provide the worker with information on early signs and symptoms of heat-related illnesses.

6.4 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.

6.5 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.

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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.

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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

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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] (adjusted for direct sun as necessary. The Study Director, at his discretion, may choose not to initiate monitoring, regardless of the HI.

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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: <u>heat cramps</u>, such as muscle spasms, heavy sweating, thirst; <u>heat exhaustion</u>, such as fatigue, headache, dizziness, fainting, heavy sweating increased

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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.

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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.

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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.

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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.

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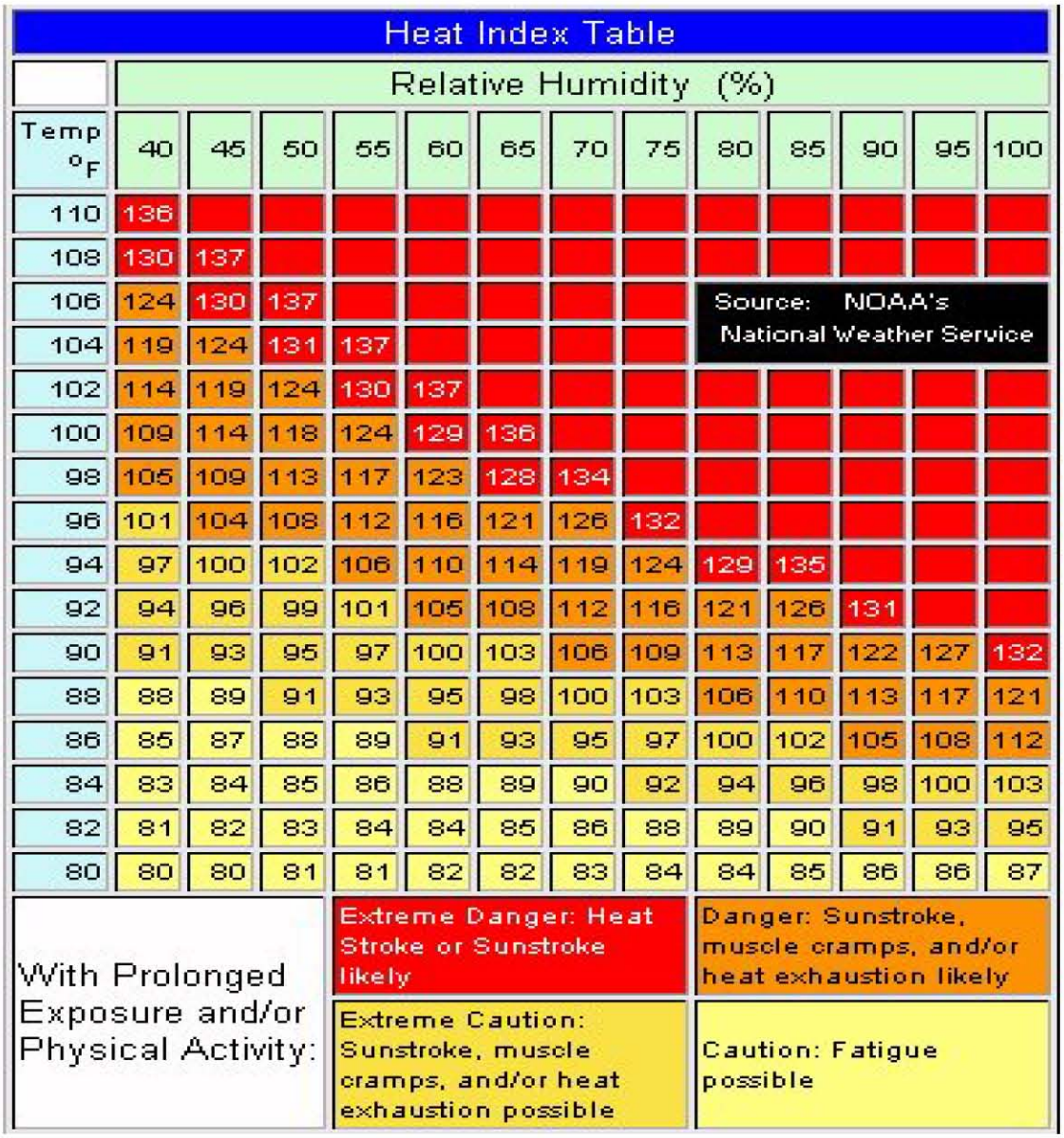
Attachment 11-G-2: Heat Index Chart



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

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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

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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.

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Emergency Procedures for Human Subjects

Chapter 11: HUMAN SUBJECT MANAGEMENT

AHETF-II.H.2.

Effective Date : **DRAFT**

APPROVAL_____	DATE_____
APPROVAL_____	DATE_____
Last Revision Date: August 31, 2008	Previous Version Number: 11.H.1

1.0 PURPOSE AND SCOPE

1.1 This SOP describes the procedure(s) to be followed in the event that a study participant requires emergency medical attention during his/her participation in an Agricultural Handlers Exposure Task Force (AHETF) worker exposure monitoring study.

1.2 The user of this SOP should be familiar with the SOP AHETF-11.G, "*Identification and Control of Heat Stress"*.

1.3 The Study Director will identify any employer plans to handle on-site emergencies. 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.

1.4 This SOP was revised to clarify the AHETF policy on medical reimbursement to volunteers participating on an AHETF worker exposure study. Section 2.2 was revised to describe who will determine when a study-related injury occurred. A new section 2.3 was added to clarify a worker may choose to refuse treatment. Section 2.4 was revised to clarify the work period covered by the AHETF. Section 6.1 was revised to specify the costs covered by the AHETF as a result of an injury during a study.

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2.0 PROCEDURES

2.1 Prior to initiation of exposure monitoring, the Study Director will determine the medical treatment facility nearest to the study site(s) that may be used in event of a medical emergency during the study.

a. Specific information about the medical treatment facility, including the address, telephone number and directions from the field site will be obtained.

2.2 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 participants are being monitored. The medical professional will be provided the product label, its MSDS, and AHETF SOPs related to pesticide safety and heat stress. The medical professional shall become familiar with these documents and conduct periodic observations of participants during monitoring and will alert the Study Director to possible signs of illness (heat-related or pesticide) or injury. The Study Director will consult with the on-site medical professional (when immediately available) when determining if a study related injury/illness has occurred that will require medical attention.

2.3 The study participant (worker) may refuse medical treatment, unless the injury or illness is directly due to pesticide exposure or is heat related, or if the worker is too sick to make a rational decision about getting medical treatment.

2.4 If a study participant is injured or becomes ill (including heat related illnesses) during the study (from the time the worker is asked to arrive at the test site until the dosimetry samples are collected), the medical professional shall provide appropriate medical care. However, if the injury or condition requires 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 participant as appropriate.

a. If cell phone service is needed to make the 911 call but service is not available, a study team member will drive to the nearest phone or until cell phone service is available.

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2.5 As deemed appropriate by the emergency medical personnel, the participant may be taken by ambulance to the nearest emergency medical facility.

a. The Sponsor will not have a physician on-call at any medical facility, but will rely on local emergency services as described above.

2.6 If a participant is taken to a medical treatment facility for examination or care, a member of the research team will accompany the participant to the facility so the Sponsor can stay informed through discussions with the physician or other medical professional that is involved.

3.0 EMERGENCY SITUATIONS AND COLLECTION OF DOSIMETRY MATRICES

3.1 No exposure samples will be collected from a participant who requires emergency medical treatment during study participation. If the medical professional determines the worker needs non-emergency medical assistance, the SD will consult with the medical professional and determine if exposure samples will be collected.

3.2 Any participant whose monitoring is terminated for medical reasons will still receive the remuneration ($80, or as specified in the study protocol) from AHETF for his/her participation in the study.

4.0 FOLLOW-UP OF MEDICAL TREATMENT EVENT

4.1 If a participant receives medical treatment related to his/her participation in the study, the Study Director will document how the participant was treated and released. This includes whether or not the participant refused treatment.

5.0 MEDICAL RECORDS

5.1 Medical records will not become part of the research records.

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6.0 EXPENSES

6.1 AHETF will cover the cost of reasonable and appropriate medical attention for a study-related injury or illness that is not covered by the worker's own insurance or insurance provided through the worker's employer. This includes any deductible or out-of-pocket expenses, including co-payments.

7.0 INCIDENT REPORTING

7.1 Any emergency event will be reported by the Study Director to the Sponsor (AHETF), the EPA, and the Institutional Review Board (SOP AHETF-11.F).

7.2 If the emergency event is a result of exposure to the pesticide product, additional reporting to EPA may be required in accordance with AHETF's SOP AHETF-1.F Potential Referable Findings.

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Language Requirements and Considerations for Study Volunteers

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-II.I.I.

Effective Date : **DRAFT**

APPROVAL_____	DATE_____
APPROVAL_____	DATE_____
Last Revision Date: October 27, 2008	Previous Version Number: 11.I.0

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines general procedures for how AHETF will, from a language perspective, accommodate English- or Spanish-speaking volunteers, including readers and non-readers. Additional study-specific detail will be included in individual protocols as needed.

1.2 The term "designee" used throughout the text refers to any person or persons designated by the Study Director (SD) to perform duties normally done by the SD. This includes, but is not limited to, Principal Field Investigators, bilingual researchers, and sponsor representatives. Any of these researchers may be the person obtaining consent.

1.3 This SOP was revised to clarify that the Product Risk Statement will be presented to the worker in their preferred language in Section 2.1; to allow the worker to choose a witness or have one assigned to them in Section 2.2.c; to clarify the witness's responsibility and remuneration in Section 2.3; how a witness will be recruited in Sections 2.3.a. – d., and to clarify the consenting process in Section 2.5.

2.0 LANGUAGE REQUIREMENTS AND CONSIDERATIONS

2.1 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

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language of their choice for reading during the consent process (if they are readers) and will sign that version of the form. For workers whose preferred reading language is Spanish, AHETF will obtain an IRB-approved translation of the Consent Form. This will also include a Product Risk Statement (PRS), which is presented in English or Spanish.

2.2 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. Potential volunteers will be informed during the recruitment meeting that:

a. Non-readers are eligible to participate in a study

b. Each potential subject will decide for himself/herself whether or not they are comfortable reading the consent form.

c. Workers self-identified as non-readers may choose a witness or a third-party witness will be identified and will be provided to the worker to assist them during the private consent meeting.

d. Workers who identify themselves as readers will have their reading ability assessed by the person obtaining consent by asking the workers to read a portion of the consent form and explain what was read.

2.3 Witnesses are only needed in cases where a worker is a non-reader. The witness is provided to attest that the person obtaining consent fully reads the Consent Form in its entirety to the volunteer. The witness must be unassociated with the conduct of the research (*i.e.,* not employed by the Sponsor or any of its contractors.) The witness will also sign the Consent Form. Such witnesses are not considered part of the study team, but will receive compensation of $20.00 for their participation.

a. A worker may choose a witness who can attend the consent meeting along with the worker. This may be a trusted co-worker, friend or family member.

b. If no one is available to attend the consent meeting, the SD or designee may ask the worker, the grower/applicator, local site coordinator, local extension agent(s), or others, for a list of people that might be interested in acting as a witness (*e.g.*, a local clergy

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member). The Study Director or designee will make every effort (*e.g*. contacting local growers, agricultural associations, local churches, *etc*.) to find a local resident to act as a witness.

c. A potential witness will be contacted by study personnel, explained what is required, asked if they would be interested in being a witness, and informed they will be brought to and from the field site (if requested) and will be compensated for their time.

d. If the worker chooses a witness, the witness will be contacted and will attend the consent meeting along with the worker.. If the witness is a third-party witness, he/she will be identified and arrangements will be made for him/her to attend the consent meeting along with the worker.

2.4 When study volunteers choose to have recruitment and consent discussions conducted in Spanish, a bilingual researcher will obtain consent. A Spanish-speaking or bilingual witness will be provided for non-readers.

2.5 The following procedures will be followed with each individual wanting to participate in an AHETF study. The person obtaining consent will go through the entire consent process with the worker (see SOP AHETF-11.J). The following paragraphs describe how workers with varying reading and language skills will be guided through the consent process. Attachment 11-I-1 provides a summary of the procedures described below.

a. Workers who read and understand English will be provided a copy of the Consent Form (and any other required documents) in English prior to the consent meeting, and will be asked to read the Consent Form in its entirety. During the consent meeting the SD (or designee) will review the entire Consent Form and encourage the volunteer to ask questions pertaining to their participation in the study. The person obtaining consent will verify that the worker has apparently understood the materials read to and discussed with them by asking specific questions to assess comprehension (see SOP AHETF-11.J). A copy of the signed Consent Form (and any other required documents) will be provided to the worker.

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b. Workers who understand English, but cannot read English, will have the Consent Form (and any other required documents) provided to them in English prior to the consent meeting, and will be asked to discuss the document with their family or trusted friend. During the consent meeting the SD (or designee) will read the entire Consent Form to them in English and will encourage them to ask questions pertaining to their participation in the study. A witness will be present to attest that all of the information was properly read to the potential subject. The person obtaining consent will verify that the worker has apparently understood the materials read to and discussed with them by asking specific questions to assess comprehension (see SOP AHETF-11.J). A copy of the signed Consent Form (and any other required documents) will be provided to the worker.

c. Workers who read and understand Spanish will be provided a copy of the Consent Form (and any other required documents) in Spanish prior to the consent meeting, and will be asked to read the Consent Form in its entirety. During the consent meeting a bilingual researcher will review the entire Consent Form and encourage the volunteer to ask questions pertaining to their participation in the study. The bilingual researcher obtaining consent will also be available during exposure monitoring to communicate with the Spanish-speaking participants. The person obtaining consent will verify that the worker has apparently understood the materials read to and discussed with them by asking specific questions to assess comprehension (see SOP AHETF-11.J). A Spanish version copy of the signed Consent Form (and any other required documents) will be provided to the worker.

d. Workers who understand Spanish, but cannot read Spanish will have the Consent Form (and any other required documents) provided to them in Spanish prior to the consent meeting, and will be asked to discuss the document with their family or trusted friend. During the consent meeting a bilingual researcher will read the entire Consent Form to them in Spanish and will encourage the volunteer to ask any questions pertaining to their participation in the study. A bilingual researcher obtaining consent will also be available during exposure monitoring to communicate with the Spanish-

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speaking participants. In addition, a Spanish-speaking or bilingual witness will be present to attest that all of the information was properly read to the potential subject. The bilingual researcher will verify that the worker has apparently understood the materials read to and discussed with them by asking specific questions in Spanish to assess comprehension (see SOP AHETF-11.J). A Spanish version copy of the signed Consent Form (and any other required documents) will be provided to the worker.

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ATTACHMENT 11-I-1

Language Procedures

	Worker Prefers English	Worker Prefers Spanish
Worker is a Reader of This Language	Person obtaining consent 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 a Non-reader of This Language	Person obtaining consent Discussions in English Person obtaining consent reads English Consent Form to worker Witness needed (English)	Bilingual researcher Discussions in Spanish Bilingual researcher reads Spanish Consent Form to worker Witness needed (Spanish/bilingual)

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Seeking Informed Consent from Study Volunteers

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-II.J.I.

Effective Date : **DRAFT**

APPROVAL_____	DATE_____
APPROVAL_____	DATE_____
Last Revision Date: October 27, 2008	Previous Version Number: 11.J.0

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines general procedures for seeking informed consent from workers in field studies being conducted by the Agricultural Handlers Exposure Task Force (AHETF). Additional study-specific detail will be included in individual protocols as needed

1.2 The term "designee" used throughout the text refers to any person or persons designated by the Study Director (SD) to perform duties normally done by the SD. This includes, but is not limited to, Principal Field Investigators, bilingual researchers, and sponsor representatives. Any of these researchers may be the person obtaining consent.

1.3 This SOP was revised to clarify the language in Sections 2.1, 3.4, and 3.7 to allow better consistency with language used in the study protocols and consent materials.

2.0 REQUIRED 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 Task Force researchers who interact with study participants (*e.g.* researchers who will contact growers to determine their willingness to participate; see SOP AHETF-11.L) 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.

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3.0 INFORMED CONSENT PROCESS

3.1 Although Consent Forms are unique to individual studies, each Consent Form will contain the elements required by 40 CFR 26.1116.

3.2 The SD (or designee) 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.

3.3 Informed consent discussions will be conducted by the person obtaining consent in private with each worker. The worker may have a friend, family member, or advisor with them during the meeting. Witnesses may also be present as described in SOP AHETF-11.I.

3.4 The person obtaining consent will inform the worker that he/she will receive $20 for participation in the consent meeting, or the amount specified in the protocol, even if he/she decides not to participate in the study.

3.5 During the private consent meeting the person obtaining consent 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 be told they will receive an additional $80, or the amount specified in the protocol, if they decide to participate (don the dosimeters) even if they withdraw before the end of the monitoring period.

3.6 The person obtaining consent 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 (referred to as Product Risk Statement {PRS}). WPS requirements, especially proper use of clothing, personal protective equipment, *etc*., will be discussed. Refer to SOP AHETF-11.E for details.

3.7 Information will be provided about the risk of heat stress, including signs and symptoms, and ways to prevent it. Information will also be provided about the availability of medical attention during the study. Details on heat stress and its presentation are outlined in SOP AHETF-11.G, while

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details on emergency medical procedures are outlined in SOP AHETF-11.H.

3.8 During the discussions between potential participants and the person obtaining consent, ample time will be provided for questions and the person obtaining consent will provide any additional information or clarification that is requested.

3.9 The IRB-approved Consent Form (and all supporting documents) 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 person obtaining consent 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 person obtaining consent will provide a copy of the signed form to the worker.

3.10 An additional IRB-approved document, "Product Risk Statement", will be attached to the Consent Form. If the study is conducted in California, the IRB-approved "California Experimental Research Subject's Bill of Rights" will also be attached. These documents (in the appropriate language) will be reviewed, signed and dated by the worker, and copies will be provided.

a. In all situations, the person obtaining consent 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 form in Attachment 11-J-1 will be used to ascertain general understanding.

3.11 The person obtaining consent will not sign the Consent Form unless he/she believes that the process has been free of any element of coercion or undue influence and the witness (when required) has signed the consent form.

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4.0 FOLLOW-UP PROCEDURES

4.1 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 (including the distribution of chemical exposure among the various body areas measured so the worker can be aware of where most dermal exposure occurs and a comparison to the results for other workers performing the same task) will be sent to the address provided by the participant(s) desiring it (the SD or designee will complete the form in Attachment 11-J-2). 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.

4.2 When the monitoring period is completed, or at the time a participant withdraws from the study, the person obtaining consent will remind the worker that he/she has received a copy of the signed Consent Form that has a toll-free phone number for reporting any health changes the worker thinks may be related to his/her participation in the study.

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ATTACHMENT 11-J-1

Consent Form Understanding – Worker Feedback Form

Worker Code: _____ Study ID: _____

QUESTIONS	ANSWERED CORRECTLY?		REVISITED MATERIAL WITH APPARENT UNDERSTANDING?	
	YES	NO	YES	NO
Introduction & Purpose				
What is the purpose of this study? ***To measure how much pesticide I might breathe or get on my skin.***				
If you agree to be in this study, will you be given a signed & dated copy of everything you sign? ***Yes***				
Eligibility				
Do you have to consider yourself to be in good health? ***Yes***				
Do you have to understand and sign this consent form? ***Yes***				
Study Duration				
How long during the day will you participate in the study? ***Four to eight hours***				
Procedures Before the Day of the Study				
What are examples of personal information that you must provide? ***Name; years experience; height; weight; gender; age; preferred language***				
Will you be photographed during dressing or undressing? ***No***				
Procedures on the Day of the Study				
What type of clothing will you wear underneath your normal work clothing? ***Long underwear***				
When will you have your hands washed? ***Before the study starts, before eating, anytime I normally wash my hands (toilet) and at the end of the day***				

Signed by: _____ Date: _____

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Worker Code: _____ Study ID: _____

QUESTIONS	ANSWERED CORRECTLY?		REVISITED MATERIAL WITH APPARENT UNDERSTANDING?	
	YES	NO	YES	NO
Products Handled				
Is the product you will be handling approved for use by the EPA? ***Yes***				
Will you know the name of the product before you sign the consent form? ***Yes***				
Risks & Discomforts				
Name two risks that you might have by participating in this study. ***Equipment, heat, product, embarrassment, eye/skin irritation, etc.***				
What are some early signs of heat stress? ***Dizziness, being tired, irritability, lack of concentration***				
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***				
Costs				
Will there be costs to you for participating in this study*?* ***No***				
Benefits				
Will you benefit directly from participating in this study? ***No***				

Signed by: _____ Date: _____

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Worker Code: _____ Study ID: _____

QUESTIONS	ANSWERED CORRECTLY?		REVISITED MATERIAL WITH APPARENT UNDERSTANDING?	
	YES	NO	YES	NO
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 still receive your normal pay from your employer if you participate in this study? ***Yes***				
Voluntary Participation / Withdrawal				
When can you withdraw from the study? ***Anytime I want***				
Will your normal pay be affected if you drop out? ***No***				
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				
Can you call the AHETF toll-free if you have questions about this study or think you have a study-related illness? ***Yes***				
Consent				
If you sign the CF, name two things 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***				

Signed by: _____ Date: _____

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ATTACHMENT 11-J-2

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: _____

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Compiling Lists of Potential Growers

Chapter 11: HUMAN SUBJECT MANAGEMENT

AHETF-II.K.O.

Effective Date : **DRAFT**

APPROVAL_____	DATE_____
APPROVAL_____	DATE_____
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 developing a Grower Universe List, a Master Grower List, and a Qualified Grower List when planning an Agricultural Handlers Exposure Task Force (AHETF) worker exposure field study.

2.0 INTRODUCTION AND BACKGROUND

2.1 Refer to SOP AHETF-1.H. for common terminology and the overall process for recruiting growers.

2.2 The word “site” as used in this document refers to the localized area (*e.g.*, counties) where exposure monitoring will be conducted.

2.3 Following investigation and selection of a crop(s) and geography for a given cluster of MUs involving growers and their workers, the AHETF will produce a list of growers called the “Grower Universe List.” The Grower Universe List is derived from a sampling frame that attempts to include the majority of specific crop growers in the selected site. While every effort will be made to include only growers in the Grower Universe List, the nature of developing lists does not insure every element listed is an actual grower.

2.4 An estimate of the number of growers in the universe will be compiled from the most recent USDA Census of Agriculture for the crop(s) and region.

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2.5 Five major sources will be used to develop the universe of growers: Farm Market ID, State and Local Government Entities, Grower Associations, Grower Publication Subscription Lists, and Commercial List Providers. Only one source will be used for the Grower Universe List if it maintains a collection that approaches the number of growers in the universe for the targeted region. Otherwise, multiple sources will be used so that their combined lists approach the number of growers in the universe. If multiple sources are used, duplicate names will be removed.

2.6 A "Master Grower List" will be developed from the Grower Universe List. When the universe of growers for a site is small, the Master Grower List is identical to the Grower Universe List. When the grower universe for a site is large, one or more random batches of growers from the Grower Universe List are used to form the Master Grower List.

2.7 Prior to recruitment, growers on the Master Grower List will be surveyed by a professional phone interviewing company to determine if they meet the minimum requirements of the worker exposure study (*i.e.*, crop acreage grown, use of pesticides or the pesticide type(s) required by the study protocol, and equipment used). The resulting list will be referred to as the Qualified Grower List, which will be used to contact and evaluate growers for potential recruitment in exposure monitoring studies.

2.8 Grower surveying will not be permitted until the study director has signed the study protocol.

3.0 DEVELOPING THE GROWER UNIVERSE LIST

3.1 AHETF will strive to develop a Grower Universe List that represents the complete universe of target growers for each selected monitoring site. An estimate of the total number of growers that exist in the target region is obtained from the most recent USDA Census of Agriculture for the crop(s) and region. (The Census of Agriculture is conducted every five years and includes information on the number of farms and acres by crop, state, and county.)

3.2 The Grower Universe List is constructed from separate lists obtained from one or more sources. Five sources are recommended for developing the Grower Universe List for a given crop and site:

a. Farm Market ID
b. Commercial List Providers

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c. State and Local Government Entities
d. Grower Associations (crop and/or region specific)
e. Grower Publication Subscription List

3.3 These sources are listed in order of preference based on the number of growers or universe of growers they represent, list reliability, amount of expected bias, difficulty in obtaining lists, and time required for cleaning (*e.g.,* looking up missing phone numbers). The sources which are actually used will depend on their availability for each scenario, crop, and site.

3.4 If a single source exists that represents at least 75% of the estimated size of the universe, this source will define the Grower Universe List. If no single source exists that represents at least 75% of the universe, use two (or more) sources whose combined list counts approach if not exceed the estimated size of the universe of growers. Following attempts to remove duplicate names, these combined lists define the Grower Universe List.

3.5 If multiple sources are used in Section 3.4, purge any duplicate records in the Grower Universe List before producing the Master Grower List. Compare duplicate records by phone number if available. If phone numbers are missing, compare duplicate records by address.

3.6 If the list provider identifies the size of the farm, remove any growers that farm an inadequate number of crop acres to achieve the smallest amount of active ingredient required by the cluster design or to be considered a commercial farm.

4.0 DEVELOPING THE MASTER GROWER LIST

4.1 If the universe contains less than 300 growers, the Master Grower List is equal to the Grower Universe List.

4.2 If the estimated size of the grower universe is greater than 300, select a random sample from the Grower Universe List that yields a batch of at least 300 callable names. This random batch is the current Master Grower List. In some cases, it may be desirable to select more than 300 names. For example, if all names in the Grower Universe List do not contain phone numbers, at least 500 names should be acquired to account for phone numbers that cannot be found. In addition, if the Grower Universe List was derived from multiple sources, the batch size can be increased to allow for duplicates that may yet occur.

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4.3 If the Grower Universe List is greater than 300, growers will be randomly selected from this list such that every grower has an equal chance of being included in the Master Grower List. In certain special cases (*e.g.*, large size of universe), an outside source like Farm Market ID may maintain the Grower Universe List. In such cases, AHETF will request that the source provide a random sample of growers using their internal randomizing techniques to select growers for the Master Grower List. In most cases, and especially when lists are combined, AHETF will maintain the Grower Universe List. In these cases, the Grower Universe List will be randomly ordered using MS-Excel® "RAND()" function. One column will be filled with random numbers using this function, the list will be sorted by the generated random numbers, and the random number sorted list will be renumbered from 1 to *n*. Growers will be selected sequentially from this randomly ordered Grower Universe List for inclusion in the Master Grower List.

4.4 If phone numbers are missing, attempt to find numbers using a minimum of three internet look-up sites. Typically, phone numbers can be found for 60% of growers using this procedure. Internet sites used in past look-ups include:

a. *Switchboard* — www.switchboard.intelius.com

b. *YellowPages.com* — www.yellowpages.com or www.superpages.com

c. *WhitePages.com* — www.whitepages.com

d. *USdirectory.com* — www.usdirectory.com

4.5 If missing phone numbers are found, remove any additional duplicate records by comparing phone numbers.

4.6 If the calling procedures described in Section 5.0 do not qualify enough growers to contact as per SOP AHETF-11.M, the list will be augmented by an additional random batch of names from the Grower Universe List. This second batch should be produced in a similar manner as described in sections 4.1 through 4.4. However, the size of the batch may be adjusted to reflect the number of growers that still need to be qualified. For example, if 60 growers need to be qualified and 45 have been qualified from the first batch of 300 growers, then a second batch of 100 names should be sufficient to qualify the remaining 15 growers. The calling procedures for this second batch of growers will be the same as

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the first batch. Additional random batches of growers can be added to the Master Grower List as long as there are growers in the Grower Universe List.

5.0 DEVELOPING THE QUALIFIED GROWER LIST

5.1 All growers on the Master Grower List will be surveyed to determine if they have the minimum acreage needed in the target location, use pesticides or use the pesticide type(s) required by the study protocol, and use the equipment type required for the field trial. A sample survey for an applicator exposure field study is attached as Attachment 11-K-1. Qualifying questions for an applicator exposure field study would typically include:

a. Crop acres grown
b. County or region where crop is grown
c. Use of pesticides or pesticide types required by the study protocol
d. Application or mixing/loading equipment used

5.2 Questions may also be asked to characterize the growers' equipment and surrogate chemical use. Questions used in the survey will depend on the type of field study to be conducted but will typically include:

a. Use of contract applicator
b. Size of application equipment used
c. Number of workers using application or mixing/loading equipment
d. Number of acres sprayed per worker in one work day
e. Use of surrogate chemistry
f. The best time of the day and week to call for any follow up questions

5.3 A professional telephone interviewing company with previous experience surveying growers will conduct the survey. The specific company used will be documented in the raw data.

5.4 A reasonable attempt will be made to reach every grower on the Master Grower List. Fifteen to twenty attempts will be made to reach each of the growers before the list is considered "exhausted."

5.5 Dispositions (*e.g.*, not contacted, initial refusal, no longer farming, deceased, completed survey) will be recorded for each grower on the Master Grower List. Dispositions will be used to help determine if

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additional growers need to be added to the Master Grower List from the Grower Universe List (see Section 4.6) and as an aid in developing future Grower Universe Lists for other exposure field studies.

5.6 Dispositions will be used to calculate the incidence rate and response rate.

a. The incidence rate is indicative of the quality of the Master Grower List and is used as a guide for measuring the difficulty in reaching potential interviewees. It is expressed as:

$$\frac{\text{Completes + Initial Refusals + Mid Interview Terminates}}{\text{Completes + Initial Refusals + Mid Interview Terminals + Not Qualifieds}}$$

b. The response rate is a reflection of the non-response rate, which indicates the amount of non-response error in the survey. It is calculated by the following formula:

$$\frac{\text{Completes}}{\text{Number in Sample - (Not Qualified + Not Contacted)}}$$

5.7 The Qualified Grower List consists of all growers who completed the survey in Section 5.1 through 5.6 and met the minimum requirements of the exposure field study (*i.e.*, acreage, pesticide type use, equipment use). This list will be used to contact and evaluate growers for potential recruitment in exposure monitoring events.

5.8 If the calling procedures described in AHETF-11.M do not recruit enough growers from the current Qualified Grower List, this list will be augmented by an additional batch of qualified growers produced in a similar manner as described in Sections 4.1 through 5.7.

5.9 All documentation collected during the development of the Master Growers List as well as during the survey and recruitment of growers will be considered raw data and shall be recorded and maintained per all applicable EPA GLPs and AHETF SOPs.

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Attachment 11-K-1: Sample Survey for Qualifying Growers on the Master Grower List

Hello, this is **[interviewer name]** calling from **[interviewing company name]**, may I speak with **[Respondent Name]**. **[If not available, schedule call back.]** We are doing a very brief survey on **[mixing, loading, applying equipment]** used in **[crop(s)]** and are talking to **[crop]** growers like yourself. We only have a couple of questions to ask and all of your answers will be held in complete confidence.

1) How many acres of **[crop]** do you have or manage in your operation? **[If less than [minimum size determined by protocol], terminate; otherwise continue.]**

2) In what county are most of your **[crop]** acres located?

   [Do not prompt:
   1) [target county 1]
   2) [target county 2]
   3) [etc.]
   4) Other _____]

3) Do you use **[pesticides or pesticide type(s), e.g., insecticide, fungicide]** to manage pests in your **[crop]**? **[If No, terminate; otherwise, continue.]**

4) Do you do most of your **[pesticide type]** spraying yourself or do you hire spraying done by a commercial applicator? **[If hire a commercial applicator, go to Q10; otherwise continue.]**

   1) Self
   2) Hire

5) Do you typically use a **[targeted equipment type, e.g., open cab or closed cab tractor for pulling your airblast sprayer]**?

   1) [targeted equipment type 1 or "Yes"]
   2) [targeted equipment type 2 or "No"]

6) How many **[targeted equipment type]** do you use in your operation?

7) What is the tank size [in gallons] of your (1st, 2nd, 3rd, 4th) **[targeted equipment type]**?

   1) [Volume 1]
   2) [Volume 2]
   3) [etc.]
   4) Other_____

8) Are you typically the person that makes the **[sprayer equipment type]** applications on your **[crop]**, or do you employ other workers to do the applications?

   1) Self
   2) Worker
   [If self, skip to Q10, otherwise continue.]

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9) How many experienced **[sprayer equipment type]** applicators do you employ in your **[crop]** operation?

10) When applying a **[pesticide type]** on a good day without wind, how many of your **[crop]** acres are routinely treated by one experienced applicator during a typical work day?

11) Do you use **[pesticide type]** products such as **[surrogate chemical 1]** or **[surrogate chemical 2]** for pest control in your **[crop]**?

1) Yes
2) No
[If No, skip Q12]

12) Which **[pesticide type]** products do you typically use? **[Accept up to three answers.]**

1) _____
2) _____
3) _____

13) If we have any further questions, when would be the best time to reach you?

1) Day of week: _____
2) Hour of day: _____

[Thanks and Terminate]

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Recruiting Potentially Eligible Growers & Commercial Applicators

Chapter 11: HUMAN SUBJECT MANAGEMENT

AHETF-II.M.O.

Effective Date: **DRAFT**

APPROVAL_____	DATE_____
APPROVAL_____	DATE_____
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 Potentially Eligible Growers or Potentially Eligible Commercial Applicators by calling Qualified Growers and Qualified Commercial Applicators for participation on an Agricultural Handler Exposure Task Force (AHETF) Study

1.2 This SOP also describes procedures for preparing a discussion guide and answer sheet as well as procedures for calling Qualified Growers/Applicators and documenting their responses when preparing to conduct an Agricultural Handler Exposure Task Force (AHETF) worker exposure field study. Attachments 11-M-1 and 11-M-2 respectively show examples of a discussion guide and answer sheet to be used by the caller.

2.0 Glossary of Terms

2.1 Please refer to SOP AHETF-1.H. which describes an overview of the terminology and the steps in the process of recruiting AHETF study participants.

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2.2 The terms "Qualified Grower" and "Qualified Applicator" used in this SOP refer to farmers or growers, agrichemical application businesses, and commercial pesticide applicators that might be qualified to participate in an AHETF study (as per AHETF SOP 11.K. and AHETF SOP 11.L.). It will refer to any person at the above named entities authorized to make the decision to cooperate with the AHETF.

2.3 The terms "Potentially Eligible Grower" or "Potentially Eligible Commercial Applicator" refer to qualified growers/applicators who agree to cooperate in the study, and if land owners will allow use of their land for the study, have the appropriate equipment for the study, will use or allow use of a surrogate pesticide while participating/cooperating in the study, and will allow one or more workers to participate in the study without the grower/applicator influencing the worker's decision to cooperate in the study. The list of potentially eligible growers/applicators that results from implementation of this SOP is referred to as the "Potentially Eligible List."

3.0 CALLER REQUIREMENTS

3.1 The AHETF will designated a person to initiate contact with the Qualified Growers or Qualified Commercial Applicators. This researcher will be referred to as the "caller" in this SOP and will directly communicate with the assigned AHETF Study Director regarding all recruitment procedures.

3.2 The caller will perform the initial contact with Qualified Grower/Applicators using a Qualified Grower or Qualified Commercial Applicator List developed under SOP AHETF-11.K or 11.L, respectively. The person who performs the calling and recruiting of Qualified Growers/Applicators shall have previous experience performing telephone interviews with farmers/growers/commercial applicators, have experience working with the AHETF and worker exposure studies, and have taken ethics training as per AHETF SOP AHETF-1.B.

4.0 REQUIREMENTS FOR RECRUITING POTENTIALLY ELIGIBLE GROWERS AND COMMERCIAL APPLICATORS

4.1 Growers or Commercial Applicators **may not be called** in any field study **until** the study Director signs the study protocol.

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4.2 All contact will be documented, either in writing or through electronic documentation. An Answer Sheet similar to the example in Attachment 11-M-2 will be used to document all initial contact as well as the responses of the Qualified Grower/Applicators. This form may be completed as a hard copy or electronically.

5.0 DEVELOPING THE DISCUSSION GUIDE

5.1 The caller will obtain the Qualified Growers or Qualified Applicators List from the person designated to develop this list. This list will have been developed according to SOP AHETF-11.K or SOP AHETF-11.L. The list will contain the names of qualified growers or qualified commercial applicators who have been qualified for crop acreage or acres treated, use of pesticide type, and use of appropriate equipment. The list will also contain information obtained by a grower survey as described in SOP AHETF-11.K. or commercial applicator survey described in SOP AHETF-11.L.

5.2 The caller will develop a discussion guide similar to the example in Attachment 11-M-1 to use during the recruitment call. This guide will be specifically designed from the protocol and the scenario-specific MU selection plan. Guides may be modified as necessary for each study site.

5.3 The guide will include the following content:

a. Introduction of the caller to the Qualified Grower/Applicator, stating that the call is a follow up of the survey described in SOP AHETF-11.K or SOP AHETF-11.L and a brief introduction of the AHETF as well as the purpose of the call.

b. The benefits of the research to the farming industry and to society.

c. Description of the technical aspects of the study.

d. Confirmation of survey responses from the Grower/Applicator Survey to assure the qualifications of the Qualified Grower/Applicator for participation in the study and to make sure the Qualified Grower/Applicator is informed of the needs of the AHETF (*e.g.*, size of the farm/applicator business, its geographical and physical location, whether or not the Qualified Grower/Applicator uses the designated application equipment,

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characteristics of the application equipment, and how many experienced applicators the grower or commercial application facility employs or hires).

e. Confirmation that the Qualified Grower/Applicator is willing or not willing to have his/her crop treated with or allow the company to use the designated surrogate for the study within the timeframe of the efficient configuration. At this time the caller might inform the Qualified Grower/Applicator that the AHETF will provide compensation for the surrogate used during the course of the study.

f. Determination if the Qualified Grower/Applicator would allow one of his/her experienced employees in the operation to be recruited as a volunteer worker for the study.

g. Determination if the Qualified Grower/Applicator would agree to document that they will not influence his/her employee(s) to participate in the study.

h. Confirmation that the Qualified Grower/Applicator would sign an agreement that would allow the worker to receive full pay from the Qualified Grower/Applicator during the course of the time that the worker spends in the study.

i. If the Qualified Grower/Applicator agrees to cooperate, inform the Potentially Eligible Grower/Applicator that he/she may be contacted and visited by the Study Director in the near future to finalize the arrangements for the research.

6.0 USING THE ANSWER SHEET

6.1 An answer sheet will be used to record all calls and communications with Qualified Grower/Applicator as well as with other individuals who are contacted in the process of recruiting Potentially Eligible Growers/Applicators for AHETF studies. An example of an answer sheet to be used for recording calls is attached in Attachment 11-M-2.

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6.2 For GLP purposes, there are signature and date spaces at the bottom of the answer sheet for the caller to sign and date when that answer sheet is completed. Data are to be recorded per GLP requirements and SOP AHETF-9.E.

7.0 CONTACTING QUALIFIED GROWERS/APPLICATORS VIA TELEPHONE

7.1 Using the appropriate Grower/Commercial Applicator Qualified List, the designated caller will begin contacting the listed Qualified Growers/Applicators.

7.2 The entire list of Qualified Growers/Applicators shall be called during the process of recruiting Potentially Eligible Growers/Applicators for the study. At least seven attempts will be made to reach each Qualified Grower/Applicator to maximize the response rate, after which the contact will be classified as unreachable. The caller will try to contact the grower/applicator on the preferred contact time obtained in the survey qualifying growers/applicators. If the Qualified Grower/Applicator is not reached after several attempts at this time, other appropriate time periods can be tried.

7.3 The Study Director has the option of limiting the number of calls to Qualified Growers/Applicators if the number of recruited Potentially Eligible Growers/Applicators is at any time sufficient to construct an efficient configuration for the study.

7.4 If an answering message/machine is encountered, the caller should leave an introductory message briefly describing the AHETF and purpose of the study. The caller should then provide the Qualified Grower/Applicator with the option of returning the call (provide phone number of the caller). The caller may resume calls to the Qualified Grower/Applicator if they do not return his/her call within 24 hours.

7.5 When a Qualified Grower/Applicator is contacted, the caller will introduce themselves and cover the points outlined in Section 5.3.

7.6 For Qualified Growers/Applicators who are not currently available or do not have the time to talk presently, the caller will ask to schedule a time to call back. Answer sheets designated for call back will be grouped separately and chronologically to insure they are made at the appointed time.

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7.7 The interview is then cordially wrapped up and if the Qualified Grower/Applicator agrees to cooperate during the study, he/she is then informed that they might be contacted and visited by the Study Director in the future to finalize the arrangements for the research.

7.8 Record all necessary information on the telephone answer sheet. Sign and date the form on the bottom of the page. A copy of the discussion guide and all answer sheets will be placed in the raw data file for Quality Assurance review, and eventually archived using all appropriate GLP procedures

7.9 All data generated from the Qualified Grower/Applicator contact calls will be collected, recorded, maintained, and archived by the AHETF, as per all applicable EPA GLPs as well as per AHETF SOP AHETF-6.D.

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Attachment 11-M-1: Sample Discussion Guide

AHETF Protocol: AHE__ Site ID: _____

1. Introduction of AHETF and reason for calling: AHETF is made up of nearly 25 major agricultural chemical companies that are working cooperatively to perform worker exposure studies while mixing, loading, and applying crop protection products. The studies, which will be submitted to EPA, will be used to insure safe working conditions for workers and to help maintain effective pest control products for protecting growers' crops.

2. Confirm answers given in qualifying survey. [Previous answers are on answer sheet.]
   - **a.** You stated you grow / treat [number] acres of [crop]. Is that correct?
   - **b.** The [crop] [you grow] / [your company sprays] is located in [county]? What is your zip code?
   - **c.** You indicated you hire a commercial applicator to spray your crop. Could I confirm the name of the commercial applicator and their phone number? [Grower's Only]
   - **d.** You typically use a [closed cab or open cab] tractor for your [equipment type] rig?
   - **e.** You use [number] [equipment type] applicator rigs in your operation?
   - **f.** Your [sprayer] type is [number] gallons in size?
   - **g.** You indicated you employ [number] experienced applicators in your operation?
   - **h.** On a typical work day, you can spray [number] acres?
   - **i.** You indicated that you use <product> or <products> for pest control in the [crop] [you / your company] sprays?
   - **j.** Which months do you typically use this (or these) product(s)?

3. At this time the caller should explain the technical aspects of the study to the respondent:
   - **a.** Explain that the Ag Handler Exposure Task Force is performing an exposure study with [applicators] or [mixer/loaders] in [crop] using [equipment type] for 1 or 2 days in the respondent's area in and around [time frame]. Explain that the task force will reimburse the Grower/Applicator for the cost of the pesticide used for the application on the day of research.
   - **b.** Explain how worker exposure data are generic and that since exposure does not depend on the chemical itself that representative or surrogate chemicals are used for the study using their spray equipment.
   - **c.** Explain the choice of surrogate chemicals for this study and that the AHETF cannot test every pesticide out there, so the AHETF has chosen specific products since they are easy to analyze and relatively safe pesticides to handle.
   - **d.** Briefly describe the AHETF research team and what they might be doing on the farm: research team of 3-5 field scientists stays at least 1 day at research site (grower's farm, applicator's facility).
   - **e.** Describe the dosimeters that the workers will wear, how the dosimeters will help provide samples for exposure information, and that the results of the analyses of the dosimeters will provide exposure data for workers spraying with their equipment.

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Attachment 11-M-1 (con't)

4. Would you be interested in using one of the potential products suggested for pest control by the Task Force on your [crop] in [date / month] of this year? [See choices in table below.]
5. Would you be interested in providing the Ag Handler Exposure Task Force with an appropriate acreage of [crop] which would allow for one full day of application of [appropriate active ingredient/product] using one of your [equipment] sprayers?
6. Would you be willing to allow one of your experienced [equipment type] applicators be recruited by the Ag Handler Exposure Task Force to participate in this important research?
7. In order to uphold the utmost ethical standards for such research, the worker who volunteers to participate in this research may do so only if there is no outside influence with respect to his or her decision to participate. As such, the Ag Handler Exposure Task Force is obligated to ask you as an employer of this potential volunteer, if you would find it difficult to withhold any influence over your worker to participate in the study?
8. Would you be willing to sign a brief agreement with the Ag Handler Exposure Task Force that would allow the Task Force to use your [crop], use your [equipment type] equipment, and recruit one of your workers for this project? This agreement will also provide that you as an employer will not influence your worker's decision to participate in the study.

[If "No" to Q4 to Q8; thanks and terminate]

[If Yes: [Study Director's name] who is the Study Director for this research and who works for the Ag Handler Exposure Task Force will be in touch with you shortly to follow up on our conversation and to provide you with more specific information about the timing of the research project. I appreciate your willingness to cooperate with the Ag Handler Exposure Task Force and look forward to working with you on this project.]

Surrogate product choices [Filled in with actual products from protocol]:

Pest Type	Active Ingredient	Product

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Attachment 11-M-2: Sample Answer Sheet

AHETF Protocol: AHE___ Site ID: _____ Final Status Code: _____

ID#: _____ Name: _____ Ph#: _____

2. Confirming Questions [Answers from qualifying survey will be inserted where brackets [] are. Circle Yes or No. Where No, write-in correct answer on line provided.]

a. [Acres] 1.Yes 2.No _____
b. [County] 1.Yes 2.No _____
Zip _____
c. [Com. App.] 1.Yes 2.No _____
Name _____
Ph# _____
d. [Equip] 1.Yes 2.No _____
e. [Equip#] 1.Yes 2.No _____
f1. [Gal 1] 1.Yes 2.No _____
f2. [Gal 2] 1.Yes 2.No _____
f3. [Gal 3] 1.Yes 2.No _____
g. [App#] 1.Yes 2.No _____
h. [Ac Trtd] 1.Yes 2.No _____
i. [Prods] 1.Yes 2.No _____
[Prods] 1.Yes 2.No _____
j. [Month Trtd] _____

4. 1.Yes 2.No Potential Product(s) _____ _____

5. 1.Yes 2.No Acres/day _____ Number of sprayers available _____

6. 1.Yes 2.No Number of workers: _____ 7. 1.Yes 2.No 8. 1.Yes 2.No

Notes: _____

_____

	Date	Time	Status Code	Initials	Call Back Date	Call Back Time
1.						
2.						
3.						
4.						
5.						
6.						
7.						

Status Codes: B = Busy; NA = No answer; AM = Answering Machine; NH = Not home (not available); CB = Call back
IR = Initial refusal; RP = Refused to Participate (put reason in notes above); WP = Will Participate

Caller: _____ Date:_____

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IRB Responses to Initial Submission

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12/12/08 Email Message from Robert Roogow to Eric Bruce

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-----Original Message-----
From: Robert Roogow [mailto:rroogow@iirb.com]
Sent: Friday, December 12, 2008 6:23 AM
To: 'Eric Bruce'
Subject: RE: AHE120 Submission

Eric,

Yes we did receive the submission and are working on it already. Yesenia or I will contact you if anything is needed.

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

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12/12/08 Email Message from Yesenia Crespo to Eric Bruce

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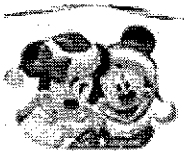
-----Original Message-----
From: Yesenia Crespo [mailto:ycrespo@iirb.com]
Sent: Friday, December 12, 2008 7:48 AM
To: 'Eric Bruce'
Subject: RE: Emailing: AHE120 IIRB Submission 12-11-08

Thanks for your submission; it will be reviewed next Tuesday.

Best Regards,

Yesenia Crespo
Project Leader



Independent Investigational Review Board INC.
6738 West Sunrise Blvd. Suite 102
Plantation, Florida 33313
Tel. (954) 327-0778
Fax. (954) 327-5778
ycrespo@iirb.com

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12/19/08 Email Message from Yesenia Crespo to Dave Johnson

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From: Yesenia Crespo [mailto:ycrespo@iirb.com]
Sent: Friday, December 19, 2008 2:37 PM
To: davejohn@marktwain.net
Subject: AHE120
Attachments: Bruce ahe120.pdf; AHE120.Acephate 75 WSP.PRS.doc; AHE120.Acephate 90 WSP.PRS.doc; AHE120.Sevin 80 Solupak.PRS.doc

Please see attached. Please let me know if I can help you with anything else.

Regards,

Yesenia Crespo
Project Leader
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Approved Documents dated 12/17/08 – see Part C

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12/30/08 Email Message from Robert Roogow to Larry Smith

US EPA ARCHIVE DOCUMENT

From: Robert Roogow [mailto:rroogow@iirb.com]
Sent: Tuesday, December 30, 2008 10:40 AM
To: 'lsconsulting@oh.rr.com'
Subject: Protocol AHE120

Dear Larry,

I hope you had a nice holiday. Here are the minutes for the December 16, 2008 meeting in regard to the AHE120 protocol. John Carley has our latest Membership List and Policies. Let me know if you need anything else. Have a Happy New Year.

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

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Minutes of IIRB Meeting on 12/16/08

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Tuesday, December 16, 2008
MINUTES

ATTENDANCE:

PRESENT	ABSENT
David Wells, MD	George Garbarino
Shari Somerstein, RPh	
Edward Wiederhorn	GUEST
Marcos Rejtman, DO	Katy Kysela, Director of Research, IRB Liaison
Rabbi Akiva Mann	Deborah Olsen, RN, IRB Liaison
Kim Lerner	
Frances Conway, RN	NOT PRESENT
	Anita McSharry, RN
ALSO PRESENT	
Glenn Moran, MD	

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 12/11/2008 MINUTES (The order of the Minutes does not reflect the order in which they were reviewed.)

The minutes of the meeting held 12/11/2008 were reviewed and unanimously approved as reviewed.

III. REVIEW PROTOCOLS

III a. STUDY INITIAL APPROVALS

D (Protocol AHE120) Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading of Pesticide Products in Water Soluble Packets in the United States
Principal Investigator: Eric D. Bruce
Approval Clinical Research;

- Informed Consent Form version 12/16/2008
- Sevin® 80 Solupak Product Risk Statement Informed Consent Form version 12/11/2008
- Acephate 90 WSP® Product Risk Statement Informed Consent Form version 12/11/2008
- Acephate 75 WSP® Product Risk Statement Informed Consent Form version 12/11/2008
- Research Protocol dated 12/11/2008
- Site Questionnaire
- Experimental Subject's Bill of Rights
- Advertisements
- Agricultural Handlers Exposure Task Force SOPs
- Sevin® Brand 80 Solupak MSDS version 2.0 dated 8/3/2006

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- Acephate 90 WSP MSDS dated 4/12/2007
- Acephate 75 WSP MSDS dated 4/12/2007
- Acephate 75 WSP Product Risk Label dated 2/7/2008
- Acephate 90 WSP Product Risk Label dated 2/7/2008
- Sevin® 80 Solupak Product Risk Label dated 7/19/2006

Motion was made, seconded and the Committee approved the Investigator(s), Informed Consent Form, Sevin® 80 Solupak Product Risk Statement Informed Consent Form, Acephate 90 WSP® Product Risk Statement Informed Consent Form, Acephate 75 WSP® Product Risk Statement Informed Consent Form, Research Protocol, Experimental Subject's Bill of Rights and Print Ad for the above noted research study. The Site Questionnaire, Agricultural Handlers Exposure Task Force SOPs, Sevin® Brand 80 Solupak MSDS, Acephate 90 WSP MSDS, Acephate 75 WSP MSDS, Acephate 75 WSP Product Risk Label, Acephate 90 WSP Product Risk Label and Sevin® 80 Solupak Product Risk Label were reviewed and accepted.

Risk

The following summarizes the discussion on Risk:

- The board discussed that subjects participating in the study are already being exposed to pesticides.
- The IRB also determined that the risk to subjects are minimized by having appropriate inclusion/exclusion criteria, safety labs, and adequate monitoring.
- The IRB noted that there is scientific merit for the conduct of the study. In addition, the study design provides the potential to support the study objectives.
- The IRB noted that there is benefit to the subjects and benefit to society including evaluating the amount of exposure during pesticide application.

The IRB reviewed the description of risks and benefits in the protocol and determined that the information in the protocol justified the determination that the risks are minimized and that the risks are justified in relations to the anticipated benefits.

Subject Selection

The IRB reviewed the description of subject selection in the protocol and determined that the information in the protocol justified the determination that subject selection is equitable.

Consent Process

The IRB reviewed the description of the consent process in the submitted documentation and determined that the information provided justified the determination that the consent process is appropriate.

Documentation of Consent

The IRB reviewed the description of the procedures for documentation of consent and determined that the information in the protocol justified the determination that documentation of consent is appropriate.

Data Safety Monitoring

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The IRB reviewed the description of the data safety monitoring plan in the protocol and determined that the information in the protocol justified the determination that the plan is appropriate.

Privacy & Confidentiality
The IRB reviewed the description of provisions for privacy and confidentiality in the protocol and determined that the information in the protocol justified the determination that the provisions are appropriate.

Vulnerable Populations
The IRB reviewed the description of protections for vulnerable populations taken by the site and in the protocol and determined that the information in the protocol justified the determination that the protections are appropriate.

The Committee recommended that changes be made to the Informed Consent Form. The Informed Consent Form is approved as revised. The approved Informed Consent Form is identified as Version 12/16/2008 and stamped, "Approved 12/16/2008". The Informed Consent Form contains all regulatory required consent elements. The Sevin® 80 Solupak Product Risk Statement Informed Consent Form is approved. The approved Sevin® 80 Solupak Product Risk Statement Informed Consent Form is identified as Version 12/11/2008 and stamped, "Approved 12/16/2008". The Acephate 90 WSP® Product Risk Statement Informed Consent Form is approved. The approved Acephate 90 WSP® Product Risk Statement Informed Consent Form is identified as Version 12/11/2008 and stamped, "Approved 12/16/2008". The Acephate 75 WSP® Product Risk Statement Informed Consent Form is approved. The approved Acephate 75 WSP® Product Risk Statement Informed Consent Form is identified as Version 12/11/2008 and stamped, "Approved 12/16/2008". The Experimental Subject's Bill of Rights is approved. The approved Experimental Subject's Bill of Rights is stamped, "Approved 12/16/2008".

The following advertisements were approved and stamped "Approved" 12/16/2008:
- 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). A final version, if revisions or reformatting is required, must be submitted to the Independent Investigational Review Board, Inc. and acknowledged prior to use.

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.

The results of the voting for the action taken was as follows: 7 Votes for; 0 Votes against; 0 Abstained

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