Antimicrobial Exposure Assessment Task Force II (AEATF II)

Aerosol Application Study

VOLUME 3

Secondary Documentation:

IIRB Communications

August 4, 2009

Table of Contents

Part 1 Transmittal (Boatwright, 7/14/09, 1:14 PM) of Initial Submission of Protocol (*AEATF Aerosol Study Protocol 071409.doc*) along with the Submission Letter, Study Set-up and Site Questionnaire forms (*Submission Letter – 070270.doc, Study Setup Form – 070270.doc and 070270 site questionnaire.pdf*) and the Rationale for Study Design for Aerosol Study, Advertisement and Certificates of Training (*AEATF Aerosol Study Scenario Design 071309.doc, advertisement.pdf and certificates of training.pdf*)

Megan Boatwright

From: Megan Boatwright
Sent: Tuesday, July 14, 2009 1:14 PM
To: 'RRoogow@iirb.com'
Cc: Sami Selim
Subject: Submission Package for 070270
Attachments: advertisement.pdf; certificates of training.pdf; AEATF Aerosol Study Protocol 071409.doc; AEATF Aerosol Study Scenario Design 071309.doc; Study Setup Form - 070270.doc; Submission Letter - 070270.doc; 070270 site questionaire.pdf

Dear Robert,

Please find attached the Submission Letter, Study Set-up Form, Site Questionairre, the protocol and Study Scenario Design for IIRB review and approval. I have also attached for submission an advertisement and training certificates. Please let me know if there is anything else you will need.

Best Regards,

Megan

Megan T. Boatwright
Laboratory Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno CA, 93722
mboatwright@gplabs.com

INDEPENDENT INVESTIGATIONAL REVIEW BOARD INC.

SUBMISSION LETTER

Use of this form is optional. The form is intended to simplify your submission process.

DATE: July 14, 2009

TO: Kim Lerner, Chair or
Anita McSharry, Vice Chair
Independent Investigational Review Board, Inc.

FROM: Sami Selim, Golden pacific Laboratories, LLC

SUBJECT:
- ☒ **New Study for IRB Review**
- ☐ **Additional Site for an Approved Protocol**
- ☐ **Modification to Already Approved Research**

Principal Investigator:Sami Selim, Ph.D.
Protocol Number: 070270

Sponsor: Antimicrobial Exposure Assessment Task Force (AEATF II)
Protocol Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using a Pressurized Aerosol Can for Indoor Surface Disinfecting

Instructions for using this form and details about the submission process are outlined in the Investigator's Guidebook located under forms at www.iirb.com

☒ **Study Protocol** *(must be a Final version) (not required for additional site submissions).*

☐ **Clinical Investigator's Brochure/Prescribing Information (Package Insert)/Device Brochure** (if applicable) *(not required for additional site submissions).*

☒ **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.(not required for additional site submissions).*

☐ **CV's and License** *for all investigator's listed on 1572 (if applicable) or participating in the study*

☒ **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)*
Select the Site Questionnaire type based on study submission.

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

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

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

☒ **Study Setup Form** *(provides shipping and invoicing information)*

☒ **Other Study Document(s)** *(i.e. subject questionnaires, subject diaries, calendars)*

Indicate documents: Aerosol Study Scenerio Design

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 us at (954) 327-0778 if you have any questions regarding a submission as incomplete submissions may delay IRB review.

INDEPENDENT INVESTIGATIONAL REVIEW BOARD INC.

STUDY SETUP FORM

PROTOCOL TITLE:A STUDY FOR MEASUREMENT OF POTENTIAL DERMAL AND INHALATION EXPOSURE DURING APPLICATION OF A LIQUID ANTIMICROBIAL PESTICIDE PRODUCT USING A PRESSURIZED AEROSOL CAN FOR INDOOR SURFACE DISINFECTING		
SPONSOR:ANTIMICROBIAL EXPOSURE ASSESSMENT TASK FORCE (AEATF II)		
Sponsor Contact Information		
Contact/Title:Sami Selim, Ph.D. / Principle Investigator	Phone/Fax:559-275-9091 (phone) 559 275-1810 (fax)	Email:sselim@gplabs.com
Address: 4720 W. Jennifer Avenue, Suite 105, Fresno CA 93722		
CRO: Eurofins/ Grayson		
CRO Contact Information		
Contact/Title:Joel Panara/ Field Coordinator	Phone/Fax:919-528-5500	Email:JPanara@graysonfarm.com
Address: 211 N Main Street, Creedmoor, NC 27522		

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.

* 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: 4720 W. Jennifer Avenue, Suite 105, Fresno CA 93722	Account #: 279923049
Copies to: ☐ Sponsor ☐ CRO ☐ Site	Send by (choose one): ☐ FedEX ☐ UPS ☐ DHL ☐ USPS ☐ Email ☐ Other:
Address:	Account #: Email Address:
Notes: Please include any additional instructions for mailing. Include if copies of routine correspondence get sent to CRO/Sponsor, sent US Mail, etc.	
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: JULY 14, 2009	

INDEPENDENT INVESTIGATIONAL REVIEW BOARD INC.

SITE QUESTIONNAIRE
Single Site Study

I. GENERAL SITE INFORMATION		
Protocol Number: **070270**	Sponsor: **Antimicrobial Exposure Assessment Task Force (AEATF II)**	
Complete Study Title: **A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using a Pressurized Aerosol Can for Indoor Surface Disinfecting**		
Principal Investigator: **Sami Selim, Ph.D.**	After Hours or 24 Hour Phone Number: (emergency contact for subjects)	**559-824-1535**
Sub Investigator(s):		
Site Address: ☐ Mail documents here	Principal Investigator's Mailing Address: (If different)	**4720 W. Jennifer Avemue, Suite 105, Fresno, CA 93722** ☒ Mail documents here
Regulatory/Study Coordinator: **Sami Selim, Ph.D.**	Phone: **559-275-9091**	
Fax Number: **559-275-1810**	Main Office Phone: **559-275-9091**	
Email: **sselim@gplabs.com**		

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.

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:

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

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).
Data and subject safety monitoring is decribed in the protocol.

III. SITE QUALIFICATIONS

9. Describe the setting(s) where the study will be conducted.
☐ private office ☐ research clinic ☐ hospital environment** ☒ Other **: **Hotels/Motels**

**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.).
NA

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 personnel are familiar with the protocol and are trained. Adequate space, storage of equipment and sufficient time will be provided to perform the assigned task.

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).
Policies and procedures for protecting the privacy of the subject's is fully discribed in the protocol.

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.
☐ Other, explain:

14. Describe the on-site emergency equipment and rescue medications available for the subjects:
911 will be called

15. Distance between the research site and nearest hospital:
NA

16. Describe how the site will store, secure, and/or dispense investigational materials.
Storage and dispensing of material is described in the protocol.

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. **NA**

18. How long has the PI been conducting research with human subjects? **24** 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

    (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*: **Subjects will be recruited through advertisements.**

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):*

** 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:

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

* *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. **We will provide documents in spanish and have Spanish Translator involved in the study.**

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

10% African American **40**% Caucasian **50**% Hispanics **0** % Asian **0**% Other

60 % Male **40** % 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.*

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:

** 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: **Spanish Translator**

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). **All staff is trained in IRB procedures and interview of human subjects prior to participating in a study.**

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. **Investigators will go over the Inform**

Consent forms with the volunteers and ask if they have any questions. Translator will be available for Spanish speaking subjects. Consent forms will be written in low grade level and will have open ended questions. ICF will have open ended questions.

42. Describe where the consenting process will take place (i.e., private room, quiet area, etc.). **A private conference room.**

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). **The subjects will be given plenty of time to ask questions and discuss it with their families before making a decision to participate.**

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. **If they decide to participate, they will give the PI written consent by filling out, signing and returning the Informed Consent Forms. No procedure will be preformed prior to receiving the IFC.**

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). **PI will use IIRB approved Informed Consent Form and Subject Bill's Of Rights. The subject will not be waiving any of their rights (stated in the protocol and the ICF and SBOR)**

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.) **Subjects will be asked open ended questions.**

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? **$20.00 for showing up at the inform consent interview. $100 for showing up at their assigned study site**
Note: If amount per visit differs, indicate each amount or attach a separate schedule.

51. What is the total payment: **$120.00**

52. When will payment occur? **at each time point** *(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: _____

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

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: **Sami Selim, Ph.D. Study Director and Principle Investigator**	Phone Number: **559-275-9091**

Print Name of Principal Investigator: SAMI SELIM	
Signature of Principal Investigator:	Date: 7/14/09

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

PROTOCOL

July 14, 2009

This Protocol is the Property of the American Chemistry Council
Antimicrobial Exposure Assessment Task Force II (AEATF II)

Sponsor

American Chemistry Council
Antimicrobial Exposure Assessment Task Force II (AEATF II)

Study Title

A Study for Measurement of Potential Dermal and Inhalation Exposure
During Application of a Liquid Antimicrobial Pesticide Product
Using a Pressurized Aerosol Can for Indoor Surface Disinfecting

Proposed Experimental Start Date

TBA

Analytical Phase Location

Golden Pacific Laboratories (GPL)
4720 West Jennifer Avenue, Suite 105
Fresno, California 93722

Field Phase Locations

Three Locations in Fresno County

Sponsor Study Identification

AEA04

GPL Study Number

070270

Total Number of Pages: 3

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TABLE OF CONTENTS

Deleted: 5
Deleted: 8
Deleted: 10
Deleted: 11
Deleted: 11
Deleted: 12
Deleted: 12
Deleted: 15
Deleted: 15
Deleted: 15
Deleted: 16
Deleted: 16
Deleted: 16
Deleted: 17
Deleted: 18
Deleted: 19
Deleted: 19
Deleted: 20
Deleted: 21
Deleted: 21
Deleted: 21
Deleted: 21
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Deleted: 24
Deleted: 25
Deleted: 25
Deleted: 25
Deleted: 25
Deleted: 28
Deleted: 29
Deleted: 29
Deleted: 30
Deleted: 30
Deleted: 32
Deleted: 32
Deleted: 32
Deleted: 34
Deleted: 35
Deleted: 37
Deleted: 38
Deleted: 38
Deleted: 39
Deleted: 41

Deleted: 41
Deleted: 41
Deleted: 41
Deleted: 42
Deleted: 42
Deleted: 42
Deleted: 43
Deleted: 43
Deleted: 44
Deleted: 45
Deleted: 45
Deleted: 45
Deleted: 46
Deleted: 46
Deleted: 47
Deleted: 47
Deleted: 48
Deleted: 48
Deleted: 48
Deleted: 48
Deleted: 49
Deleted: 49
Deleted: 49
Deleted: 50
Deleted: 50
Deleted: 51
Deleted: 51
Deleted: 51
Deleted: 51
Deleted: 51
Deleted: 52
Deleted: 53
Deleted: 54

List of Appendices

1. GENERAL INFORMATION

Study Title

A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using a Pressurized Aerosol Can for Indoor Surface Disinfecting

Sponsor Study No:	AEA04
GPL Study No:	070270

Objective

This study is being conducted to determine potential dermal and inhalation exposures associated with the use of hand-held, pressurized aerosol cans.

Proposed Experimental Start Date:	TBA
Proposed Experimental Termination Date:	TBA
Proposed Final Report Issue Date:	TBA

Applicable Guidelines

This study is based upon the U.S. Environmental Protection Agency's (EPA) guidance documents for dermal and inhalation exposure measurements under Series 875: Occupational and Residential Exposure Test Guidelines and the OECD guidelines (OECD, 1997). Data development methods will follow the requirements defined in these guidelines.

Applicable Ethical Standards

This is a protocol for third-party research involving what EPA has interpreted to be intentional exposure of human subjects to a pesticide. The study is being conducted with the intention of submitting the resulting data to EPA under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). Thus, the primary ethical standards applicable to this proposal are 40 CFR 26, Subparts K and L. In addition, the requirements of FIFRA §12(a)(2)(P) for fully informed, fully voluntary consent of subjects apply, and since the study will be conducted in California, the provisions of the California Code of Regulations, Title 3, §6710 would apply. The protocol will be reviewed by an Institutional Review Board (IRB).

Good Laboratory Practice

This study will be conducted in compliance with the US EPA FIFRA Good Laboratory Practice (GLP) Standards (40 CFR 160). The study will adhere to applicable SOPs of the Antimicrobial Exposure Assessment Task Force II (AEATF II) as referenced in the table below. Not all citations for a particular SOP may be listed.

SOP Number	Topic	Section Reference
4A.1	Study Report Preparation	18.0
5A.1 - 5C.1; 5E.1 - 5K.1	Chapter 5: Quality Assurance Unit	16.0
6A.1	Storage of Raw Data	13.0
7A.1	Test, Control, and Reference Substances Receipt and Shipment	7.0
7B.1	Test, Control, and Reference Substances Labeling	12.0
7C.1	Disposal of Test, Control, and Reference Substances	17.0
7D.1	Test, Control, and Reference Substances Chain of Custody	13.0
7E.1	Test and Reference Substances Analysis	7.0
8A.2	Whole Body Sampling – Inner, Outer and Sock Dosimeters	10.0
8B.3	Hand Wash Samples	10.0
8C.2	Dermal Face/Neck Wipe Samples	10.0
8D.1	Collection of Air Samples Using OVS Tubes	10.0
8E.1	Fortification of Matrix Samples	10.0
8F.1	Sample Identification	10.0
8H.0	Pre-Washing Dosimeter Garments	10.0
10B.1	Packing, Handling and Shipping of Samples	10.0
10C.1	Worker and Study Observations	10.0
10E.1	Worker Sample Collection Sequence	10.0
10F.1	GPI Electronic Digital Flow Meter	10.0
10G.1	Personal Air Sampling Pump Calibration	10.0
11A.1	Pregnancy Testing and Nursing Status	10.0
11B.1	Heat Stress	9.0
11C.1	Emergency Procedures	9.0
11F.0	Adverse Events Reporting to IRB	9.0

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2. SUMMARY

The Antimicrobial Exposure Assessment Task Force II (AEATF II) was formed to generate generic exposure data on a broad range of use patterns and associated application methods, as well as post application exposures to support registration and re-registration by its member companies of such uses for antimicrobial ingredients. The data will be representative of subject activities and methods used in the handling of antimicrobial products. Determining exposure of professional janitorial workers who occasionally handle antimicrobial pesticides using methods described in this research study will produce reliable data about the dermal and inhalation exposure of professional workers as well as the general population performing this task. The data generated from these studies will be used by the EPA in assessing potential exposure and risks to users of antimicrobial products and will be used in developing exposure assessments and human health risk analyses. The primary objective of this study is to use synthetic application-days called monitoring events (MEs) to monitor exposure to professional workers who apply liquid antimicrobial pesticide products with pressurized aerosol cans (also referred to in this protocol as canisters).

All study participants will be adult subjects capable of and experienced in performing the functions described in the protocol. Subjects will be required to provide their signed Informed Consent using a form approved by an Institutional Review Board (IRB) prior to participation in the study. The total number of subjects monitored will be at least 18 but could be as large as 24 if some of the subjects do not complete their assigned monitoring event (ME). Potential dermal and inhalation exposure of each individual study participant in a ME will be measured during aerosol application of an amount of product that is estimated to be representative of the use by professional antimicrobial products. All participants will be independently monitored while performing the functions described in the protocol.

The test substance, Clorox Commercial Solutions® Clorox® Disinfecting Spray (EPA Registration Number 67619-3), hereafter referred to as Clorox Disinfecting Spray), an EPA approved product[1], containing didecyl dimethyl ammonium chloride (DDAC), CAS No. 7173-51-5, n-alkyl (C12, C14, and C16) dimethyl benzyl ammonium chloride (ADBAC), CAS No. 68424-85-1, octyl decyl dimethyl ammonium chloride (ODAC), CAS No. 32426-11-2 and dioctyl dimethyl ammonium chloride (DODAC) CAS No. 5538-94-3 will be applied at a target concentration not to exceed the maximum label-recommended rate. The test substance will be supplied in commercially available, 19 oz aerosol canisters (or aerosol spray cans). The EPA-approved label for the product is provided in Appendix A. The test substance will be used in accordance with the product label.

The study will be conducted at three commercial lodging facilities (e.g., hotels, motels with kitchenettes or motels with full kitchens), each large enough and having indoor rooms/areas (e.g., bathrooms, kitchens) that provide relevant and adequate surface areas for conduct of the study. Each facility will be used to monitor exposure on a different range of dates. The areas involved in aerosol application will be bathrooms (including countertops, tub/showers, fixtures, and toilets), kitchens or kitchenettes (including countertops, sinks and appliances) and other indoor surfaces where disinfectants might typically be used. The ambient air temperature and humidity in each of the facilities during exposure monitoring will be recorded. A description of the HVAC system in use during each ME will also be documented.

The total amount of test substance applied (sprayed) by a subject will be purposively varied between the amount contained in one to four 19-oz canisters. The rationale for the range in amount of test substance applied is provided in "Aerosol Application Scenario: Rationale for Study Design" (AEATF 2009). Monitoring events are expected to range from 30 to 180 minutes, allowing time for moving between surfaces and rooms, and intermittent breaks desired by the subject. The amount of time spent actually applying the test substance may be less, as would be typical of the work activity. The approximate time spent applying the test substance, the approximate amount of surface area covered, and the total duration of each ME will be recorded in the raw data. The amount of test substance applied will be determined from the change in weight of the aerosol canisters used by each ME. Subjects will be given and required to wear all PPE (i.e., protective eyewear) specified by the product label throughout the ME.

Potential dermal exposure to the test substance will be measured externally using whole body inner and outer dosimeters, hand washes, and face/neck wipes. All monitored subjects will wear the outer dosimeter (representative outer

[1] The EPA approved label (Appendix A) for EPA Reg. No. 67619-3 identifies Clorox Disinfecting Spray as "CPPC SPRAY 1."

clothing consisting of cotton long pants and cotton long sleeve shirts) directly over the inner dosimeter (consisting of 100% cotton long underwear). Inner and outer dosimeters will be provided by AEATF. Subjects will wear their own socks and shoes. Hand exposure will be measured by rinsing the hands with a solution of 50% isopropyl alcohol/ 50% distilled water. Face and neck exposure will be measured by wiping the face and neck with gauze pads moistened with 50% isopropyl alcohol / 50% distilled water.

The potential total inhalation exposure for each subject will be measured with an OSHA Versatile Sampler (OVS) tube attached to a personal air sampling pump set at a typical sampling rate (2 L/minute). Potential exposure to respirable, thoracic and inhalable particles (100, 10 and 2.5 µm, respectively) will be characterized with a three stage RespiCon™ Particle Sampler (Model 8522, TSI Inc.) attached to a personal air sampling pump operating at ~3.1 L/min.

The inner and outer dosimeters, OVS tubes, filters from the RespiCon™ Particle Sampler, hand wash solutions, and face/neck wipes will be analyzed for residues of C14 ADBAC using validated analytical methods.

3. RATIONALE AND OBJECTIVE OF THE STUDY

Currently, US EPA relies upon the results of the PHED study conducted more than 15 years ago to characterize exposure from using an aerosol antimicrobial (EPA, 1998). That study has a total of 15 measurements of whole body exposure at levels above the Limit of Quantification (LOQ) on the outer dosimeter only (inner dosimeters were universally non-detect) after each subject sprayed an entire can of aerosol. Increased sensitivity of the analytical methods, exposure dosimetry methods and regulatory needs have changed significantly since that time. EPA has requested confirmatory exposure monitoring data for a number of antimicrobial use scenarios in Registration Eligibility Decision (RED) documents issued over the last 3 years. Study number 521 of PHED produced high quality data for both dermal and respiratory exposure, but there was no variability in amount used. Also, no attempt was made to characterize particle size (e.g., the percent respirable) in that study. The CMA study (Popendorf et al., 1992) has five individual measurements of aerosol exposure with detection on the hands only. There appears to be no other publicly available data with which to make a credible estimate of exposure for persons using an aerosol. Thus, the rationale for conducting this study is to measure dermal and inhalation exposure in a large enough group of typical users to reasonably characterize central tendency and variability for this use (scenario) of antimicrobial pesticides. Based upon the existing data, it appears that an outer dosimeter consisting of normal work clothing is necessary to capture measurable exposure over the entire body even using an extremely sensitive analytical method, although dosimeters under the outer clothing will also be used. However, the primary interest is estimating dermal exposure (the amount of antimicrobial that gets through or around the

work clothing), since that represents actual dermal exposure for most workers and typically is the route of primary exposure.

A recent summary of available passive dosimetry and biomonitoring studies conducted in the same individuals indicates that the passive dosimetry methods proposed by AEATF will neither over- nor under-estimate actual dosage (Ross et al., 2008). However, under certain circumstances, it is possible that there will be some over-estimation bias in the study design proposed in this protocol as outlined in section 5.4 of the scenario design document. Generally, from a regulatory perspective a slight overestimation bias in estimating human exposure is preferable to underestimation.

4. RATIONALE FOR USE OF HUMAN SUBJECTS

Human subjects are required in this study because they will normally be exposed to the test substance when performing their daily activities. There are no acceptable methods or models that could be used to extrapolate subjects' exposure. One subject is needed for each synthetic monitoring event (ME). A minimum of 18 MEs are required in order to capture the expected variation in aerosol application conditions using the product. Sufficient data is not available from other studies. The low toxicity of the test materials and very low expected exposure of subjects wearing extra dosimetry clothing should mean that there is little incremental risk associated with performing this task, compared to their daily duties.

AEATF may consider tracers in lieu of antimicrobials if they offer an advantage in detection limit. Most tracer substances that AEATF is aware of are not as well-tested toxicologically as the antimicrobials that will be used in this study. Given that all of the antimicrobials used in this study are commonly available and in wide use, there really is minimal risk from using them in the study, and thus no reason to exchange that risk for exposure to a less well characterized chemical at much higher concentration than a person would normally encounter it. Moreover, it would be extremely difficult to formulate *de novo* a new "product" as an aerosol containing tracer material.

5. OVERSIGHT OF ETHICAL CONDUCT

To comply with regulations regarding studies involving human subjects, written approval from the Independent Investigational Review Board Incorporated (IIRB, Inc.) located in Plantation, Florida [phone number: *(877) 888-4472*] will be obtained prior to study initiation.

The submission package to the IRB includes the Study Protocol, justification for amount of product applied and area treated (Aerosol Application Scenario: Rationale for Study Design; AEATF, 2008a), a copy of the product label

(Appendix A), the Informed Consent Form (Appendix B), the Experimental Subject's Bill of Right (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), the test substance MSDS (Appendix E), as well as all recruiting materials, such as flyers (Appendix F), interview scripts (Appendix G), and an executive summary of EPA's REDs for ADBAC and DDAC summarizing their risk assessment conclusions (Appendix I). The documents utilized with subjects (Appendices A, B, C, D, E, F, G, H) will be available in English and Spanish. Following approval by the IRB, the Study Protocol, approved ICF and supporting information will be submitted to the EPA, California DPR and HSRB for review. Recruitment of subjects into the study will not be initiated until all reviews (EPA, HSRB, and California DPR) have been completed, and IRB approval of the final protocol has been granted.

All protocol changes (amendments and deviations) shall be reported to the IIRB, Inc. in writing by letter, fax or email. Proposed changes (amendments) deemed necessary to eliminate apparent immediate hazards to the human subjects may be implemented without prior IIRB, Inc. approval. All other amendments must be reviewed and approved by the IIRB, Inc. prior to implementation, or as specifically instructed by IIRB, Inc. policy in this regard. Approval will be granted in accordance with IIRB, Inc. policy and procedures, and may be granted by telephone provided it is documented in writing (e.g., email, letter) in the final study report and associated documentation as specified in 40 CFR 26.1303. The IIRB, Inc. may provide expedited review of minor changes as defined by 40 CFR Part 26.1110 at its discretion.

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by the IIRB, Inc. prior to implementation. Deviations will be reported in writing by letter, fax or email as soon as possible following the change. Deviations and any response from the IIRB, Inc. will be included in the final study report and associated documentation as specified in 40 CFR 26.1303.

The Principal Investigator shall follow written instructions provided by the IIRB, Inc. for prompt reporting to the IIRB, Inc., appropriate institutional officials, and the EPA of unanticipated problems involving risks to human subjects or others.

The Principal Investigator shall also follow the protocol change notification and approval policies, if any, of all other agencies (e.g., California DPR) whose notification and prior approval of the study was required.

6. BALANCE OF RISKS AND BENEFITS

A. Risks to the Subjects

Risks to the subjects including those resulting from both chemical and physical hazards are discussed in this section.

Using the best existing data available to EPA from the Pesticide Handlers Exposure Database (PHED; EPA, 1998) the Agency estimated risk to individuals applying the quaternary ammonium antibacterials broadly represented by ADBAC (collectively known as "quats" in the Reregistration Eligibility Decision document; EPA, 2006a). EPA assumed an occupational handler would use THREE 16 oz cans of 0.2% ADBAC per day for air deodorization or surface disinfection. EPA estimated risk only by the inhalation route, and determined it was well above the target Margin of Exposure. The maximal AEATF II exposure scenarios in this study will require use of approximately twice the amount of active ingredient assumed by EPA. Thus, approximately one-third of the workers involved in this study will have smaller Margins of Exposure than calculated by EPA.

Dermal exposures and risks for ADBAC were not estimated for occupational handlers by EPA. Instead, they assumed that risks would be mitigated by default personal protective equipment requirements based on the signal word of the end-use product. The signal word required by EPA for use on the label of the Clorox product is "Warning." Direct contact with the product can cause reversible eye damage, skin irritation, and may be harmful if inhaled. Thus, workers will be required to wear safety glasses that provide front, and supplemental brow and temple protection during application of the Clorox product. Subjects' exposure will be reduced not only by long sleeve shirt and long pants, but also by a second layer of dosimetry clothing (long underwear).

The antimicrobial active ingredients ADBAC, DDAC, DODAC, and ODAC in Clorox Disinfecting Spray have been extensively tested in animals. They were shown to have a low acute toxicity at label dilution rates and low chronic hazard profile. The toxicity profile of DDAC and ADBAC has been reviewed in the US by the EPA and California DPR. Based on their safety profiles, DDAC DODAC, ODAC, and ADBAC have been approved for use in many formulations, and are extensively used in many janitorial products. The test substance, Clorox Disinfecting Spray, has also been tested for acute effects and has been approved by the EPA. The EPA has recently re-registered both DDAC and ADBAC and issued REDs for both (EPA, 2006 a,b). The other structurally-related quaternary amine antimicrobials rely on the toxicology data generated for ADBAC and DDAC. Additionally, the safety of the test substance has been established through long term professional use of the product. The product will be used according to its label. The subjects selected to participate in the study will be experienced in the use of janitorial products. Any subject with known allergic reaction to quaternary ammonium compounds will be excluded from participating. At high concentration quats can produce dermal irritation, but this is not commonly seen at use dilution. Significant

risks associated with either inhalation or ingestion by experienced subjects is very unlikely and would require gross intentional mishandling by subjects. Actual chemical risk during the study would likely be lower than during their normal workday, due to wearing of inner dosimeter clothing. Risk from irritation due to rubbing alcohol used on the hands and face/neck can occur if the subjects have existing abrasions or skin conditions that reduce barrier properties of the skin, e.g., eczema or psoriasis. Subjects' actual duration of exposure during product application (aerosol spraying) will be limited, i.e., less than approximately 30 minutes[2],, and the time involved in performing the described activity will not exceed the maximum normal daily activity. Subjects will be provided regular breaks to minimize overheating and fatigue, and each subject will be closely observed by a study staff member. The protocol and Informed Consent will be reviewed by an IRB prior to enrolling subjects.

There could be some discomfort and possibly the risk of heat-related illness associated with wearing two layers of clothing, although the duration, close observation, and controlled temperature in the facility should mitigate against that possibility. There is a small risk from discomfort or inconvenience of wearing the air sampling devices. There could also be some risk of embarrassment from disrobing to the subject's underwear in the presence of a researcher of the subject's own sex. Females of child-bearing age may be surprised by the outcome of the required pregnancy test.

The toxicity of the active antimicrobial ingredients in the registered product is low. The likelihood of exposure to low levels of the ADBAC, DDAC, ODAC, and DODAC quats in this study is very high. The test substance will be used by experienced subjects at concentrations approved by the EPA, resulting in low exposure during this limited time of use which is further reduced by the extra layer of clothing worn by the subjects. Embarrassment risk from disrobing is low because the researchers are of the same sex as the subjects, they are experienced, and subjects are asked to wear their own underwear. Exposure to rubbing alcohol is uniformly high, but the low toxicity coupled with warnings to subjects about the consequences of prior abrasions reduces risk to low levels. The risk of discomfort from wearing the air sampling pumps is equivalent to that from wearing two portable radios, and most would consider this negligible. The potential damage caused by release of positive pregnancy findings is very high, but the likelihood of this happening is quite low. Beginning with healthy subjects, the intensive individual observation of each subject and controlled temperature environment reduce the possibility of excessive

[2] An aerosol can contains 19 oz (538 g); assuming a spray rate of approximately 1.2 g/sec, a full can would require approximately 7.5 minutes (538 g / 1.2 g/sec / 60 sec/min) to discharge its entire contents. No more than 4 full cans will be sprayed by a given volunteer; thus, the upper-bound amount of time actually spent spraying would be approximately 30 min (7.5 min/can x 4 cans).

heat. Combined these factors indicate that subjects will not be at any significant health or safety risk during study conduct or after the study is completed.

B. Benefits and to Whom Benefits Accrue

While there are no direct benefits to the subjects participating in this research study, there are indirect benefits to both the volunteers and society. Products containing antimicrobial chemicals are used extensively in hospitals, schools, homes, etc. to control pathogenic bacteria and viruses known to produce increased morbidity and mortality in humans, domestic animals and pets. Society may benefit from continued ability to use antimicrobials that improve the quality of life. Measuring exposure of workers in this research study will produce reliable data about the dermal and inhalation exposure of workers and the general population performing these tasks. The resulting data will improve the completeness and accuracy of the database used by the EPA to assess exposure to these chemicals. The ability to accurately predict risk may allow other chemical classes of antimicrobials to also be registered based on exposure estimates generated from the data to be produced by this study. If individual workers request their results, they may find that their work practice produces more or less exposure than average, and this could be a useful learning tool. Results from the study may benefit EPA and janitorial workers by reducing uncertainty about the range of exposure experienced by consumers and workers handling antimicrobials. Registrants of antimicrobials will benefit because they will provide EPA with data on exposure that has been made a condition of re-registration for a number of antimicrobials, and they may be aided in registering new antimicrobials using the data generated from this study.

C. Balance of Risk and Benefit

The benefit of maintaining and potentially adding new antimicrobials that protect both the subjects involved in this research as well as society (including subjects' families) in general from microbial diseases far outweighs any incremental risks to subjects. Mortality and morbidity from microbial pathogens is well-documented. The very slight risks from participation in this study are far lower than the risk of not being able to use effective antimicrobials for lack of information on the exposure to users.

D. Community Involvement

While the aerosol exposure study is not a community-based participatory research program, there are multiple communities that may be affected by conduct of the study as well as by the data generated from the aerosol exposure study. The community of individuals that use an aerosol to

clean/disinfect surfaces is enormous and includes thousands of workers and at least 100 million residents in the U.S. alone.

In contrast, there is a specific group of individuals who could be more directly impacted by the conduct of this study. These are individuals in the local community who work or may be staying at the lodging facility, and those who work or visit nearby buildings. People dressed in laboratory research garments, or just an unusual amount of activity at the lodging facility may cause concern. Thus, a flyer will be generated, posted at the study site, and distributed to businesses immediately adjacent to the study site explaining the purpose of the study and providing individuals with phone numbers of the principals to contact if they have any questions or want additional information. That flyer is presented in Appendix H.

E. Alternative Data Sources

Biological monitoring is not reasonable with quats, because dermal absorption is typically less than 1%, and the primate metabolism of the quats (if any) is not known. The best exposure monitoring data currently available comes from PHED (EPA, 1998), and is inadequate for use with many antimicrobials. All of the dosimetry at the skin level were non-detects limiting exposure estimates to an upper bound determined by the Analytical Limit of Quantification at the time. Further, the study did not measure the particle size distribution of the aerosols in the subject's breathing zone, so that it is not possible to determine dose in the upper versus lower respiratory tract. This is critical information for appropriate risk assessment with some antimicrobials.

7. TEST SUBSTANCE

The test substance for these studies is the formulated product, Clorox Commercial Solutions® Clorox® Disinfecting Spray (referred to as Clorox Disinfecting Spray in this protocol), containing didecyl dimethyl ammonium chloride (DDAC), n-Alkyl (C12, C14, and C16) dimethyl benzyl ammonium chlorides (ADBAC), octyl decyl dimethyl ammonium chloride (ODAC), and dioctyl dimethyl ammonium chloride (DODAC). The quaternary ammonium antimicrobials are commonly known as "quats". C14 ADBAC is the active ingredient selected for measurement, based on its stability, abundance in the formulation, and sensitivity of its analytical method.

A. Test Substance Identification

Product Name:	Clorox Commercial Solutions® Clorox® Disinfecting Spray
Manufacturer:	Clorox Professional Products Co.

EPA Reg. No.:	67619-3
Active Ingredients Name:	DDAC, ADBAC, ODAC, DODAC
CAS Numbers:	[7173-51-5] – DDAC [68424-85-1] - ADBAC [32426-11-2] - ODAC [5538-94-3] - DODAC [64-17-5] - Ethanol
Composition:	0.0945% DDAC, 0.252% ADBAC (40% C12, 50% C14 and 10% C16), 0.0945% DODAC, 0.189% ODAC, 65% ethanol
Lot No.:	to be recorded in the raw data

Stability: The stability of the active ingredient(s) in the test substance under recommended storage conditions will be documented before the start of the study. Generally, AEATF II will rely on data supplied by the product registrant that were submitted to support the EPA registration of the test substance. An expiration date and recommended storage conditions will be based on the stability data to ensure the test substance strength does not change appreciably prior to use in the study.

GLP purity analysis (content of active ingredient in the test substance) will be performed by the Sponsor, and a Certificate of Analysis will be kept in the raw data file.

Test substance received for, but not used in the study will be retained in its original container under monitored storage conditions until the release from the study is authorized by the Study Director. Retained samples from each lot of test substance used in the study will be archived with GPL.

B. Justification for Use of Test Substance

Clorox Disinfecting Spray is an end use product registered with the EPA for use on smooth surfaces in indoor environments. Clorox Disinfecting Spray contains ADBAC, DDAC, ODAC and DODAC. ADBAC was selected as the analyte based primarily upon its abundance in aerosol products, on its stability, and the sensitivity of its analytical method. The quats ADBAC, ODAC, DODAC, and DDAC have complete toxicology databases with low mammalian toxicity. Virtually all quat antimicrobial products contain more than a single quat, i.e., a readily available product containing only ADBAC was not apparent.

The analytical method for ADBAC on the proposed monitoring matrices at very low concentrations has been validated (GPL, 2004). The freezer storage stability of ADBAC on the different matrices to be used in this study is ongoing (GPL, 2009; in progress).

The very sensitive and selective analytical method developed for the analysis of ADBAC on different study matrices will allow for the detection and quantification of extremely low levels of active ingredient in the collected samples. This will allow for shorter exposure time, thus minimizing the risk to research study subjects. Additionally, Clorox Disinfecting Spray has been deemed suitable by the Sponsor and EPA as a surrogate compound for generating exposure data for other antimicrobial pesticides.

C. Safety Precautions

A copy of the Materials Safety Data Sheet (MSDS) and the product label (English and Spanish versions) will be included in the study file, and provided to the study team (professional observers and researchers). A copy of the product label (English or Spanish, as requested) will provided to each subject, and each subject will be made aware of the MSDS and a copy in the preferred language provided upon request. Label safety requirements will be explained to the subjects involved in the study. The label-specified PPE (protective eyewear) will be provided and use directions will be followed by the subjects and ensured by the study research personnel. If a subject does not use required PPE or does not follow use directions within reason, or does so in a manner that presents safety issues in the judgment of the study research personnel, the study research personnel may terminate the subject's participation and proceed with collection of the subject's dosimeters. The final study report will include the dosimetry data from the subject, but will also include notations and qualifying text.

Heat stress signs and symptoms will be explained to the subjects. A copy of the poster entitled "Controlling Heat Stress Made Simple" in English and Spanish will be posted in the dressing area at each site.

Test substance which may get on the skin will be removed through one or more hand washes and the face/neck wipe procedure (sample collection events) during the ME. Following completion of each ME each subject will wash their hands thoroughly with soap and water. The Principal Investigator or designee will examine their hands and note any irritation to the skin at termination of each participant's monitoring. Section 9D includes additional details regarding stop criteria and medical management.

D. Calibration of Application Equipment

The application equipment (aerosol canisters) to be used in this study cannot be calibrated (i.e., the rate of discharge cannot be adjusted). Information concerning the typical rate of discharge would be useful in estimating the amount of test substance applied while an ME is in progress, and for that reason, the typical discharge rate for each lot of test substance will be determined. The typical rate of discharge will be determined by discharging three representative unused canisters for three 10 second intervals per canister. The weight before and after each discharge interval will be documented, and the average amount discharged/second from each canister calculated. The average amount discharged/second from all three canisters will then be calculated, and this rate of discharge will be used, in conjunction with measurements of actual spray time during an ME, to estimate the cumulative test substance applied while an ME is in progress. The actual amount applied during an ME will be determined as described in Section E - Application Parameters and Amount Applied below. In order to assure uniform starting pressure and homogeneity, each aerosol canister should be shaken for approximately 10 seconds immediately prior to beginning each trial. Canisters used for emission rate trials will not be used in the study.

E. Application Parameters and Amount Applied

Each ME will apply the test substance to bathrooms and/or food preparation areas which include horizontal and vertical surfaces (e.g. shower stall/tub, toilet, countertops, sinks, cabinets and appliances). Each bathroom is expected to include some combination of shower stall/tub enclosure, toilet, and/or sink/countertops. Each kitchen or food preparation area is expected to include counter tops and some appliance surfaces. All interior surfaces of the shower/tub, the horizontal surface of the countertop/sink, and exterior surface only of toilets will be sprayed with the test substance. One complete can of aerosol product will cover the shower, sink and toilet in approximately two bathrooms if every surface were sprayed; however, that is not typical practice and each participant will be encouraged to apply the spray as they would in normal practice.

In order to assure uniform starting pressure and homogeneity, subjects will be asked to shake each aerosol canister for approximately 10 seconds immediately prior to beginning each application cycle An "application cycle" is defined as the process of applying the test substance in one room or area (e.g. one bathroom, one food preparation area).

The Clorox Disinfecting Spray will be applied by janitorial professionals according to typical practices, i.e., spraying surfaces from a distance of approximately 6-10 inches in a manner to apply enough formulation to

provide an adequate amount for cleaning. Hard surface applications are typically sprayed until visibly "thoroughly" wet per label direction. No wiping will be conducted as part of this application scenario. Surface applications are typically made in smooth, sweeping, overlapping patterns. Examples of "representative" spray application methods that this study is expected to capture (i.e., "horizontal spraying moving upward and downward from the starting point to hard surfaces such as laminate, tile, porcelain, glass, and metal") are specified in the informed consent form.

To determine when a particular subject has applied the amount of test substance in the assigned ME, field personnel will periodically weigh the canister(s) in use, and maintain a running estimate of the total amount applied. Unless the subject voluntarily stops spraying short of the target amount, the ME will end following completion of the application cycle in which the amount applied is first confirmed to fall within the assigned strata.

The amount of test substance applied during each ME will be determined by the total change in weight of all canisters used in the ME. Each canister will be uniquely identified prior to experimental start. Prior to each ME a sufficient number of unused canisters will be individually weighed, and the beginning weights of each canister recorded in the raw data. Following completion of the ME, each canister used in the ME will be individually weighed, and the end weight and amount of change for each canister recorded in the raw data. The total amount of test substance applied will be determined by the amount of change (i.e., test substance discharged) from all canisters used in the ME. All information necessary to reconstruct the amount of test substance applied by each ME will be documented. The same canister(s) will not be used in more than one ME.

The Clorox Disinfecting Spray label indicates "For use on non-food contact surfaces only. A potable water rinse is required for surfaces which may be in direct contact with food [such as counter tops or high chairs]." This potable water rinse procedure is not part of the aerosol spray scenario, and will therefore not be performed by monitored subjects. If any food contact surfaces are treated during an ME, field research personnel will conduct a potable water rinse of those treated surfaces after the subjects have completed their tasks and have left the treated area.

F. Rationale for the Method and Procedure of Application

The procedures described represent typical consumer and professional worker methods of applying the test substance to indoor surfaces. The test substance chosen is utilized in the described scenario that employs aerosol application of antimicrobials.

G. Test Substance Storage

The test substance will be stored at room temperature. Storage will be at Golden Pacific Laboratories, and the temperature will be recorded.

8. STUDY DESIGN

A. Overview

The target study design involves construction of 18-24 synthetic antimicrobial aerosol application days, called monitoring events (or MEs). From 6 to 8 MEs will be conducted at each of 3 different monitoring sites. Each monitoring site is a separate building (or building complex) and occurs during a separate range of dates. The MEs conducted at the same monitoring site comprise a ME cluster. Each of the MEs in a cluster will involve the application of a different amount of active ingredient (AaiH). Only six MEs are needed in each cluster. However, extra subjects are allocated to each monitoring site to permit a maximum of two additional MEs in the event some subjects are unable to apply the full assigned amount of aerosol product. Thus, a cluster might contain as many as eight valid MEs. (The two additional subjects assigned to each site might also substitute for MEs for which a subject withdraws for any reason.) Each of the 18-24 MEs will be performed by a different subject applicator. Each ME will be monitored for dermal and inhalation exposure. The scenario design document provides a detailed discussion of the rationale for each component of this design (AEATF, 2009).

Procedures for the selection of monitoring sites and the assignment of amounts of active ingredient and subjects to MEs are described in the following sections (8.A, 8.B, and 8.C). Procedures for the recruitment, selection, compensation, and possible withdrawal of subjects are described in Section 9. Exposure monitoring procedures for MEs are described in Section 10.

B. Random Selection of Facilities as Monitoring Sites

The study will be conducted at three commercial lodging facilities in Fresno County, California. Each facility will provide an independent configuration of appropriate indoor aerosol application surfaces (e.g., tub/shower stalls, toilets, sinks, kitchen countertops, appliances). The combination of facilities (physical location) and span of days set aside for MEs within each facility (temporal 'location') define the monitoring site. Each site will be used for a single cluster of 6-8 aerosol application MEs.

A random sampling approach will be used to select acceptable facilities. First, a list of all properties that meet the following criteria will be compiled:

- The property is commercially advertised on YellowPages.com under "hotel or motel with kitchenette or full kitchen" in "Fresno, California." If motels with full kitchens are not available, small, empty apartments will be considered.
- The property is at least partially within the boundaries of Fresno County, California.

This list of properties is then randomized and investigated (in random order) until three qualifying facilities have been found. To qualify, the three selected properties must all meet the following general criteria:

- The facility management is willing to cooperate in the study.
- The configuration of available and ME-suitable units provides acceptable diversity of application surfaces (e.g., horizontal and vertical surfaces, kitchens, bathrooms, sinks, countertops, toilets).
- There is a functional HVAC system.
- Electrical service is on or available for a short period (i.e., less than 32 days).
- The property does not require specialized cleaning or maintenance prior to use.

It addition, a qualifying facility must belong to one of the following three categories based on building type and availability of rooms with a food preparation area (i.e., a stove/oven, refrigerator, and food preparation sink):

A. The facility is a hotel/motel with a full kitchen and facility management is willing to provide 20 or more units for use in the study.

B. The facility is a hotel/motel with kitchenette and facility management is willing to provide 20 or more guest rooms with a food preparation area for use in the study.

C. The facility is a hotel/motel without a food preparation area and facility management is willing to provide 20 or more guest rooms for use in the study.

One facility will be selected from each of the above three categories. The first facility on the (randomized) list meeting all criteria for A, B, or C is located and selected. The process of investigating and qualifying properties on the list then continues until one facility is selected for each category. Once a category is satisfied no further facilities in that category need be selected.

Because the properties are screened in random order, the site selection process results in a (stratified) random sample of three acceptable facilities from the population of all such facilities in Fresno County, California. In addition, no two or more facilities will be from same category. The three selected facilities will have different aerosol application spaces (i.e., kitchens and bathrooms) and are likely to have different internal architectures.

Once the three facilities have been selected, dates for monitoring the cluster of MEs at each location will be scheduled in a manner that is logistically convenient. However, monitoring activities for different clusters must be separated by 7 or more days between the last ME of one cluster and the first ME of the next cluster.

In the event a selected facility becomes unavailable or is later determined to be unsuitable, the selection process for that category will resume, using the original randomized facility list, and starting with the facility which next follows the one last investigated. The reason any previously selected facility cannot be used will be documented in the raw data.

C. Assignment of Amount of Active Ingredient Handled to MEs

In this study all MEs will apply the same substance, i.e., Clorox Disinfecting Spray in 19 oz (538 g) canisters (see Appendix A). As described in section 7.A above, this substance contains several active ingredients. However, only one of these, C14 ADBAC, will be quantified.

Because the concentration of ADBAC in the aerosol canisters is the same for all MEs, the amount of active ingredient 'handled' (AaiH) is varied simply by having MEs that apply different amounts of the formulated product. The total amount of product sprayed, will range between 1 and 4 canisters (i.e., 538 to 2152 grams of formulated product). This range is partitioned into six AaiH intervals (or 'strata') as follows:

A. 1 to 1.5 canisters
B. 1.5 to 2 canisters
C. 2 to 2.5 canisters
D. 2.5 to 3 canisters
E. 3 to 3.5 canisters
F. 3.5 to 4 canisters

Within each monitoring site, a single ME is targeted for each of the above six strata (see exceptions in section 8.D below). As long as the subject is within the correct AaiH interval, it is unnecessary to control the exact amount of product precisely. However, the actual amount of product sprayed by each subject will be recorded.

D. Random Selection and Assignment of Subject Applicators to MEs

As described in Section 9 below, 24 subjects are randomly sampled from the pool of qualifying volunteers and divided into three groups of eight subjects each. Each group of eight subjects is assigned to a different monitoring site. Subjects are arranged and processed by their unique SISN which corresponds to a random order (see 9.B below). Therefore, the assignment of subjects to sites is also random. This allocation provides the potential for an additional two MEs per monitoring site beyond the six MEs needed if all workers are able to complete their assigned spraying tasks.

The eight subjects allocated to each site are assigned to MEs in random order (i.e. by their SISN). The first subject is then assigned to the ME with the largest spraying amount (i.e., stratum F, 3.5 to 4 canisters). No other assignments of subjects to MEs are made until this subject completes the monitoring task in this stratum. When the ME is complete, the next subject in (randomized) order is assigned to the next highest AaiH stratum (E, 3 to 3.5 canisters). As long as each subject achieves the target spraying amount, the process is continued down to the smallest spray amount stratum (A, 1 to 1.5 canisters) and six MEs have been obtained, one for each of the six strata. If this process proceeds as expected, the last two subjects allocated to each site are never used for MEs and will remain alternates.

It is conceivable that, due to irritation or other difficulty, a subject might not complete the spraying task for the assigned amount of product applied. If this should occur, the data from this ME can still be used provided the subject sprays at least one canister and, therefore, falls within one of the other (smaller amount) strata. If the subject failed to spray a single canister, however, the data from this ME will not be used and the monitoring media will not be analyzed. Regardless, the next subject in the (randomized) sequence will be assigned to an ME for the largest uncompleted spraying amount stratum. This process will be continued until there is at least one ME in all six monitoring amount strata or until the set of eight subjects has been depleted, whichever occurs first. If such difficulties do occur, then it is possible that some larger amount strata will not be monitored and that some smaller amount strata will have more than a single ME. A consistent failure to complete the larger amounts of spraying for reasons such as fatigue would be an indication that such amounts are inappropriate and/or unlikely to occur in practice.

9. SUBJECT RECRUITMENT, SELECTION, COMPENSATION, AND WITHDRAWAL PROCEDURES

Twenty-four subjects are required for this study to serve as surrogate applicators (or 'workers') for the MEs. This includes the planned 18 surrogate workers needed for the target design (i.e., six workers at each of three sites). As described above, the additional six subjects (two per site) are included as insurance against subject withdrawal or other failure to complete the assigned spraying tasks (see 8.D).

A. Subject Recruitment

i. Population Base

Adult subjects will be recruited from the janitorial/cleaning service population of Fresno County, CA, and the surrounding area. The most-recent US Census indicates that 40% of the population in Fresno, CA metropolitan area is Hispanic. The proportion of Hispanics in service industries, e.g., janitorial services, may be even higher than the general population. Therefore to adequately capture the ethnic diversity in the Fresno area, recruitment materials and all communications with potential subjects will be available in English and Spanish, as preferred by the subject

ii. Recruitment of Surrogate Workers

Janitorial services providing professional cleaning services for commercial buildings in Fresno County, CA will be contacted by qualified research personnel and asked whether they would be willing to post a flyer soliciting volunteers for a study to be conducted independent of the janitorial service. The list of janitorial service providers will be compiled from telephone directories, Chamber of Commerce, and additional information supplied by service providers themselves. The initial contact with service providers will determine language preference (English and/or Spanish) for the flyers. The employer script shown in Appendix G will be used to call janitorial services to see if they would be willing to post a flyer (Appendix F).

Research personnel will follow up by phone or in person to confirm receipt of the flyer and answer any questions the owner/manager may have. If the firm wishes to post the flyer, research personnel will provide a general description of the study, explain the need and importance of remaining neutral (un-coercive) in their interactions with employees regarding study participation, and determine whether the flyer seems intelligible for the firm's employees. Assuming the owner/manager still wishes to post the

flyer, research personnel will provide approval to do so. All communication with janitorial firms will be documented.

To avoid the potential for coercion, subjects will not be recruited directly through contract janitorial service companies. Flyers will direct interested workers to contact research personnel directly. The recruiting flyers will include telephone numbers for both English and Spanish speakers, and voicemail in the appropriate language will be available for messages when direct human contact is not possible. The recruitment period will be opened for 4 weeks.

IRB approved recruiting advertisements (appendix F) will be simultaneously (within the same week) placed in the Fresno Bee, the California Advocate and the Fresno edition of Vida en el Valle. The Fresno Bee is a large, general circulation daily paper in Fresno County. The California Advocate is the dominant African American community weekly paper in Fresno County, and Vida en el Valle is a weekly targeting the San Joaquin Valley, with separate editions for Fresno and other central valley municipalities. The recruiting advertisements will include a brief description of the study and include telephone numbers for English and Spanish speakers to call for more information.

Individuals contacting research personnel and expressing an interest in participating in the study will be informed of the study according to the IRB approved script (Appendix G). Callers will be screened for janitorial experience by asking each caller if they are currently employed by, or own and operate a janitorial firm providing services to commercial buildings within Fresno County. Employment and/or ownership experience within the last 18 months will also be considered sufficient.

Callers responding to flyers posted by janitorial firms and interested in participating in the study may be scheduled for Informed Consent meetings at the volunteer's convenience. It is not necessary to wait until the recruiting period is closed before enrollments begin.

During the scheduled informed consent, the Principal Investigator or designee will share information on the study design with interested participants, and provide them with copies of the IRB approved Informed Consent Form (Appendix B) and answer their questions. The Principal Investigator or designee will describe the study to the individual in great detail and encourage each potential subject to ask questions and request clarification at any time during this process as well as in all activities that follow. The Principal Investigator or designee will provide each potential subject a copy

of the product label (Appendix A), make available the MSDS (Appendix E) and answer any questions regarding the product to be tested. The Principal Investigator or designee will go over the Inclusion and Exclusion Criteria (see 9.A.iii. below) for the study and answer any questions that the potential subjects have. Potential subjects will be provided with copies of the Subject Self-Reporting Demographic Form (Appendix D) and the State of California Department of Pesticide Regulation "Experimental Subject's Bill of Rights" (Appendix C) and asked if they would like to take any of the materials home to discuss with family and friends before deciding whether to enroll in the study. If the potential subject wishes to continue with the enrollment process at that time, the Principal Investigator or designee will explain to potential subjects they may withdraw from the research study at any time without penalty to their compensation. The Principal Investigator or designee will then read the "Experimental Subject's Bill of Rights" to the potential subject. The amount and form of compensation, the potential risks and discomforts and treatment and compensation for injury will be more fully explained and potential subjects will be encouraged to ask questions. If the potential subjects do not have any questions and are interested in participating in this research study, they will then be asked to sign the Informed Consent Form and then fill out the Subject Self-Reporting Demographic Form.

The Principal Investigator or designee will check the potential subject's driver license or state-issued identification card to verify identity as required by California DPR, and review the package of information provided for completeness against the protocol's inclusion/exclusion criteria. When at least three attempts have been made to reach and schedule Informed Consent meetings for every caller on the primary call-in list, and all scheduled Informed Consent meetings have been held, the pool of enrolled volunteers will be randomized, and the random order subsequently used to accept participants into the study, assign participants to specific clusters, and assign participants to specific ME slots.

The recruitment process will terminate at the end of the time period when a minimum of 24 subjects have been recruited for the study, i.e., have agreed to participate and signed the ICF forms. If fewer than 24 subjects have been recruited during the 4 weeks open recruitment period, the enrollment period will be extended in 7 days increments, until at least 24 subjects have been enrolled into the study, terminating at the end of the 7 day extension. Termination will be done at the end of a specific time window to minimize the potential for an "early responder" bias.

A Spanish-speaking member of the research team will be available at recruitment meetings to assist and ensure communication with anyone preferring Spanish over English.

The Principal Investigator will retain the final right to refuse participation to any potential subject; however, all potential subjects who attend the screening interview will be compensated $20 for their inconvenience, and all enrolled subjects who report to their assigned study site will receive $100. See Section 9.C for additional information.

For female potential subjects, final eligibility for participation in the study will be determined on each study day following a pregnancy test.

iii. Inclusion/Exclusion Criteria

Not all volunteers are eligible for participation in this study. The subjects will be asked to fill out a demographic questionnaire the results of which will be used to determine eligibility. While this study may require physically strenuous activities, no upper age limit has been imposed, given that an inclusion criterion is that the volunteer is "in good health." In addition, the actual participation of female subjects will be conditional on the results of a pregnancy test taken on the day of scheduled monitoring.

Inclusion Criteria

- Males or females, at least 18 years of age
- In good health
- Willingness to sign the Informed Consent Form and Subject Self Reporting Demographic Form
- Speak and read English or Spanish
- Resident of Fresno County
- Experience in providing janitorial services

Exclusion Criteria

- Skin conditions on the surface of the hands (e.g., psoriasis, eczema, cuts or abrasions)
- Pregnancy, as shown by a urine pregnancy test
- Lactation
- Allergies to household chemical-based products,

soaps or isopropyl alcohol

- Declines to sign the Informed Consent Form or the Subject Self Reporting Demographic Form
- Does not read and understand English or Spanish
- Is less than 18 years old
- Is not in good health
- Severe respiratory disorders (e.g., moderate or severe asthma, emphysema)
- Cardiovascular disease (e.g., history of myocardial infarcts, stroke, congestive heart failure or uncontrolled high blood pressure)
- Is, or is related by blood or marriage to, an employee of Golden Pacific Laboratories, Eurofins |Grayson, or a cleaning product manufacturer.

iv. Community Involvement

There is no single group identifiable that would represent the community of potential users of aerosol spray antimicrobials. Because of cost relative to trigger sprays, aerosols are not preferentially used by commercial janitors that will be involved in this study, although they all certainly have used aerosols professionally.

B. Subject Identification Sequence Number (SISN)

Individuals on the primary call-in list for this study will be initially identified by only their first and last name. After this list has been randomized, each individual is assigned a unique study identification sequence number (SISN) that indicates his/her position in the random order. Because all processing of individuals is in order of SISN, the final list of 24 enrolled subjects comprises a random sample and their SISNs preserve the random order. The first sequential group of eight SISNs will be assigned to the first simulated application site, the second sequential group of eight will be assigned the second site, and the third sequential group of eight will be assigned to the third site. Thus, allocation of subjects to monitoring sites is also random.

Individual data, excluding the subject's name and address, will be entered in Golden Pacific Laboratories' computer data base by SISN. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their SISN will be retained separately from the study file in an area clearly marked "CONFIDENTIAL". Golden Pacific Laboratories will retain subject's records indefinitely. Subjects may obtain copies of their own records from the Principal Investigator on request.

C. Compensation

All individuals that show up for the informed consent interview will be compensated $20 in cash at completion of the interview for their time and inconvenience. All individuals who are qualified, sign the informed consent form, and report to their assigned study site, will receive $100 in cash for their time and inconvenience when they leave the study site, whether they are monitored or not. If a subject signs the consent form and fills out the demographic form, information that may disqualify them from participation may become evident. If this occurs, the disqualified subject will be paid $100 as if a participant and dismissed.

The value for compensation is based roughly on a day's wage of $100 and represents potential lost time from secondary sources of employment, travel time and incidental expenses incurred in study participation. Compensation will be provided to individuals who complete their assigned participation or who need to withdraw for whatever reason.

D. Stop Criteria and Medical Management

It is not expected that test subjects will experience any adverse effects from participation in this study. In the unlikely event adverse effects are experienced, they will likely be related to skin reactions during or following the study, or heat stress or odor aversion during the study. The Principal Investigator or designee will discuss the symptoms of heat stress, odor aversion and eye and skin reactions with the subjects prior to participation in the study. Subjects will be instructed to inform the Principal Investigator or research staff (or personnel) immediately if they feel ill, suffer an eye or skin reaction or experience any other unanticipated adverse effects they feel may be related to the study during or following conduct of the study. The research personnel will also examine the hands immediately prior to the monitoring period to ensure there are no existing abrasions, cuts or skin conditions that increase the risk of skin problems during the monitoring period. A Spanish-speaking member of the research team will be present during monitoring events involving subjects whose preferred language is Spanish.

If a subject reports an adverse eye or skin reaction during the work period, they will be asked to immediately stop working. Research staff will then assist the subject in gently washing exposed skin with clean water and mild soap. After drying the area with a clean towel, the Principal Investigator or designee will be contacted for further instructions.

The extra layer of clothing worn by subjects may increase the risk of heat-related illness. To minimize the possibility of heat stress, the study will be conducted indoors in an environment where the heat index (HI) is expected to be less than 85. Research personnel shall monitor the heat index, and stop subjects' work if the heat index exceeds 95. The SOP AEATF 11B describes the procedure for identification and control of heat stress. The poster "Controlling Heat Stress Made Simple" will be posted in the subject dressing area, and the information contained on the poster available to subjects and research personnel at the field site.

In brief, researchers will observe subjects for possible signs of early heat illness such as fatigue, dizziness, irritability, or decreased concentration, especially if the worker has been working for a while. If these symptoms are observed, the subjects will be asked whether they would like to rest for a moment. If they answer affirmatively, they will stop working, be given their choice of water or a sports drink, and the Principal Investigator will be immediately contacted for further medical management instructions. If they answer negatively, they will be permitted to continue working, and frequently thereafter asked whether they would like to rest for a moment. Any affirmative answer will be handled as described above.

If subjects develop visible signs or report symptoms of distress such as pronounced fatigue, headache, cramps, feeling faint, increased pulse, muscle spasms, heavy sweating (or dry skin if previously sweating), extreme thirst, or rapid breathing, the subjects will be required to stop working immediately, and given their choice of water or a sports drink. The Principal Investigator will immediately be contacted for further medical management instructions. If the worker's condition appears to be serious, a member of the study team will call 911 and allow emergency medical personnel to respond and treat the subject.

Study personnel will be instructed to inform the Principal Investigator immediately of any skin reactions, heat stress, or other unanticipated adverse effects observed or reported during conduct of the study. The medical management procedures set forth in SOP AEATF 11C will be implemented for any instance where the subject's work is halted for medical reasons (other than solely because of a heat stress index above 95), and for any post-study reports of illness, skin reactions or other unanticipated adverse effects. If two or more subjects withdraw or are withdrawn from the study for the same medical reasons, the study will be

suspended until the cause of the withdrawal is fully investigated and determined. If two or more subjects develop an adverse skin reaction after they leave the study site, all subjects will be contacted by the Principal Investigator to determine whether further medical management is appropriate.

The Principal Investigator will maintain a record of adverse health observations and reports, and follow Sponsor, IIRB, Inc., EPA and California DPR policies for medical event reporting per AEATF II SOP 11F. Sufficient personnel will be present at the study site to maintain an appropriate level of technical support, scientific supervision and observations relevant to the safety of test subjects.

10. MONITORING EVENT PROCEDURES

Monitoring of each ME is expected to take a maximum of 3 to 4 hours on a single day. This includes discussion with the study director prior to initiation, and all study procedures. During that time subjects will change into inner and outer dosimetry clothing and get fitted with two air sampling pumps and sampling train. Subjects will then be asked to apply the test substance using pressurized aerosol canister(s) until they have completed applying their assigned amount of test substance or are told to stop by the research team. Finally subjects will remove the dosimetry clothing with aid of the research team and change back into subjects' own clothes.

A. Air Sampling for Ambient Pre-Existing ADBAC

Duplicate air samples using personal air sampling pumps and OVS tubes described for worker samples will be collected in the subject dressing area for a fifteen minute period within two hours prior to the start of exposure monitoring on each day of the study. Similarly, duplicate air samples will be collected from each unit (e.g. hotel/motel room or apartment) intended for exposure monitoring that day. Samples will be collected at a height of five feet, and analyzed at the discretion of the Study Director.

B. Subject Preparation

1. On the day of the study, each subject will go to the study location at the designated time, and meet the researchers.

2. If a subject is female, she will be taken to a private area and asked to take a urine pregnancy test using an over-the-counter pregnancy test kit. After the subject has taken the pregnancy test she will be asked if she still wants to participate in the study. If she declines, she will be paid $100 for her inconvenience and will be free to go. If she wants to continue, a female member of the research team familiar with

interpretation of the test will confirm the results of the pregnancy test. Results of the pregnancy test will be kept in confidence, they will not be recorded, and they will be discussed only with the subject that provided the urine sample. A note indicating that the pregnancy test was performed in accordance with AEATF SOP 11A will be made in the raw data.

3. The Principal Investigator and the research team will review with the subject their role in the study, and the subject will have a chance to ask additional questions. Subjects will be reminded that they may withdraw at any time before or after the study begins, and that there will be no penalty of any kind to subjects if they decide to withdraw from the study.

4. Subjects will wash their hands and face with Ivory soap and water, and dry them thoroughly using paper towels.

5. When an individual subject is ready, the subject will be accompanied to a private dressing area by a researcher of the same sex. Subjects will be asked to remove their street clothes down to their underwear, and put on the inner dosimeter (cotton long underwear), followed by the outer dosimeter (long sleeved cotton shirt and long cotton pants) provided by the AEATF. Care should be taken to provide clothing of adequate fit. The inner dosimeter arm and pant cuffs should not extend beyond the outer dosimeter cuffs (wrists and ankles). If necessary, the excess may be cut from inner dosimeter pant legs and arms at the wrists so the inner dosimeter will not come out from underneath the outer dosimeter during the ME. The outer dosimeter pant cuffs may be cut for proper fit, at a length where the cuffs do not drag on the floor or expose the worker's socks or inner dosimeter. The outer dosimeter pants will not be tucked into boots/shoes. The outer dosimeter shirt will be tucked into the pants. A secured locker or similar storage area will be provided for the subjects' personal belongings during study participation.

6. A low-volume personal air-sampling pump with Tygon® tubing (or equivalent) attached to an OVS tube with glass filter and XAD2 sorbent will be attached to the subject's belt (or a belt provided by the AEATF). The OVS tube will be placed in the subject's breathing zone with the inlet facing downward, similar to the nasal passage of the subject. A second low-volume personal air-sampling pump with Tygon® tubing (or equivalent) attached to a three stage RespiCon™ Particle Sampler will be attached to the same belt in a manner which does not interfere with the ME or the first air pump. The RespiCon™ will be placed in the subject's breathing zone using a chest harness. Airflow of pumps attached to the OVS tube and RespiCon™ sampler will be calibrated to a nominal flow rate of approximately 2 and 3.1 L/min respectively using SOPs of field study procedures. The beginning flow rate of each pump

will be checked and documented just before being fitted to the subject.

7. Subjects will be given safety glasses that provide front, and supplemental brow and temple protection. The subjects must wear the safety glasses while applying the aerosol spray to surfaces. If subjects remove their safety glasses while spraying the aerosol, study research personnel will ask them to place them back on.

8. Photos of each subject will be then be taken. If facial features are shown, the photos shall be treated as confidential subject information and maintained in a separate, secure raw data file.

C. ME Activities

1. The air pumps will be turned on, and subjects will put on their safety glasses. Subjects will be provided a 19 oz canister of Clorox Disinfecting Spray, directed to the appropriate ME application area, and asked to select an appropriate starting point and apply the aerosol spray to the surfaces the way they normally do on the job. Subjects will be asked to shake the can for approximately 10 seconds before each application cycle. If ventilation fans are available, the subject may turn them on during the spraying procedures at their discretion, as would be typical of their normal practice. A researcher will observe each subject as they work, recording information necessary to characterize each ME. Following each application cycle, the subject will be directed by research personnel to the next application area.

2. Periodically throughout the monitoring period, the pumps will be checked to ensure they are still running and the tubing checked to ensure that there are no kinks Subjects will be instructed to inform a study team member if the pump fails to operate or the tubing becomes kinked. Pumps and/or pump batteries which fail during the work activity will be replaced with another calibrated pump or a replacement battery, as appropriate. The sample train (OVS tube or RespiCon™, with connective tubing) will be retained and moved to the second pump if a replacement pump is necessary. Air pumps will not be turned off during breaks, and will remain operating until the subjects' work duration is complete.

3. Each subject is assigned to a particular stratum and will be asked to move from room to room (or area to area) applying the test substance as they typically would until they are asked to stop by the observer or decide they wish to withdraw from the study. Subjects will be provided with fresh canisters as necessary, instructed to take breaks at their discretion, and be provided a drink during breaks as requested. Hand wash samples (Section 10D2 below) will be collected if a subject elects

to use the toilet during a break. The duration of a completed ME will depend on the assigned stratum, but is not anticipated to exceed 180 minutes for the highest stratum. Each individual application cycle (period of applying test substance in one room or area) is expected to range from four to eight minutes.

4. The ME will be terminated by the observer when the test substance applied by the subject falls within the target stratum. The weight of the aerosol canister in use will be periodically determined between application cycles at the discretion of the observer to provide an estimate of the amount of test substance applied, and a means of determining when the ME has been completed.

D. Sample Collection

1. At conclusion of the monitoring period, the subject will return to the private area with a researcher of the same sex. Exposure monitoring samples will be collected as described in SOP 8A to minimize cross contamination. The sequence of sample collection is outlined below. A more complete description of each sample collected follows.

   a. The air sampling tubes will be removed and saved for analysis.
   b. The researcher will rinse subjects' hands with a 50% IPA / 50% distilled water solution and save the rinse solution for analysis.
   c. The researcher will wipe the subject's face and neck with 50% IPA / 50% distilled water solution moistened pads, and save the pads for analysis.
   d. The researcher will remove shoes and socks, and help subjects take off the outer shirt and pants, and save the outer shirt and pants for analysis.
   e. The researcher will help subjects take off the long underwear, and save it for analysis.
   f. When all samples have been collected, subjects will dress again in their street clothes.
   g. The Principal Investigator or designee will check subjects' hands before they leave for redness or other signs of irritation. They will be paid for their time and inconvenience in cash, and be free to go

2. Inhalation Samples. Upon completion of the ME, the inhalation sample will be collected as described in SOP AEATF II-8D. The ending flow rate of the pump with OVS tube attached will be measured, the OVS tube will then be disconnected from the tubing, sealed at both ends, and placed in a pre-labeled "Ziploc®"-style bag. RespiCon™ filters will be collected in "Ziploc®"-style bags as described in SOP AEATF II-8H. Both OVS and

RespiCon™ filters samples will be placed in temporary frozen storage as soon after collection as possible. Samples will then be maintained in frozen storage until analyzed.

3. Hand Wash Samples. Hand exposure will be assessed by washing the subjects' hands with a 50% IPA / 50% distilled water solution according to a standardized washing procedure described in SOP AEATF II-8B. The high solubility of ADBAC in both IPA and water indicates that this combination of solvents will provide excellent recovery of hand residues. The AEATF has identified existing human hand wash removal efficiency data for a structurally similar quaternary ammonium chemical using relevant solvents, volumes and methods and these data indicate ~90% recovery (Boatwright 2006). The data indicate that a correction for removal efficiency from skin will not be necessary.

   A hand wash sample will be collected at the end of each ME. An interim hand wash sample will be collected if/each time a subject uses the toilet during an ME. Interim hand wash samples will be numbered sequentially. All samples will be analyzed separately and the results will be added to generate one hand wash number. Subjects will not be allowed to use tobacco, or eat, but they may drink without collection of a hand wash sample.

   All hand wash samples will be placed in pre-labeled containers and placed in temporary frozen storage as soon after collection as possible. Samples will then be maintained in frozen storage until analyzed.

4. Face/Neck Wipe Samples. Face/neck exposure will be measured by wiping the exposed areas with two gauze pads that have each been wetted with a 50% IPA / 50% distilled water solution as described in the SOP AEATF II-8C. After the specified task is completed, a dermal face/neck wipe sample will be collected from each subject after the hand wash sample is collected and before removal of the whole body dosimeters. Face/neck wipe samples will be placed directly into pre-labeled glass jars. All glass jars will be placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed. Because the label requires use of protective eyewear, concern was expressed that exposure to a consumer might be underestimated if they were using a product that did not require eye protection. The frontal surface area of the protective eyewear will be measured using xerography and conversion of the weight of a piece of paper and surface area to mass ratio of the paper. The exposure data for the face will be normalized to ng/cm^2 of facial area. For products not requiring eye protection, the frontal surface area and corresponding exposure may be added to the measured value for the face. Alternatively, this exercise may demonstrate that the exposure to the covered area of the face is so

low that it is negligible.

5. Outer and Inner Dosimeter Samples. The outer and inner layer of clothing (outer and inner dosimeter) will be removed with the assistance of a researcher (study team member) of the same sex and sectioned into upper and lower arms, front and back torso, and upper and lower legs per SOP AEATF II-8A. The sections will be individually placed in pre-labeled glass jars and placed into temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

Research personnel will wear disposable gloves when handling personal protective equipment (PPE) and exposure samples. Gloves will be changed after handling PPE, and between collection of each sample type. Plastic or paper sheeting will be used on seating, counter and floor surfaces at conclusion of each monitoring period to minimize transfer of any residues to clean surfaces. The dressing area will be cleaned with cleaning agents appropriate for the study between subjects. Cleaning the same surfaces with antimicrobials each day is common in facilities such as hospitals, so the surfaces will not be wiped with clean water between subjects, unless the surface treated (sprayed) is a food contact surface, in which case research personnel will perform a potable water rinse and wipe after the subject has left the area.

E. Exposure Observations

Volunteers will be observed throughout the exposure monitoring period in accordance with SOP AEATF II-10C. All activities during the monitoring period, especially specific occurrences that may affect exposure will be documented. While research staff (or personnel) will be instructed by the Study Director to be minimally intrusive with subjects (participants) and to avoid interfering with or influencing their work activities, documenting behavior that may be relevant to the magnitude of potential exposure requires observation of the subjects. For example, activities such as brushing against previously sprayed surfaces, over-spraying one's arm/hand, spraying near air exhaust vents, spraying surfaces above the head, walking into the spray, or standing in the shower enclosure while spraying all constitute examples of increased exposure potential that require careful observation.

Subjects will apply the test substance in application cycles, each lasting 4 to 8 minutes. Each cycle will consist of test substance application to appropriate surfaces within a specific room or area (e.g., bathroom or food preparation area). Observations of each ME will include a description of each application cycle.

The time spent actually applying (spraying) the test substance will be documented for each application cycle of each ME. The amount of test substance applied will be monitored by periodic weighing of the canister(s) in use during an ME. Records of periodic weights of specific canisters and estimated total test substance applied will be documented in observation notes. The observer will identify and describe the surfaces treated, and estimate the surface area treated in each application cycle. Surface area estimates may be based on inspection/measurement following the ME, or estimates of anticipated ME application areas prepared prior to exposure monitoring.

Observations will include detailed time logs adequate to allow the exposure period to be calculated as either the total time or the time actually spent applying (spraying) the test substance (e.g., excluding time between application cycles).

Work activities will be appropriately documented in the observation notes and a detailed time log maintained for all activities. A photographic record (digital photography and videography) will be taken of representative study-related activities during exposure monitoring, with care taken by research personnel to avoid interfering with or influencing subjects work activities. The study subjects will not be photographed at any time while changing into or out of the dosimetry clothing. Photos in the final report will not show faces or identifying marks such as tattoos to preserve anonymity of participants.

F. Environmental Monitoring

Air temperature and relative humidity of the work area for the duration of exposure monitoring will be documented with automated instrumentation logging and recording at intervals appropriate for the duration of the work period per SOP AEATF II-10C. Environmental monitoring equipment will be calibrated or standardized according to SOPs. HVAC and room volume will be described in detail and documented in study field notes, and it will be noted for each room sprayed whether the HVAC and/or vent fans were on at the time of application.

G. Field Study Personnel

One researcher will be assigned to each subject, and will remain in contact with that subject throughout the study. Study research personnel will attempt to minimize any unnecessary interaction with and intrusion on the study subjects. The study team will be comprised of a sufficient number of people to conduct the following activities:

1. Assist 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.
2. Calibrate air-sampling pumps and record the begin and end flow rates.
3. Observe and record all work practices and record site and treatment details.
4. Take a photographic record of representative study-related activities that may be useful in study interpretation.
5. Observe and document operation and representative output of application equipment.
6. Prepare field fortification samples.
7. Monitor temperature, humidity, room dimensions and whether vent fans and/or HVAC were on or off.
8. Determine total weight of test substance applied and the estimated surface area covered.

H. Field Recovery Evaluation

Full details regarding field recovery evaluation procedures for all sampling media are given in the most recent version of the SOPs of the AEATF II-8E. The SOP instructions for "spiking" will be followed.

Sample matrix fortifications designed to assess the stability of the active ingredient under field, storage and transit conditions in or on the sampling materials (inner and outer dosimeters, hand wash solutions, face/neck wipes, and air sampling matrices) will take place on each day of the study. Field fortification solutions of the formulated product diluted in water will be prepared at the appropriate concentrations. The fortification solutions will be taken to the field site and to the study team for field recovery evaluation on all matrices except OVS tubes. The OVS tubes will be pre-spiked with the formulation at the analytical laboratory and kept frozen until their use in the field.

Storage conditions of the diluted formulated product used for fortifications, and of the fortified OVS tubes, will be specified by the analytical laboratory and the actual storage details will be recorded in the study file. Any unused vials or unused fortified OVS tubes will be returned to the analytical laboratory.

With the exception of OVS tubes and Respicon™ fiberglass filters, a predetermined amount of the fortification solution will be applied to the different matrices using pipettes or syringes to deliver the correct fortification levels listed in the table below. Field fortifications will be conducted at the following levels during the study.

Matrix	Fortification Level
Air Sampling Tubes	10 ng/sample and 2.0 µg/sample
Hand Washes	2.0 and 400 ng/mL
Face/Neck Wipes	50 ng/sample and 10 µg/sample
Inner Dosimeter Section	3.0 µg/sample and 1.0 mg/sample
Outer Dosimeter Section	3.0 µg/sample and 1.0 mg/sample
Respicon Fiberglass Filters	20 ng/filter and 2.0 µg/filter

On each study day when field fortifications are conducted, samples of each matrix will be fortified at the two levels shown above. The levels are based on expected exposure levels for the spraying tasks being monitored on that day.

For each matrix/level combination used during the study, three samples (i.e., triplicates) of that matrix will be fortified and analyzed.

After fortification, the inner and outer dosimeters and OVS tubes will be exposed to ambient conditions (i.e., weathered) for the longest expected exposure monitoring period in a location away from possible contamination. The weathered samples are typically put out before the worker exposure monitoring commences, and are gathered after the monitoring interval stops, and the time is always recorded. Outer and inner dosimeters will be left uncovered per EPA suggestion. An air sampling system will be set up in the same manner as that of the workers, attached to the fortified OVS tubes in the field, and the pumps will be run during weathering.

Hand wash and face/neck wipe samples will be fortified and immediately placed in frozen storage without exposure to ambient conditions.

In addition, duplicate samples of the inner and outer dosimeters fortified in the field at the highest level, duplicate OVS tubes, and RespiCon™ filters fortified in the laboratory at the highest fortification level, will be processed for immediate frozen storage. Segments of inner dosimeter representing any body area may be used for fortification samples. These spikes will be analyzed only if deemed necessary by the Principal Investigator, for example to help determine the cause of unusually low field fortification recovery results.

Finally, two untreated control samples of each matrix will be processed similarly 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 experimental exposure samples.

11. SAMPLE IDENTIFICATION, SHIPPING AND STORAGE

A. Sample Identification

Samples will be identified and tracked by unique sample numbers assigned by GPL consistent with SOP AEATF II-8F. For example for the identification number AEA04-AS-01-ID-LA:

AEA04 = Task Force Study Number
AS = Aerosol Worker Sample
01 = Subject 1
ID = Inner Dosimeter
LA = Lower Arm
Additional designations are as follows:
OD = Outer Dosimeter
AR = Air Sampling Tube
RES-01 = RespiCon™ Filter 100 µm
RES-02 = RespiCon™ Filter 10 µm
RES-03 = RespiCon™ Filter 2.5 µm
FW = Face and Neck Wipe
HW = Hand Wash

Sample identification numbers are appended to this protocol (Appendix J). During the analytical phase of the study, the laboratory may assign its own sample numbers as long as the initially assigned number is cross-referenced and included in the documentation of the sample.

B. Shipping

Samples will be transported from the exposure site to the analytical laboratory on dry ice by study personnel on the day of collection. A chain-of-custody record will be available for each sample.

C. Storage

All samples will be placed into frozen storage within 4 hours of collection. The samples will be stored in a freezer maintained at ≤ -15°C until analyzed.

12. ANALYTICAL PROCEDURES

Experimental exposure and laboratory recovery samples will be analyzed according to the analytical methods specified in Section 12.B. of this protocol. The methodology has been validated for use in the relevant matrices.

A. Reference Substance, Fortification Solution and Internal Standard

i. Reference Substance

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

Name:	Benzyldimethyltetradecylammonium Chloride
CAS Number:	[139-08-2]
Active Ingredient:	C14 ADBAC
Lot Number:	442531/1
Purity:	99.5%
Date Received:	03/21/05
Expiration Date:	Not assigned

The Principal Investigator or an authorized representative will obtain analytical standard from the AEATF II. 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, AEATF II 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.

Purity analysis (content of active ingredient in the reference substance) will be available for each lot of reference substance used in the study. Documentation of purity will be retained in the study raw data file. The analytical standard will be stored under the recommended conditions.

ii. Fortification Solution

The fortification solution for this study is the formulated product used to prepare the aerosol canisters, but without the propellant.

Name:	BTC-885
CAS Numbers:	68424-85-1 7173-51-5 32426-11-2 5538-94-3
Active Ingredients:	20% n-Alkyl (C12 40%, C14 50%, C16 10%) dimethyl benzyl ammonium chloride 7.5% Didecyl dimethyl ammonium chloride 15% Octyl decyl dimethyl ammonium chloride 7.5% Dioctyl dimethyl ammonium chloride

The formulated product will be obtained from the Clorox Company. Receipt of the formulated product will be documented, including label identification, date of receipt and the amount received. The formulated product will be used to prepare the stock solution, and the spiking solutions will be prepared by serially diluting the stock solution. The preparation of all stock solutions will be documented. The concentration of C14 ADBAC in the spiking solutions will be determined prior to fortifying field samples. The formulated product will be stored under the recommended storage conditions.

iii. Internal Standard

The internal standard, deuterated C14 ADBAC was supplied by Chemalong Laboratories (Lemont, IL).

Name:	Benzyl-2,3,4,5,6-d_5-dimethyl-tetradecylammonium chloride
CAS Number:	Not Applicable
Active Ingredient:	C14 ADBAC
Lot No.:	CA079202
Purity:	>95%
Date Received:	9/8/05
Expiration Date:	NA

The above substance will be used for the preparation of the internal standard solution. A copy of the Certificate of Analysis of the internal standard will be kept in the archives at GPL. The internal standard will be stored at room temperature.

B. Analytical Method

The analysis of C14 ADBAC in all matrices will be conducted at Golden Pacific Laboratories using HPLC/MS/MS. The HPLC/MS/MS methods have been validated by GPL and are extremely sensitive and selective, thus minimizing subjects' exposure by allowing for very low detection limits. The limit of quantification (LOQ) for air sampling tubes and Respicon filters, hand washes, and face/neck wipes are 10 ng/sample, 2.0 ng/mL and 50 ng/sample respectively. The LOQ for inner and outer dosimeters are 3.0 µg/sample. The method (GPL-MTH-059) includes the use of deuterated C14 ADBAC internal standard to increase accuracy and minimize suppression problems. The validated methods will be followed as rigidly as possible. No changes are permitted without prior approval of the Principal Investigator. All data will be measured against a standard curve (five point minimum, one of which will be at 50-70% of the LOQ concentration) that brackets the levels of the matrix spikes. A solvent blank will be injected prior to injecting the analytical standards for each run.

Each analytical set will include two laboratory fortified samples, a solvent blank and a control. The fortification levels will bracket the expected levels in the field sample.

The following GPL validated analytical method will be used:

GPL Analytical Method GPL-MTH-059 entitled, "Analytical Method for the Determination of C14 Alkyl Dimethyl Benzyl Ammonium Chloride (C14 ADBAC) in Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Air-Sampling Tubes, and Fiberglass Filters"; GPL, 2004) will be used.

All samples, except hand washes, and inner and outer dosimeters, will be extracted using 70% acetonitrile/30% water/0.016% formic acid, and an aliquot will be transferred to a chromatography vial and analyzed using HPLC/MS/MS. The inner and outer dosimeters will be extracted using 70% methanol/30% water/0.016% formic acid. An aliquot of the hand wash sample will be transferred to a chromatography vial and analyzed using HPLC/MS/MS. Samples may require dilution using 70% acetonitrile or methanol/30% water/0.016% formic acid, to quantitate.

The filter, plus front and rear sorbent sections of the OVS tubes, (along with the retainer ring and sorbent section separators) will be analyzed together as one unit. The RespiCon™ will be disassembled and the three filters (2.5, 10, and 100 µm) will be separated and transferred to separate vials for extraction and analysis.

The inner dosimeter sections will be analyzed in accordance with SOP AEATFII-8A, which states that when the outer dosimeter section is below the limit of quantification (<LOQ) the corresponding inner dosimeter section will not be analyzed.

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

C. Storage Stability

A storage stability study to determine the stability of ADBAC on the various matrices under freezer storage conditions is being conducted (GPL, 2009; ongoing). ADBAC was shown to be stable for 6 months on all matrices under freezer storage.

D. Sample Quantification

Chromatographic quantification (using HPLC/MS/MS) will be achieved using an internal standard and a standard curve obtained from peak areas of injections of several concentrations of standards. The standard curve will be a least square fit unless otherwise approved by the AEATF II. Means and standard deviations (arithmetic or geometric), and coefficients of variation may be calculated on the data generated.

E. Data Analysis

The AEATF II will not statistically analyze the monitoring data in order to characterize exposure or investigate the relationship between exposure and other factors (e.g., room size, level of residual organic matter, environmental conditions including temperature, humidity, air turnover rate, etc.) However, regulators and other users of the constructed database (BHED) may choose to conduct such analyses. The extent of AEATF II's data analyses will be limited to the statistical characterization of data adequacy for inclusion in BHED scenario monographs. Two specific types of analyses will be performed (these analyses are discussed in more detail in the AEATF II's Governing Document (AEATF II, 2008).

1. Evaluation of benchmark adequacy. A confidence interval based approach will be used to determine the realized relative accuracy for the arithmetic mean and 95th percentile of exposure normalized by amount of ai handled.
2. Cluster effects. The intraclass correlation for clusters (ICC) and its confidence interval will be estimated using a variance components model. In addition, the effects, if any, of ignoring clusters in the estimation of means and percentiles will be determined by

comparing the estimates of a no-cluster model to those of the random effects model.

13. STUDY RECORDS

A. Field Records

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

1. Test and reference substance lot numbers, receipt and storage location(s), use records;
2. Application equipment details;
3. Environmental conditions during each monitoring event;
4. Subjects' Self-Reporting Demographic Forms, Informed Consent Forms and photos or video showing facial features or distinguishing marks on the body maintained apart from other raw data in a secure archive marked confidential;
5. Site location maps, including building floor plans or sketches and plans or sketches of the treatment rooms or areas with approximate dimensions. The location of the dressing area and sample collection areas in relation to treatment areas will be noted.;
6. The duration of each application cycle, the duration of each ME, total amount of test substance applied, and an estimate of the surface area treated in each ME.;
7. Dermal exposure sampling information;
8. Inhalation exposure sampling information, including pump identification, calibration, flow rates and times of sampling;
9. Test and reference substance, and sample storage temperature records;
10. Observations on work practices; including photographs and videography (if any of these include faces or other identifiers of subjects, they will be stored separately and securely along with other records identifying subjects);
11. Sample information (including inventory, chain of custody);
12. Resume or curriculum vitae of each study team member participating in the study, including the Spanish-speaking team members.

Field raw data will be recorded directly into a raw data file customized for use in the study. All data generated in this study will be kept in secure

files bearing the study number until transferred to a permanent location selected by the Sponsor. Study subject personal information will be kept in a separate location and will be marked confidential.

B. 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 AEATF II 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. Communications logs or records.

C. Communication with IRB

Prior to conducting studies involving human subjects, written approval from an IRB will be obtained by the Study Director/Principal Investigator. The package of information that will be submitted to the IRB is composed of the Study Protocol, a copy of the product label (Appendix A), the Informed Consent Form (Appendix B), the Experimental Subject's Bill of Rights (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), test substance MSDS (Appendix E), as well as all recruiting materials, such as flyers (Appendix F), interview scripts (Appendix G), community notification flyer (Appendix H), and an executive summary of EPA's REDs for ADBAC and DDAC summarizing their risk assessment conclusions (Appendix I). Justification for Amount of Product Applied and Area Treated will be provided as a stand-alone document (AEATF, 2008a). Following submission of the package of information to the IRB for review, all correspondence with the IRB, including any requests for changes in the protocol, informed consent and recruitment materials will

be documented and saved. All correspondence with the IRB, all intermediate drafts as well as the final approved ICF will accompany the study protocol when it is submitted to the EPA for review, before initiation of the study. Following final review of the protocol by the EPA, any additional communication with the IRB will be submitted to the EPA with the final report.

Since this study will be conducted in the state of California, changes requested by California DPR will be implemented and will also be documented. The study will not be initiated prior to receiving review from the EPA and approval from California DPR.

All study-specific documents, including correspondence and changes in the protocol, and Informed Consent Form generated in the course of this study will be maintained in the raw data.

14. STUDY LOCATIONS

The analytical location for this study will be at 4720 W. Jennifer Ave., Suite 105, Fresno, CA. The field locations will be 3 commercial lodging facilities in Fresno County, California. The location of each facility will be recorded in the study files.

15. DATA HANDLING

A. Communication of Results

Results will be communicated from the Principal Investigator to the Sponsor's representative or designated AEATF II Study Monitors on a regular and timely schedule.

Following completion of the study, a simple summary of the study will be made in which the range of exposure (low to high clearly labeled) is shown on a single page. For individual participants requesting their results, an arrow will be drawn on the continuum indicating where the individual result fell compared to the group. A very short narrative will indicate what work task was measured, and clearly indicate that generally less exposure is desirable when handling any chemical.

B. Statistical Methods

Proposed calculations are limited to the calculations specified in Section 12.D. and 12.E.

16. QUALITY ASSURANCE

This study will be conducted according to FIFRA GLP Standards (40 CFR 160). The field site as well as the analytical facility will be inspected by the QAU. The QAU will report to the Golden Pacific Laboratory's Vice President (Robert Testman). The QAU will review the protocol prior to study initiation. Different phases of the field study and the exposure matrix analyses will be inspected. Field and analytical data generated will be audited as the study progresses. The final report will be audited for completeness and accuracy. Results of the audit will be transmitted to both the Principal Investigator and the Sponsor's Representative. QAU organization and responsibilities are summarized in SOPs AEATF II-5A – 5C; 5E – 5K.

17. SAMPLE RETENTION

All sample extracts and analytical standards will be retained until the Study Director and Sponsor's Representative determine they are no longer useful. These materials are the property of the AEATF II and will be stored or disposed of in a safe and lawful manner by the appropriate authorized personnel with the approval of AEATF II.

18. FINAL STUDY REPORT

One report will be written summarizing the entire study. A final report will be prepared by the Study Director following procedures in SOP AEATF II 4A. The original signed copy of the final study report will be maintained at Golden Pacific Laboratories, LLC until the Sponsor requests that the report be transferred to another facility.

The report must contain, but is not limited to containing the following:

1. Identification of the location of the study, and the general environmental conditions during the exposure monitoring period(s).
2. A record of the application, including a description of the subjects and their activities.
3. A summary of subject observations identifying any specific occurrences that may contribute to unusual subject exposure.
4. A detailed summary of the amount of test substance applied by each subject.
5. A detailed summary of the length of time each subject was monitored.
6. A complete description of collection, handling and storage of field samples.
7. Results of analysis.
8. A detailed description of the methods.

9. Example calculations.
10. A summary of the recovery data.
11. Representative chromatograms of control, treated, fortified samples and calibration standards.
12. A typical standard curve.
13. Statistical analysis plan for the data generated.
14. The signed protocol, including all amendments and deviations.
15. The signed study report in 86-5 format.
16. All correspondence between the IRB and Principal Investigator, including information sent to the IRB to support the protocol.
17. A copy of the IRB approval documentation and a copy of the approved Informed Consent Form.
18. Minutes of IRB meetings, showing attendance and vote.
19. Any adverse findings and the nature and magnitude of every event.
20. All correspondence with Cal DPR regarding Section 6710.

19. PROTOCOL CHANGES

Protocol changes (amendments and deviations) shall be reported to the IIRB, Inc. in writing by letter, fax or email. The Principal Investigator shall follow written instructions provided by the IIRB, Inc. for prompt reporting to the IIRB, Inc., appropriate institutional officials, and the EPA of unanticipated problems involving risks to human subjects or others. The Principal Investigator shall also follow the protocol change notification and approval policies, if any, of all other agencies or boards whose notification and prior approval of the study was required.

A. Amendments

Proposed changes (amendments) deemed necessary to eliminate apparent immediate hazards to the human subjects may be implemented without prior IIRB, Inc. approval. All other amendments must be reviewed and approved by the IIRB, Inc. prior to implementation. Approval will be granted in accordance with IIRB, Inc. policy and procedures, and may be granted by telephone provided it is documented in writing (e.g., email) in the study raw data. The IIRB, Inc. may provide expedited review of minor changes as defined by 40 CFR Part 26.1110 at its discretion.

B. Deviations

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by the IIRB, Inc. prior to implementation. Deviations will be reported in writing by letter, fax or email as soon as possible following the change.

20. PERSONNEL

A. Study Director (Principal Investigator)

Sami Selim, Ph.D.
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Telephone: 559-275-9091
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E-mail: sselim@gplabs.com

B. Quality Assurance Unit

Anantdeep K. Kang
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Fresno, California 93722
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*A.K. Kang will report directly to GPL Vice President, i.e., independent of any involvement of the Study Director or other investigators.

C. Field Personnel

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Victoria Standart
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Noé Galván
Field Research Associate (English and Spanish)
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D. Analytical Coordinator

Megan Boatwright
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Telephone: 559-275-9091

21. PROTOCOL APPROVALS

Has Shah, Ph.D. Date
Sponsor's Representative

Sami Selim, Ph.D. Date
Study Director/ Principal Investigator
Golden Pacific Laboratories, LLC

Joel Panara Date
Field Coordinator (English)
Eurofins | Grayson

Megan T. Boatwright Date
Analytical Coordinator
Golden Pacific Laboratories, LLC

Anantdeep K. Kang Date
Quality Assurance
Golden Pacific Laboratories, LLC

22. REFERENCES

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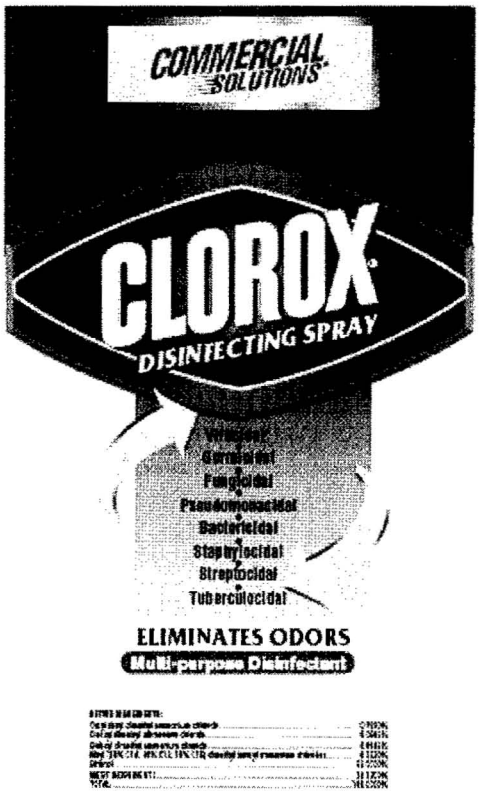
APPENDIX A: LABEL FOR PRODUCT TO BE USED IN STUDY

July 13, 2009

EPA Reg. No. 67619-23 Commercial Solutions Clorox Disinfecting Spray, Page 1 of 2

Artwork shown at approximately 110% of actual size



KEEP OUT OF REACH OF CHILDREN

WARNING: See back panel for first aid.

NET WT. 19 OZ.

NO CFCs

Federal Regulations Prohibit CFC Propellants in Aerosols

July 13, 2009

Artwork shown at approximately 110% of actual size

- **This product meets AOAC Germicidal Spray Product Test efficacy standards for hospital disinfectants.**
- **Kills and prevents the growth of mold.**
- **Deodorizes by killing the germs that cause odors.**
- **Does not contain bleach.**

Use on hard, nonporous surfaces in:
• Restrooms • Hotels • Motels • Offices • Military Installations • Schools • Day Care Centers • Nurseries • Dorms • Shelters • Laboratories • Health Clubs • School Buses • Ambulances • Bowling Alleys • Play Areas • Convenience Stores • Locker Room Facilities • Storage Areas • Kennels

For use on:
• Garbage Cans • Waste Baskets • Diaper Pails • Diaper Changing Tables • Toilet Seats • Faucets • Doorknobs • Telephones • Showers • Plastic Shower Curtains • Counter Tops • Desks • Metal Work Benches • Handles

Use on non-critical surfaces in:
Hospitals • Patient Rooms • Nursing Homes • Medical Clinics • Veterinary Offices.

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS & DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eye wear (safety glasses). Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. If skin contact with product occurs, wash thoroughly with soap and water, especially prior to food handling and preparation.

FIRST AID: IF IN EYES: Hold eyelids 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 the eye. 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. Questions? Call 1-800-787-7225.

PHYSICAL HAZARDS: Flammable. Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° Fahrenheit may cause bursting.

STORAGE/DISPOSAL: Pesticide Storage and Disposal: Do not contaminate water, food, or feed by storage and disposal. Store at temperatures below 130° Fahrenheit. **Container Disposal:** Do not puncture or incinerate. Do not reuse empty container. Recycle empty container or discard in trash.

• This can is made of an average of 25% recycled steel (10% post-consumer) • Recyclable • Contains no phosphorus • Avoid use on polished wood, painted surfaces or acrylic plastics.

Questions? Comments?
Call toll-free
1-888-787-7225

Mid Atl Clorox Professional Products Company, Oakland, CA 94612
© 1997
The Clorox Company
Made in USA or Argentina
EPA Reg. No. 67619-3
EPA Est. No. 11525-AL-1
6613-SAC-041
See note on bottom of can.
Patent Pending

Disinfects against the following bacteria, viruses* and mold:

- Campylobacter jejuni
- Corynebacterium diphtheriae
- Enterobacter aerogenes
- Enterococcus faecalis (Vancomycin resistant)
- Escherichia coli 0157:H7
- Klebsiella pneumoniae
- Listeria monocytogenes
- Mycobacterium bovis (Tuberculosis)
- Mycobacterium smegmatis
- Proteus mirabilis
- Proteus vulgaris
- Pseudomonas aeruginosa
- Pseudomonas cepacia (Burkholderia cepacia)
- Pseudomonas putida
- Salmonella choleraesuis
- Salmonella choleraesuis paratyphi B1 (schottmuelleri)
- Salmonella choleraesuis serotype enteritidis
- Serratia marcescens
- Shigella dysenteriae
- Staphylococcus aureus
- Staphylococcus aureus (Methicillin & Gentamicin resistant)
- Streptococcus pyogenes
- *Adenovirus type 2
- *Cytomegalovirus
- *Echovirus
- *Hepatitis A virus
- *Herpes simplex virus type 1
- *Herpes simplex virus 2
- *Human immunodeficiency Virus Type 1 (HIV-1).
- *Influenza A2 virus (Hong Kong) (Flu virus)
- *Influenza virus type B
- *Polio virus
- *Respiratory syncytial virus (leading cause of fever (respiratory infection in children)
- *Rhinovirus (cold virus)
- *Rhinovirus 39
- *Rotavirus (leading cause of infectious diarrhea in children)
- *Vaccinia virus
- Alternaria alternata
- Candida albicans
- Cladosporium herbarum
- Trichophyton mentagrophytes (Athlete's foot fungus)

Sanitizes in 30 seconds against: Klebsiella pneumoniae, Staphylococcus aureus.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For use on non-food contact surfaces only. A potable water rinse is required for surfaces which may be in direct contact with food. **This product must not result in the direct or indirect contamination of food products.**

SPECIFIC INSTRUCTIONS FOR "HIV-1": This product kills "HIV-1 on precleaned surfaces/objects previously soiled with blood/body fluids in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluid) can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 ("HIV-1) (associated with AIDS).

Special Instructions for Using this Product to Clean and Decontaminate Against "HIV-1 on Surfaces/Objects Soiled with Blood/Body Fluids.

Personal Protection: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks, and eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and other objects before applying this product.

Contact Time: Spray 6 to 10 inches from precleaned surface for 3-4 seconds until thoroughly wet. Surface must remain wet for 10 minutes before wiping or air drying.

Disposal of Infectious Materials: Use disposable latex gloves, gowns, masks, and eye coverings. Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

To Disinfect: Spray 6 to 10 inches from precleaned surface for 3-4 seconds until thoroughly wet. Surface must remain wet for 10 minutes before wiping.

To Sanitize Non-food Contact Surfaces: Spray 6-10 inches from precleaned surface for 3-4 seconds or until thoroughly wet. Surface must remain wet for 30 seconds before air drying.

To Control and Prevent the Growth of Mold and Mildew: Spray precleaned surface until thoroughly wet. Surface must remain wet for 10 minutes before wiping or air drying. Respray product as necessary for ongoing control.

To Deodorize: Spray on precleaned surfaces as needed.

R0401-2

Artcode # 63987.117 rev1

INSERT SPANISH TRANSLATION OF LABEL

July 13, 2009

July 13, 2009

APPENDIX B: INFORMED CONSENT FORM

July 13, 2009

INFORMED CONSENT FORM
(5/23/09)

Title: (Protocol No. 070270) A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using a Pressurized Aerosol Can for Indoor Surface Disinfecting

Principal Investigator:

Sami Selim, Ph.D.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Field Coordinators:

Joel Panara (English)
Field Coordinator
Eurofins | Grayson
211 N. Main Street
Creedmoor, NC 27522
Phone: 919-528-5500

Victoria Standart (English and Spanish)
Field Research Associate
Eurofins | Grayson
211 N. Main Street
Creedmoor, NC 27522
Phone: 919-528-5510

Noé Galván, Ph.D. (English and Spanish)
Field Research Associate
Product Safety Scientist
PS&RC, Global Stewardship
Clorox Services Co.
7200 Johnson Drive
Pleasanton, CA 94588
Phone: 925-425-6708

Field Locations:

(Subject Informed Consent Interview Location)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Suite 105
Fresno, CA 93722

(Study Site Location)
3 Sites in Fresno County, CA

July 13, 2009

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 559-824-1535 (Sami Selim)

We're asking you to think about being in a research study because you have experience doing janitorial work. Your participation is voluntary. This Informed Consent Form explains the study.

You may take a copy of this form home to think about and discuss with friends or family before you decide whether you want to be in the study. If you have any questions, or if you do not understand anything in this form, please ask one of us to explain. If you would prefer to talk in Spanish, please ask. We can explain the study to you in English or Spanish.

Purpose of this Study

Golden Pacific Laboratories is doing this research to find out how much spray may reach your skin when you use a cleaning product in a pressurized aerosol can. We will measure how much of the spray gets on the clothing you wear during the study, and on your hands, face and neck, while you clean indoor surfaces like bathrooms and kitchens. We will also measure how much of the spray is in the air you breathe during the study. An important purpose of this study is to collect information that will be provided to the U.S. Environmental Protection Agency or EPA. The EPA will use this information to evaluate the levels of exposure to the aerosol spray product in this study and other spray products that are similar to it.

The spray in this study will be Clorox Commercial Solutions® Clorox® Disinfecting Spray. This is a commercial cleaning product used to clean hard surfaces such as bathroom tiles and fixtures and kitchen cabinets and counters. This product is used in offices and buildings such as hospitals, schools, and hotels. It contains chemicals called quaternary ammonium salts, which kill germs.

A group of companies that make germ-killing cleaning products is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products kill germs on indoor surfaces, and are registered by the US Environmental Protection Agency (EPA) as pesticides.

Sami Selim, Ph.D., of Golden Pacific Laboratories is the Principal Investigator in charge of the study. Victoria Standart of Eurofins | Grayson is his main Spanish-speaking assistant.

Test Product

The material being tested in this study is Clorox Disinfecting Spray. This is a commercial cleaning product used to disinfect and deodorize hard, non-porous surfaces such as bathrooms (walls, showers, toilets, etc.), kitchens (cabinets, faucets, etc.). This product is recommended for use in offices and commercial and institutional buildings, such as hospitals, schools, and hotels. Clorox Disinfecting Spray contains chemicals known as quaternary ammonium salts which kill germs. You will be given a copy of the product label, and if you want it you will be provided the Material Safety Data Sheet or "MSDS" for this product.

Subject Selection

To be in this study you must be healthy, ages of 18 and older, and you must be able to read and speak English or Spanish. You will need to prove your age with a government-issued photo ID—a driver's license or passport. You must have experience doing janitorial work, and must want to be in this study. You must be willing to sign a consent form, and to provide some additional personal information, and to follow the directions of the investigators.

You will not be able to participate in this research if you are related by blood or marriage to employees of Golden Pacific Laboratories, Eurofins | Grayson or a cleaning product manufacturer; if you are pregnant or breast-feeding; if you've had allergic reactions to soap, rubbing alcohol, or other cleaning products; if you have sores on your skin; if you are taking medicines that might react with the test product; or if you have heart or breathing problems.

Eighteen to 24 people like you will be in this study. We will sign up a few more people than we need, in case anyone can't participate on the day of the test.

We'll do the study in a vacant building (or in unoccupied rooms of non-vacant buildings) here in Fresno County. You can be in the study only once, but if you are the alternate on one day and are not selected, you may be able to be in the study on another day.

Study Enrollment

Before the day of the study you need to come to the offices of Golden Pacific Laboratories at 4720 W. Jennifer Ave., Suite 105, in Fresno. This visit will take about an hour. You'll meet with the Principal Investigator, Dr. Selim, or if you prefer, with a researcher who speaks Spanish. They will tell you more about what to expect during the study and what will be expected of you. They will also answer any questions you have about the study.

We'll ask you about your work and about your general health. We'll ask for your name and age, and about your experience using spray products for cleaning or pest control. If we decide you are eligible, and if you decide you want to be in the study, we will ask

you to sign this Informed Consent Form. We will then measure your height and weight, and we will ask you for your clothing sizes.

If we enroll you in the study we will ask you to come to the study site on a certain day and time. We will call you the day before to remind you and to make sure you still want to be in the study. We'll also ask you to be sure to take a shower or a bath before coming to the study site.

Study Procedures

We will do the testing at a vacant building (or unoccupied rooms in non-vacant buildings) in Fresno County, and it will take 3 or 4 hours on one day. After you arrive you will change into special clothing for the test and get fitted with two small pumps to sample the air you breathe. Then we'll ask you to spray walls, counters, and fixtures until the surfaces are visibly wet in bathrooms or kitchens. You will use the aerosol for hard surfaces as you normally would with horizontal spraying moving upward and downward from the starting point to hard surfaces such as laminate, tile, porcelain, glass, and metal. You will be asked to use one to four cans for spraying in multiple rooms, taking breaks if you need to in between the rooms. This may involve up to 30 minutes of actual spraying time. After that you'll give the special clothing back to us, change back into your own clothes, get paid, and go your way.

Here's exactly what will happen.

1. On the day of the study you will go to the study location at the time you've been told, and meet the research team.

2. Because it's important that you NOT be in this study if you are pregnant, on the day of the test each female volunteer will go to a private area and will be given a pregnancy test kit like the ones you can buy at the drug store. A female researcher will be able to explain how to use it and answer questions. After you give yourself the test we'll ask you if you want to stay in the study. If you decide not to, you won't be asked why, and the results of the test will not be recorded. You'll be paid $100 for coming to the test site, and then you'll be free to go. If you want to stay in the study, a trained female researcher will double-check the results with you. No-one but you and she will see the results, but we will make a note that the test was performed.

3. Dr. Selim and the research team will review with you and the other participants what will happen, and you'll have another chance to ask questions. We will remind you that you may change your mind about being in the study at any time before or after the study begins. All you need to do is tell us you've changed your mind. There will be no penalty of any kind to you if you decide to withdraw from the study.

4. Someone of your own sex will show you to a clean, private changing area and help you get ready for the study. We will ask you to take off your street clothes

down to your underwear. Then you will put on cotton long underwear (long johns), a long sleeved cotton shirt, and long cotton pants. We will provide all these clothes to you. We may need to trim the arms or legs of the long underwear so it doesn't stick out. You'll put your street clothes and valuables in a locked storage area, and keep the key with you.

5. We'll give you safety glasses to wear while you are using the spray.

6. Before the test begins you will wash your hands and face with Ivory soap and water, and dry them with paper towels. We will check your hands to make sure you don't have cuts, scrapes, or any conditions that might increase the risk of skin problems during testing.

7. We will attach two small air sampling pumps to a belt around your waist. If you don't have a belt, we will provide one for you to use. We will attach a small tube to your shirt collar and connect it to one of the pumps. We will attach a small air sampler to the other pump and position it in front of you with a small strap around your neck. Both of these pumps will sample the air you breathe while you are using the aerosol. Each pump is about the size of a portable radio. The tube is about the size of a pen, and the air sampler is about the size of a tennis ball.

8. We will give you a can of Clorox Disinfecting Spray. The label on the can says it can be sprayed on hard surfaces in bathrooms and kitchens. The label on the can says to spray the surface until thoroughly wet. We will tell you that if the bathroom or kitchen you are cleaning has a fan, you may turn it on during cleaning if that is what you would normally do. We will ask if you have any questions.

9. We will take you to a bathroom or kitchen area where you will begin your work, and show you the other areas to work in after you finish that room. We will turn on your air pumps and ask you to put on your safety glasses. We will ask you to enter the bathroom or kitchen, shake the spray can for about 10 seconds, and begin spraying surfaces as you normally do on your job. One of us will watch you as you work, keeping track of how long you work and how much surface you spray. We may also take pictures or video to show what happened in the study, but those pictures will not show faces or tattoos in the final report. **If you still do not want to have your picture taken, you should not participate in this study.**

10. We will ask you to apply at least one can of spray, and maybe as many as 4 cans. You will work in as many rooms as it takes to use up the assigned number of cans. We will sometimes ask you to stop between rooms and place your spray can on a scale so we can weigh it to see how much has been used. When you empty one can you'll be given a fresh one. You can also ask for a fresh can at any time. You may take a short break at any time you want, just like you would do at work. You won't be able to smoke or eat during the test, but you can have a

cold drink during the break. If you need to use the toilet, one of the researchers will rinse your hands before you go to collect any spray that may be on them.

11. When you finish spraying, a researcher of your own sex will take you back to the changing area and collect samples:

    a. The researcher will remove the air sampling pumps and equipment;.

    b. The researcher will rinse your hands with rubbing alcohol and water and save the rinse water;

    c. The researcher will wipe your face and neck with a damp pad to collect any of the spray that might be on your skin;

    d. The researcher will help you remove your shoes and socks;

    e. The research will help you take off your outer shirt and pants and will save them for analysis;

    f. The researcher will help you take off the long underwear, and will save it for analysis.

When we've collected all these samples, you will dress again in your street clothes. We'll check your hands before you leave for redness or other signs of irritation. We will pay you $100 in cash and you will be free to go.

Risks

If you are in this study you would be exposed to several kinds of risks:

1. Risk of a reaction to the aerosol spray. Direct contact with the product can cause temporary eye redness, pain and swelling or skin irritation, and breathing it can cause coughing and irritate your throat. You will wear safety glasses to keep the spray out of your eyes, and long sleeves and pants to keep it off your skin. You might also have an allergic reaction to the spray, or it might interact with medicines you are taking. If you have had a reaction to a cleaning product before, or if you are taking medicine, be sure to tell us. If you notice any redness or itching, or if you think you may have gotten some of the spray in your eye, stop spraying right away and tell a researcher.

2. Risk of discomfort. The air pumps on your belt and the air hoses used to sample the air you breathe may be uncomfortable. Wearing two layers of clothing may also be uncomfortable.

3. Risk of stinging from alcohol wash and wipes. The diluted rubbing alcohol used to rinse your hands and wipe your face and neck may sting, if you have any cuts or abrasions on your hands or face.

4. Risk from heat. Because you'll be wearing an extra layer of clothing you might get too hot. We will monitor the temperature and humidity during the test, and will stop the study if it gets too hot to be safe. If you feel faint or too hot, or are sweating a lot, stop spraying right away and tell a member of the research team.

5. Risk of embarrassment. You may find it embarrassing to have a researcher with you while you change clothes. This is necessary to make sure the special underwear fits properly, and that it and the outer clothing don't get dirty when the test is over. The researcher who helps you will be of your own sex, and will be the only other person with you. You will wear your own underwear all the time.

6. If you are female, you might be surprised to learn on the day of the research that you are pregnant. No-one but you will know if the test shows that you're pregnant, and the results will not be recorded.

Unknown/Unforeseeable Risks

Participating in this study may pose other risks to you that we don't know about or can't predict. If we learn anything new that might influence your decision to participate, we'll share it with you right away.

Research-Related Injuries

If you are hurt while you are in this study, a nearby medical facility that knows about this study will provide care. If necessary, we will take you there. We will pay for needed medical treatment that is not paid for by your own insurance or by someone else. To find out more, or if you think you may have been hurt during the study, call Dr. Selim at Golden Pacific Laboratories (559 275-9091) from 9 am to 5 pm Monday through Friday.

You do not waive any of your legal rights by signing this form.

Alternatives to Participation

If you decide to be in this study it will be because you want to. There will be no direct benefit to you if you do decide to participate, and no harm to you if you decide not to. The choice is up to you.

Benefits

You will not benefit directly from being in this study. What we learn from this study will help make sure that cleaning products like Clorox Disinfecting Spray can be used safely. This may indirectly benefit you and others who do janitorial work. You may also

benefit if you ask for your own results from this study, so you can learn how much spray got on you compared to other workers doing the same job. The people who are paying for the study will also benefit from it, since they need to do this study to keep their cleaning products on the market.

Questions about this Study

If you have questions, you can ask them at any time—before, during, or after the study. Just ask Dr. Selim or any other member of the research team.

If you have any questions about your rights as a volunteer, or to report a problem in the study, please call Kim Lerner, Chair of the Independent Investigational Review Board, Inc., toll-free at 1-877-888-4472. You can reach her from 6am to 2pm Pacific time, Monday through Friday. The Independent Investigational Review Board has reviewed this study, and is charged with protecting the rights of you and the other volunteers. You can also find out more about your rights and role in research at the IIRB, Inc. website—www.iirb.com.

Costs and Payment

It will cost you nothing to participate in this study. At the end of the informed consent interview you will be paid $20 in cash for your time and trouble coming to our office. If you are selected for the study and come to the assigned study site, you will be paid $100 in cash when you are finished for the day, whether or not you are actually tested.

Confidentiality

We will give you a special ID number for this study, and we will record and report all data under that number. We will keep only one record linking your name to this ID number, and we will store it apart from other data, in a locked cabinet. We will not identify you by name or in any other way in study reports. Any pictures of you in a report of this study will not show your face.

We will restrict access to records of this study to only a few people. But the people who are paying for it, the government agencies who will review the reports, and the IIRB, Inc., that looks out for your safety may all review study records. Because of this we can't completely guarantee confidentiality.

Right to Withdraw

You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team. If you decide not to participate in this study or to withdraw from it, you will not be penalized in any way.

Removal from Study

Dr. Selim, the Principal Investigator in charge of this study, can remove you from this study even if you'd like to stay in it. He might remove you if, for example:

- He thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped because it gets too hot to continue safely, or for other reasons.

If you are removed from the study, or if the entire study is stopped, you will still be paid for your time and trouble.

Consent and Signature

I have read this Informed Consent Form and all my questions have been answered in a language I understand well. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this form. I'll get my own copy of this form with all signatures.

Date/Time: _____ _____
Subject's Signature

_____
Subject's Name (Print)

[*For Spanish language version of the IC document only, but in English*]
This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____
Spanish Speaking Researcher's Signature

_____
Spanish Speaker's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____

Sami Selim, Ph.D.
Principal Investigator, Golden Pacific Laboratories, LLC

INSERT SPANISH TRANSLATION OF INFORMED CONSENT FORM

July 13, 2009

July 13, 2009

July 13, 2009

July 13, 2009

July 13, 2009

July 13, 2009

July 13, 2009

APPENDIX C: EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

July 13, 2009

EXPERIMENTAL SUBJECT'S 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 the purpose of the study;
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 during the study;
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 alternatives to participating 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 status with my employer;
9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether I wish to participate in the study.

You may contact the *Independent Investigational Review Board, toll free at (877) 888-IIRB (4472) from 6 am to 2 pm Pacific Time*, if you have a question about your rights as a research subject.

If you have other questions, you should ask the Principal Investigator or Field Staff

Phone contacts:

Principal Investigator, Sami Selim (English): (559) 275-9091 from 8 am-5pm, Pacific Time

Field Staff: Joel Panara (English) at 800-870-0294, Ext 5500,Victoria Standart (English or Spanish) or Noé Galván (English or Spanish) at 800-870-0294 Ext 5510 from 8 am-5 pm, Pacific Time

INSERT SPANISH TRANSLATION OF EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

July 13, 2009

APPENDIX D: SUBJECT SELF-REPORTING DEMOGRAPHIC FORM

SUBJECT SELF-REPORTING DEMOGRAPHIC FORM

Volunteer Name _____

Street Address _____

City, State, Zip Code _____

Telephone number(s)_____

Current age _____ yrs Gender ☐ Male ☐ Female

Weight_____ lbs Height _____ ft_____ inches

Shirt size: ☐ Small ☐ Medium ☐ Large ☐X Large ☐XX Large ☐ XXX Large

Waist size: ☐ 24-28 in ☐ 28-32 in ☐ 32-36 in ☐ 36 - 40 in ☐ 40 - 44 in ☐ 44 – 50 in

Years experience using aerosol sprays _____

How often do you use aerosol sprays? _____per ☐ week ☐ month

Do odors from perfumes, of gasoline at the gas station or diesel trucks seem to bother you more than your friends?

☐Yes ☐ No

How would you describe your general health? ☐ Excellent ☐ Good ☐ Fair ☐ Poor
Comments _____

Check here if you would like to get your results from this study compared to the lowest, highest and middle of the group ☐ Yes ☐ No

My signature below indicates the information provided above is correct:

_____ _____
Volunteer's Signature Date

INSERT SPANISH TRANSLATION OF SUBJECT SELF-REPORTING DEMOGRAPHIC FORM

APPENDIX E: MATERIAL SAFETY DATA SHEET FOR CLOROX DISINFECTING SPRAY

July 13, 2009

Clorox Professional Products Company
1221 Broadway
Oakland, CA 94612
Tel. (510) 271-7000

Material Safety Data Sheet

I Product: CLOROX COMMERCIAL SOLUTIONS® CLOROX® DISINFECTING SPRAY

Description: FRAGRANCED AEROSOL

Other Designations	Distributor	Emergency Telephone Nos.
EPA Reg. No. 67619-3 Clorox Disinfecting Spray	Clorox Professional Products Company 1221 Broadway Oakland, CA 94612	For Medical Emergencies call: (800) 446-1014 For Transportation Emergencies Chemtrec (800) 424-9300

II Health Hazard Data

EYES: Will cause moderate, reversible eye irritation.
SKIN CONTACT: Will cause minor irritation after prolonged contact. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
INGESTION: Low toxicity if ingested. May cause minor irritation of the mouth. Ingestion of large quantities may result in ethanol intoxication.
INHALATION: Intentional misuse by concentrating and inhaling vapors may be harmful or fatal. Inhalation of high concentrations may cause irritation of the respiratory tract. Symptoms include headaches, dizziness, nausea, vomiting, and malaise.
MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: None known.
EMERGENCY FIRST AID PROCEDURES: EYES: Immediately flush eyes with plenty of water for at least 15 minutes. If irritation persists, call a physician. SKIN: Wash with plenty of soap and water. IF SWALLOWED: Drink a glass of water. Call a physician.

III Hazardous Ingredients

Ingredients	Concentration	Worker Exposure Limit
Ethanol CAS #64-17-5	60-80%	1000ppm TLV - TWA
Propane CAS #7409806 (propellant)	1-5%	1000ppm PEL - TWA
Isobutane CAS #75-28-3	5-10%	Not Established

None of the ingredients in this product are on the IARC, NTP or OSHA carcinogen lists.

TLV\TWA: Threshold Limit Value\Time Weighted Average.

PEL: Permissible Exposure Limit. Source: OSHA

IV Special Protection and Precautions

No special protection or precautions have been identified for using this product under directed consumer use conditions.

The following recommendations are given for production facilities and for other conditions and situations where there is increased potential for accidental, large-scale, or prolonged exposure:

Hygienic Practices: Wear safety glasses and protective gloves when handling product. Engineering Controls: Use explosion proof ventilation to minimize exposure to vapor or mist. Work Practices: Minimize skin contact and inhalation of vapor or mist.

V Transportation and Regulatory Data

U.S. DOT Hazard Class: ORM - D

U.S. DOT Proper Shipping Name: Consumer Commodity.

EPA - SARA Title III/CERCLA: Bulk product is regulated under sections 311/312. Packaged product is not reportable.

TSCA Status: All components of this product are on the TSCA inventory.

VI Spill Procedures/Waste Disposal

Steps to be taken in case material is released or spilled: Eliminate all sources of ignition. Ventilate area. Mop up excess. Flush off any remaining material with soapy water. Flush again. Respiratory Protection: If handling large industrial or warehouse spills, people should use NIOSH approved respiratory protection. Waste Disposal Method: Do not puncture or incinerate (burn) empty or full cans. Dispose of in accordance with state and local regulations for consumer products. Empty cans may be landfilled. Precautions to be taken in Handling and Storage: Do not store above 120°F. Do not puncture or burn. Keep aerosols from fire or sparks. Store in accordance with NFPA 30B for Level 2 Aerosols. Other Precautions: N/A

VII Reactivity Data

Stability: Stable

Conditions to Avoid: Temperatures over 120°F

Incompatibility/Materials to Avoid: Alkalis and acids

Hazardous Polymerization or Decomposition: None known

VIII Fire and Explosion Data

Flashpoint: Flashpoint of liquid is 66°F using a closed cup Herzog tester. Flame extension is between 16-18 inches with no flashback.
Fire Extinguishing Agents: All types.
Special Fire Fighting Procedures: N/A
Unusual Fire and Explosion Hazards: Alcohol flames may not be readily visible. Exposure to temperatures over 120°F (49°C) may cause bursting or venting. Keep containers cool. Use equipment or shielding to protect personnel from bursting containers.

IX Physical Data

pH (no propellant)	9.2
Viscosity (no propellant)	3.2 cps at 20°C
Density (no propellant)	0.86 g/ml at 25°
Appearance and Odor	Floral/Fruity odor

DATA SUPPLIED IS FOR USE ONLY IN CONNECTION WITH OCCUPATIONAL SAFETY AND HEALTH DATE PREPARED 2/05

July 13, 2009

INSERT SPANISH TRANSLATION OF MSDS

July 13, 2009

APPENDIX F: FLYER SOLICITING RESEARCH SUBJECTS

July 13, 2009

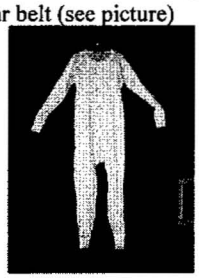
Research Study Volunteers

The Antimicrobial Exposure Assessment Task Force II (AEATF II), a group of companies that make antimicrobial cleaning products, is doing research to measure how much chemical gets on workers' skin and into the air they breathe when they use antimicrobial products. We are looking for experienced janitorial workers to spray surfaces in rooms and let us collect exposure data. Study participants will receive $100 for their inconvenience.

To volunteer you must be:	You are not qualified if you:
• At least 18 years old • Able to read and speak English or Spanish • In good health • Male or non pregnant, non-nursing female • Experienced and trained in using antimicrobial cleaning products • Live in Fresno County	• Are less than 18 years of age • Do not have a government-issued photo identification card • Read neither English nor Spanish • Are not in good health • Work for a cleaning product manufacturer • Are a pregnant or nursing female • Do not live in Fresno County

You will be asked to do the following:

- Let us monitor you as you do your work for a day using an aerosol can containing antimicrobial chemicals
- Sign a consent form before participating (in English or Spanish)
- Wear long underwear under cotton pants and shirt, which will be supplied to you (see pictures)
- Let us have the supplied clothes at the end of the day
- Let us wash your hands and wipe your face with rubbing alcohol (see picture)
- Wear two small air samplers on your belt (see picture)



You should also know that:

- Participation is completely voluntary
- You can withdraw from the study whenever you want
- Information from the study will be used by EPA to better understand worker exposure.

APPENDIX G: EMPLOYER CONTACT SCRIPT AND SUBJECT INVITATION TO PARTICIPATE SCRIPT

If you are interested, for additional information please contact:

Joel Panara (English)
800-870-0294, Ext 5500; or
Victoria Standart (English / Spanish)
800-870-0294, Ext 5510

July 13, 2009

EMPLOYER CONTACT SCRIPT and SUBJECT INVITATION TO PARTICIPATE SCRIPT

For English speaking employers -

Introduction

My name is [ ] and I work with .....

My company has been hired to do a study which measures how much cleaning product gets on the clothes and skin of janitors when cleaning surfaces using an aerosol cleaner

Does your company provide cleaning services to businesses in Fresno County?

[If yes, continue. If no, thank him/her and terminate call]

This study would be conducted outside normal working hours and does not involve your company or customers in any way. We would like to post a flyer at your place of business which mentions the study and asks anyone interested to contact us directly during non-working hours. Would you be willing to post a flyer for the study?

[If yes, continue. If no, thank him/her and terminate call]

We are holding two meetings to explain the study to managers of janitorial firms, and answer any questions they may have. The flyers will be distributed at these meetings. One is [date and location] and the other is [date and location]. Would you be able to attend either of these meetings?

[If yes, record their name and the meeting they will attend, thank them for their time, indicate you look forward to seeing them at the applicable meeting, and terminate the call]

[If no or not sure, ask if they would like to receive a copy of the recruiting flyer and have someone contact them to further discuss the study.]

[If yes, record their name, address, preferred method of flyer delivery, and best time to contact for follow-up.]

[If no, thank them for their time and terminate call.]

Subject Invitation to Participate Script

[Identify yourself and company affiliation, ask if they are calling about the aerosol study. If yes, ask how they found out about the study and document response. Ask the potential subject if he/she would like more information on the study. If yes, continue.]

We are conducting research to find out how much cleaning chemical may reach your skin when you use an aerosol can to clean bathrooms and kitchen areas. We will measure how much of the cleaning chemical gets on the clothing you wear during the study, on your hands, face and neck, and how much is in the air you breathe while you clean bathrooms.

The material being tested in this study is a product called CLOROX DISINFECTING SPRAY, a product used to clean hard surfaces like showers, toilets, counters, walls, and stainless steel.

The project itself will take about 3 to 4 hours on one day. During that time you will change into special clothing for the test and get fitted with a device to sample the air you breathe, then you'll be asked to apply liquid antimicrobial using a pressurized aerosol can to surfaces, including showers, toilets, counters and walls until they are wet with spray. You will be requested to apply one or more full cans, up to a total of 4 full cans, to surfaces in multiple rooms, as you would normally when using this type of product. As you empty a can, the empty can will be collected, and a new full can will be provided to you. You will then give the special clothing to the research team and change back into your own clothes.

If you are selected to participate in the study, you will receive $100 in cash at the end of the day of the study. To be qualified for participation, you must show your picture identification to prove your age. You must be over 18 and able to read either English or Spanish. You must be in good health. If you are female, you must not be pregnant or nursing a child. Also, you must be experienced and trained in using germ killing cleaning products.

Would you like to get more information on the project?

(If no, thank them for their time.)

(If yes, instruct them as follows)

If you would like to participate in the project, you would first come to the offices of Golden Pacific Laboratories at 4720 W. Jennifer Ave., Suite 105, in Fresno, to meet with the Principal Investigator, Dr. Sami Selim between the hours of 1 and 5 pm, Monday through Friday. A Spanish-speaking researcher will be there if you prefer to discuss the study in Spanish,. We can make arrangements to meet with you on the weekend as well. The office is just off of Shaw Avenue behind Costco. We will go over the study in great detail and answer all your questions regarding the study, and tell you more about

what to expect while participating and what is expected of you. This first visit will take about one hour. If you are interested, we can arrange a meeting time now. Would you prefer a weekday or weekend visit? What time would work best for your schedule?

(Time and date of appointment will be documented.)

(Note: if the potential subjects ask questions not addressed in this telephone script, inform them additional questions can be answered by Dr. Sami Selim or the Spanish speaking researcher.

INSERT SPANISH TRANSLATION OF SOLICITING FLYER AND SCRIPTS

July 13, 2009

APPENDIX H: COMMUNITY NOTIFICATION FLYER

July 13, 2009

NOTICE

Over the next few days you may notice some unusual activity next door. The American Chemistry Council will be conducting a worker exposure monitoring study. This study is being conducted with janitors from the area. While these janitors are working, they will be wearing work clothes consisting of white long-sleeved shirts and long pants, and they may be wearing what looks like MP3 players on their belts. You may also see study staff wearing white lab coats. The people involved in this study are measuring the amount of chemical exposure that janitors get when using an aerosol cleaning product, similar to what you may use in your home or business. This project will last about one week. If you would like more information, or are concerned in any way with this project, please contact one of these individuals:

Dr. Sami Selim at Golden Pacific Laboratories (559-275-9091)

or

Dr. Has Shah at the American Chemistry Council (703-741-5637)

If you prefer to speak Spanish, please contact:

Victoria Standart (English and Spanish)
Field Research Associate
Eurofins | Grayson.
211 N. Main Street
Creedmoor, NC 27522
Phone: 919-528-5510

or

Noé Galván, Ph.D. (English and Spanish)
Field Research Associate
Product Safety Scientist
PS&RC, Global Stewardship
Clorox Services Co.
7200 Johnson Drive
Pleasanton, CA 94588
Phone: 925-425-6708

July 13, 2009

INSERT SPANISH TRANSLATION OF COMMUNITY NOTIFICATION FLYER

July 13, 2009

APPENDIX I: EPA EXECUTIVE SUMMARIES FROM ADBAC AND DDAC REGISTRATION ELIGIBILITY DECISION DOCUMENTS

July 13, 2009

Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC)

Occupational and Residential Exposure Assessment

Office of Pesticide Programs
Antimicrobials Division
U.S. Environmental Protection Agency
1801 South Bell St.
Arlington, VA 22202

Date: August 1, 2006

July 13, 2009

EXECUTIVE SUMMARY

This document is the Occupational and Residential Exposure Chapter of the Reregistration Eligibility Decision (RED) document for the Group II Quat Cluster. It addresses the potential risks to humans that result from the use of chemicals in this group in occupational and residential settings. The Group II Quat Cluster group consists of structurally similar quaternary ammonium compounds ("quats") that are characterized by having positively charged nitrogen covalently bonded to three alkyl group substituents and a benzyl substituent. In finished form, these quats are salts with the positively charged nitrogen (cation) balanced by a negatively charged molecule (anion). The most common anion for the quats in this cluster is chloride. However, other anions, such as saccharinate and bromide are also used. The group will be referred to as ADBAC (alkyl dimethyl benzyl ammonium chloride) in this document.

ADBAC is the active ingredient in numerous types of products. The products are mainly disinfectants and deodorants that are used in agricultural, food handling, commercial/ institutional/industrial, residential and public access, and medical settings (Use Site Categories I, II, III, IV, and V respectively). Examples of registered uses for ADBAC in these settings include application to indoor and outdoor hard surfaces (e.g., walls, floors, tables, toilets, and fixtures), eating utensils, laundry, carpets, agricultural tools and vehicles, egg shells, hands and gloves, shoes, milking equipment and udders, humidifiers, RV tanks, medical instruments, human remains, ultrasonic tanks, reverse osmosis units, and water storage tanks. There are also ADBAC-containing products that are used in residential and commercial swimming pools (Use Site Category XI), in aquatic areas (Use Site Category XII) such as decorative ponds, decorative fountains, and agricultural watering lines, and in industrial process and water systems (Use Site Category VIII) such as once-through and re-circulating cooling waters systems, cooling towers, evaporative condensers, pasteurizers, drilling muds and packer fluids, oil well injection and wastewater systems, and in pulp and paper products, water, and chemicals. Additionally, ADBAC-containing products are used for wood preservation (Use Site Category X) through non-pressure and pressure-treatment method. There are registered uses for fogging and/or air deodorization in both occupational and residential settings. Products containing ADBAC are formulated as liquid ready-to-use, soluble concentrate, pressurized liquid, and water soluble packaging. The percentage of ADBAC in the various end-use products ranges from 0.06% to 80%. Residential products such as EPA Reg. No. 10324-45 range up to 50% ADBAC for swimming pools and spas.

The durations and routes of exposure evaluated in this assessment include short-term (ST), intermediate-term (IT), and in some instances long-term (LT) inhalation exposures, ST dermal exposures, and ST oral exposures. The inhalation endpoint (all durations) is based on an oral NOAEL of 3 mg/kg/day from a developmental toxicity study in rats. The adverse effect for this endpoint is based on clinical signs of toxicity in maternal rabbits. For the oral exposure scenarios, the ST endpoint (10 mg/kg/day) is based on adverse effects of decreased bodyweight and food consumption in a developmental toxicity study in rats. No short-term dermal endpoint for systemic effects was selected for ADBAC, since no systemic effects were identified. However, short- and intermediate-term dermal irritation endpoints were identified. The short-term endpoint was determined from a 21-day dermal toxicity in guinea pigs where a denuded non-vascularized epidermal layer was observed at 80 mg ai/kg/day. The NOAEL from this study is 20 mg ai/kg/day which is equivalent to 333 µg ai/cm^2. The intermediate-term dermal was determined from 90-day dermal toxicity in rats. The NOAEL from this study is 20 mg ai/kg/day

which is equivalent to 80 µg ai/cm^2. The endpoint is the highest dose tested before irritation became significant (effect first observed at day 43). Because the effect is to the skin, a skin concentration (µg/cm^2), rather than a dose (mg/kg/day) was used to assess the dermal risk concerns. No body weight is needed for the dermal irritation endpoint, since no systemic dose is calculated. Note: Although the dose of 20 mg/kg/day is the same for both dermal studies, the concentration of the skin of the animal was different in each study because of the difference in the size of the skin area dosed and the total amount of chemical applied (i.e., body weights differed). Because the toxicological endpoint for inhalation is female-specific, a body weight of 60 kilograms is used in the assessment. Antimicrobial Division's (AD) level of concern (LOC) for occupational and residential ADBAC inhalation and oral exposures is 100 (i.e., a margin of exposure (MOE) less than 100 exceeds the level of concern). The level of concern is based on 10x for interspecies extrapolation and 10x for intraspecies variation. The level of concern for the dermal route of exposure is a target MOE of 10 (i.e., 3x for interspecies extrapolation and 3x for intraspecies variation).

This occupational and residential assessment was based on examination of product labels describing uses for the product. There are many end-use products that contain ADBAC; therefore, only labels on the Master Label developed by AD and the registrants were reviewed. It has been determined that exposure to handlers can occur in a variety of occupational and residential environments. Additionally, post-application exposures are likely to occur in these settings. The representative scenarios selected by the Antimicrobials Division (AD) for assessment were evaluated using maximum application rates as stated on the product labels. The representative scenarios are believed to represent high-end uses resulting in dermal, inhalation, and incidental oral exposure.

To assess most handler risks, AD used surrogate unit exposure data from the Chemical Manufacturers Association (CMA) antimicrobial exposure study and the Pesticide Handlers Exposure Database (PHED). Post application/bystander exposures were assessed using EPA's Health Effects Division's (HED) *Standard Operating Procedures (SOPs) for Residential Exposure Assessment*, MCCEM (Multi-Chamber Concentration and Exposure Model), and Swim Model. Additionally, handler and post-application exposures resulting from wood preservation activities were assessed using surrogate data from the studies *Measurement and Assessment of Dermal and Inhalation Exposures to Didecyl Dimethyl Ammonium Chloride (DDAC) Used in the Protection of Cut Lumber (Phase III)* (Bestari et al., 1999, MRID 455243-04) and "*Assessment of Potential Inhalation and Dermal Exposure Associated with Pressure Treatment of Wood with Arsenical Wood Products*" (ACC, 2002a).

Residential Handler Risk Summary

Dermal

For the residential handler dermal exposure and risk assessment, dermal risks were calculated by comparing residues on the surface of the skin to the short-term dermal irritation endpoint. Residues on the surface of the skin (dermal irritation exposure) were determined using hand unit exposures from CMA/PHED adjusted for the surface area of the hand (mg/lb ai/cm^2), application rates, and use amounts. The dermal MOEs were above the target MOE of 10 for all scenarios. Therefore, the risks do not exceed EPA's level of concern.

Inhalation

For the residential handler inhalation assessment, the inhalation risks were calculated by comparing the daily doses to the short-term inhalation endpoint. The inhalation MOEs were above the target MOE of 100 for all scenarios, and therefore, are not of concern.

Residential Post Application/Bystander Risk Summary

Dermal

The residential post-application dermal risks were assessed by comparing the surface residue on the skin (dermal irritation exposure) to the short-term dermal endpoint. It was assumed that during the exposure period the skin repeatedly contacts the treated surface until a steady-state concentration of residues is achieved on the skin. The short-term endpoint was used because it was assumed that exposure to the residues is not a daily occurrence. For all of the residential scenarios, the post-application dermal MOEs were above the target MOE of 10; therefore, the risks do not exceed the level of concern.

Inhalation

For the residential post-application exposure and risk assessment, the MOEs were below the target MOE of 100 for the following scenario:

Humidifier: ST/IT 8-hr MOE = 71 for adults and 11 for children; ST/IT 24-hr MOE = 10 for adults and 4 for children

Incidental Oral

For the residential post-application incidental oral assessment, the MOEs were above the target MOE of 100 for all scenarios; therefore, the risks do not exceed AD's level of concern.

Occupational Handler Risk Summary

Dermal

ADBAC dermal irritation exposures and risks were not estimated for occupational handler exposures. Instead, dermal irritation exposures and risks will be mitigated using default personal protective equipment requirements based on the toxicity of the end-use product. To minimize dermal exposures, the minimum PPE required for mixers, loaders, and others exposed to end-use products containing concentrations of ADBAC that result in classification of category I, II,

or III for skin irritation potential will be long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and chemical-resistant apron. Once diluted, if the concentration of ADBAC in the diluted solution would result in classification of toxicity category IV for skin irritation potential, then the chemical-resistant gloves and chemical-resistant apron can be eliminated for applicators and others exposed to the dilute. Note that chemical-resistant eyewear will be required if the end-use product is classified as category I or II for eye irritation potential.

Inhalation

For the occupational handler inhalation exposure and risk assessment, the MOEs were above the target MOE of 100 for all scenarios except for the following scenarios listed below.

Agricultural fogging (mixing and loading): ST/IT Inhalation MOE = 26
Medical premises, mopping: ST/IT Inhalation MOE = 95
Pulp and paper, liquid pump: ST/IT Inhalation MOE = 33
Once-through cooling water, metering pump: Using the average flow rate for high flow streams (153 MGD) the ST Inhalation MOE = 50 for initial applications and the IT MOE = 95 for maintenance applications; however, using the average flow rate for low flow streams (5.9 MGD) the ST Inhalation MOE = 1,300 for initial applications and the IT MOE = 2,500 for maintenance applications.
Small process water systems, liquid pour: ST/IT Inhalation MOE = 6
Wood Preservation (non-pressure treatment), blender/sprayer operator: ST/IT/LT Inhalation MOE = 84
Wood Preservation (existing homes), airless sprayer: ST/IT/LT Inhalation MOE = 17

A confirmatory inhalation toxicity study may be warranted because inhalation MOEs were below 1,000 (additional 10x uncertainty factor is considered because of the lack of an inhalation route-specific toxicological endpoint) for the following scenarios:

Agricultural - hard surfaces, wiping: ST/IT Inhalation MOE = 590, and for low pressure hand wand MOE = 380.
Food handling - hard surfaces, wiping: ST/IT Inhalation MOE = 580
Commercial/Institutional premises -- hard surfaces, wiping: ST/IT Inhalation MOE = 360

Occupational Post Application/Bystander Risk Summary

Dermal

Dermal irritation exposures are assumed to be negligible for all post-application occupational scenarios, except those associated with wood preservation. As with occupational handlers, dermal irritation exposures and risks from post-application activities in a wood preservation treatment facility will be mitigated using default personal protective equipment requirements based on the toxicity of the end-use product.

Inhalation

For the inhalation post-application exposure and risk assessment, the MOEs were above the target MOE of 100 for all scenarios except for the following scenarios listed below.

Fogging in a hatchery: The 8-hr MOE from 0 to 8 hours (immediately after fogging) = 0.5; however, the 8-hr MOE from 2 to 10 hours (2 hour re-entry interval) = 1,500.
Fogging in a food processing plant: The 8-hr MOE from 2 to 10 hours (2 hour re-entry interval) = 1. The difference in the MOEs for hatcheries versus food processing plants is the assumed ventilation rate (hatcheries assigned a higher ventilation rate; refinements are warranted to the food processing plants if additional ventilation rates were available).

A confirmatory inhalation toxicity study may be warranted because the inhalation MOE was below 1,000 (additional 10x uncertainty factor is considered because of the lack of an inhalation route-specific toxicological endpoint) for the following scenario:

Non-pressure treatment wood preservation, clean-up worker: ST/IT/LT Inhalation MOE = 480

Data Limitations and Uncertainties:

There are a number of uncertainties associated with this assessment and these have been reiterated from Sections 4.2.3 (residential) and 6.4 (occupational). The data limitations and uncertainties associated with the residential handler and post-application exposure assessments include the following:

- Surrogate dermal and inhalation unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study (USEPA, 1999: DP Barcode D247642) or from the Pesticide Handler Exposure Database (USEPA, 1998) (See Appendix B for summaries of these data sources). Most of the CMA data are of poor quality therefore, AD requests that confirmatory monitoring data be generated to support the values used in these assessments.
- The quantities handled/treated were estimated based on information from various sources, including HED's Standard Operating Procedures (SOPs) for Residential Exposure Assessments (USEPA 2000 and 2001). In certain cases, no standard values were available for some scenarios. Assumptions for these scenarios were based on AD estimates and could be further refined from input from registrants.
- Some labels for products which can be used by homeowners in residential settings, as well as by workers in occupational settings, indicate that low pressure sprayers can be used for application of the disinfectant to hard, non-porous surfaces such as floors and walls. A low pressure spray scenario was not assessed for the residential scenario because it is not a typical cleaning method for homeowners.
- At this time, the Agency does not have exposure data to assess oral exposures to children and adults from using treated mouthpieces and reeds; therefore, the Agency is requesting residue data from treated mouthpieces and reeds.
- In this assessment, incidental ingestion and dermal exposures to treated wood were estimated for ADBAC using surrogate DDAC data. The degree of uncertainty (under- or overestimation) associated with using the surrogate DDAC hand residue data for ADBAC

dermal and oral exposure from contacting treated lumber are unknown. The amount of residue measured on the test subjects hands is variable and are influenced by the duration of exposure, how often wood is contacted, and the degree of contact (i.e., do the hand residues from the DDAC study mimic a child's play activity on decks and play sets?). A confirmatory wipe study with ADBAC and/or DDAC treated wood will need to be determined during the risk mitigation phase of the RED process.

- Available data to assess the levels of ADBAC in soil contaminated with ADBAC-treated wood do not exist at this time. In addition, leaching data were also not available. Because of this data gap, EPA was not able to accurately predict dermal and incidental ingestion residential post-application exposures to soil contaminated with ADBAC-treated wood.

The data limitations and uncertainties associated with the occupational handler and post-application exposure assessments include:

- Surrogate dermal and inhalation unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study (USEPA, 1999: DP Barcode D247642) or from the Pesticide Handler Exposure Database (USEPA, 1998) (See Appendix B for summaries of these data sources). Since the CMA data are of poor quality, the Agency requests that confirmatory data be submitted to support the occupational scenarios assessed in this document.
- Unit exposures are not available for some of the specific scenarios that are prescribed for ADBAC. These scenarios include the following: open loading into oil-well/field environments and metering into once-through cooling water systems at power plants.
    - The CMA data used for oil-well uses are based on open pouring of a material preservative. Although these data are only represented by 2 replicates each, the exposure values are similar to open loading of pesticides in PHED. Furthermore, there are no representative unit exposure data for chemical metering into secondary recovery oil operations. Since the volume of water being treated in secondary recovery operations is so large, the available CMA data cannot be reliably extrapolated because they are based on activities that handle much lower volumes and possibly different techniques. Therefore, it was assumed that if the open pour handling activities for the other oil well operations resulted in MOEs that are not of concern, then the MOEs for the closed system chemical metering into secondary recovery operations would also be not of concern. AD requests that confirmatory data be conducted to show that this is accurate.
    - The CMA data used for once-through cooling water systems at power plants are based on closed metering for pulp and paper. The pulp and paper unit exposures were deemed more appropriate than the cooling water tower data because of the large volume of water treated in once-through cooling water systems at power plants. However, the CMA data for pulp and paper does not reliably represent the volume of water treated and the possibly different techniques used to treat the water.
- For the wood preservative pressure treatment scenarios, CCA exposure data were used for lack of ADBAC-specific exposure data and for the wood preservative non-pressure treatment scenarios, DDAC exposure data were used for the lack of ADBAC-specific exposure data. The assumption was made that exposure patterns for workers at treatment facilities using CCA and DDAC would be similar to exposure patterns for workers at treatment facilities

using ADBAC, and therefore the exposures could be used as surrogate data for workers that treat wood with ADBAC.

- The quantities handled/treated were estimated based on information from various sources, including HED's Standard Operating Procedures (SOPs) for Residential Exposure Assessments (USEPA 2000, and 2001) and personal communication with experts. In particular, the use information for the pulp and paper processing, oil-well uses, and small process water system uses are based on personal communication with biocide manufacturers for these types of uses. The individuals contacted have experience in these operations and their estimates are believed to be the best available without undertaking a statistical survey of the uses. In certain cases, no standard values were available for some scenarios. Assumptions for these scenarios were based on AD estimates and could be further refined from input from registrants. For example, the quantities handled/treated for the application of ADBAC to the surface of metal/wood cooling towers could be refined.
- The type of spray equipment to be used was not specifically mentioned on the labels for some scenarios, such as for surface sprays to metal and wood cooling water towers. Therefore, these scenarios were assessed using the PHED airless spray unit exposures, which represents high-end exposure. In these cases, the appropriate application equipment could be further refined.
- The percent active ingredient in solution for the pressure treatment of lumber needs to be refined by the registrants. The labels only provided a retention rate. For this assessment, the application rate on the master label was used, which is the same as the application rate for non-pressure treatment of lumber.

DRAFT

Didecyl Dimethyl Ammonium Chloride (DDAC)

Occupational and Residential Exposure Assessment

Office of Pesticide Programs
Antimicrobials Division
U.S. Environmental Protection Agency
1801 South Bell St.
Arlington, VA 22202

Date: August 1, 2006

EXECUTIVE SUMMARY

This document is the Occupational and Residential Exposure Chapter of the Reregistration Eligibility Decision (RED) document for the Group I Quat Cluster. It addresses the potential risks to humans that result from the use of chemicals in this group in occupational and residential settings. Group I Quat Cluster is a group of structurally similar quaternary ammonium compounds ("quats") that are characterized by having a positively charged nitrogen covalently bonded to two alkyl group substituents (at least one C_8 or longer) and two methyl substituents. In finished form, these quats are salts with the positively charged nitrogen (cation) balanced by a negatively charged molecule (anion). The anion for the quats in this cluster is chloride or bromide. In this document, the Group I Quat Cluster will be referred to as DDAC (didecyl dimethyl ammonium chloride).

DDAC is the active ingredient in numerous types of products. The products are mainly disinfectants and deodorants that are used in agricultural, food handling, commercial/ institutional/industrial, residential and public access, and medical settings (Use Site Categories I, II, III, IV, and V respectively). Examples of registered uses for DDAC in these settings include application to indoor and outdoor hard surfaces (e.g., walls, floors, tables, toilets, and fixtures), eating utensils, laundry, carpets, agricultural tools and vehicles, egg shells, shoes, milking equipment and udders, humidifiers, medical instruments, human remains, ultrasonic tanks, reverse osmosis units, and water storage tanks. There are also DDAC-containing products that are used in residential and commercial swimming pools (Use Site Category XI), in aquatic areas (Use Site Category XII) such as decorative ponds and decorative fountains, and in industrial process and water systems (Use Site Category VIII) such as re-circulating cooling water systems, drilling muds and packer fluids, oil well injection and wastewater systems. Additionally, DDAC-containing products are used for wood preservation (Use Site Category X) through non-pressure and pressure-treatment methods. There are registered uses for fogging in occupational settings. Products containing DDAC are formulated as liquid ready-to-use, soluble concentrate, pressurized liquid, and water soluble packaging. The percentage of DDAC in the various end-use products ranges from 0.08% to 80% as reported in the Master Label spreadsheet (Appendix A). Residential products such as EPA Reg. No. 10324-69 range up to 50% DDAC for swimming pools and spas.

The durations and routes of exposure evaluated in this assessment include short-term (ST), intermediate-term (IT), and in some instances long-term (LT) inhalation exposures, ST dermal exposures, and ST oral exposures. The ST inhalation endpoint and the ST oral endpoint are based on a NOAEL of 10 mg/kg/day from a prenatal developmental toxicity study in rats. The LOAEL (20 mg/kg/day) was based largely on increased incidence of skeletal variations in females. The developmental study does not indicate increased susceptibility from *in utero* and postnatal exposure to DDAC. The IT/LT inhalation endpoint is also based on a 10 mg/kg/day but from a chronic toxicity study in dogs. No short-term dermal endpoint for systemic effects was selected for DDAC, since no systemic effects were identified. However, a short-term dermal irritation endpoint was identified. The short-term dermal endpoint for DDAC (i.e., NOAEL of 2 mg/kg/day which is equivalent in this particular study to 8 $\mu g/cm^2$) was determined from a LOAEL of 6 mg/kg/day based on increased clinical and gross findings (erythema, edema, exfoliation, excoriation, and ulceration). A 21-day dermal toxicity study was also conducted

using a 0.13% ai formulation. No short-term dermal endpoint was identified for this formulation because no irritation or systemic effects were identified up to and including the limit dose of 1,000 mg/kg/day. Intermediate- or long-term dermal irritation endpoints were not identified for DDAC. Because the effect to the skin is a localized skin irritation, a skin concentration ($\mu g/cm^2$) of exposure, rather than a dose (mg/kg/day) was used to assess the dermal risk concerns. No body weight is needed for the dermal irritation endpoint, since no systemic dose is calculated. Since the toxicological endpoint for inhalation is female-specific, a body weight of 60 kilograms is used in the assessment. This represents the body weight of an adult female. They Agency's level of concern (LOC) for occupational and residential DDAC inhalation and oral exposures is 100 (i.e., a margin of exposure (MOE) less than 100 exceeds the level of concern). The level of concern is based on 10x for interspecies extrapolation and 10x for intraspecies variation. The level of concern for the dermal route of exposure using dermal irritation as an endpoint is a target MOE of 10 (i.e., 3x for interspecies extrapolation and 3x for intraspecies variation).

The dermal and inhalation margins of exposure were not combined for the DDAC risk assessment because the toxicity endpoints for the dermal and inhalation routes of exposure are based on different toxicological effects. No cancer endpoint was identified; therefore, cancer risks are not assessed.

This occupational and residential assessment was based on examination of product labels describing uses for the product. There are many end-use products that contain DDAC; therefore, only labels on the Master Label developed by AD and the registrants were reviewed. It has been determined that exposure to handlers can occur in a variety of occupational and residential environments. Additionally, post-application exposures are likely to occur in these settings. The representative scenarios selected by the Antimicrobials Division (AD) for assessment were evaluated using maximum application rates as stated on the product labels. The representative scenarios are believed to represent high-end uses resulting in dermal, inhalation, and incidental oral exposures.

To assess most handler risks, AD used surrogate unit exposure data from the Chemical Manufacturers Association (CMA) antimicrobial exposure study and the Pesticide Handlers Exposure Database (PHED). Postapplication/bystander exposures were assessed using EPA's Health Effects Division's (HED) *Standard Operating Procedures (SOPs) for Residential Exposure Assessment*, MCCEM (Multi-Chamber Concentration and Exposure Model), and Swim Model. Additionally, handler and post-application exposures resulting from wood preservation activities were assessed using surrogate data from the studies *Measurement and Assessment of Dermal and Inhalation Exposures to Didecyl Dimethyl Ammonium Chloride (DDAC) Used in the Protection of Cut Lumber (Phase III)* (Bestari et al., 1999, MRID 455243-04) and "*Assessment of Potential Inhalation and Dermal Exposure Associated with Pressure Treatment of Wood with Arsenical Wood Products*" (ACC, 2002a).

Residential Handler Risk Summary

Dermal

For the residential handler dermal exposure and risk assessment, dermal risks were calculated by comparing residues on the surface of the skin to the short-term dermal irritation endpoints. Residues on the surface of the skin (dermal irritation exposure) were determined using hand unit exposures from CMA and/or PHED adjusted for the surface area of the hand (mg/lb ai/cm^2), application rates, and use amounts. The dermal MOEs were below the target MOE of 10 only for the carpet spray application and at the maximum application rate for the mopping and wiping.

Inhalation

For the residential handler inhalation assessment, the inhalation risks were calculated by comparing the daily doses to the short-term inhalation endpoint. The inhalation MOEs were above the target MOE of 100 for all scenarios.

Residential Post-Application/Bystander Risk Summary

Dermal

The residential post-application dermal risks were assessed by comparing the surface residue on the skin (dermal skin irritation exposure) to the short-term dermal endpoint. It was assumed that during the exposure period the skin repeatedly contacts the treated surface until a steady-state concentration of residues is achieved on the skin. For residential scenarios, the post-application dermal MOEs were above the target MOE of 10 for the laundered clothing (assuming 1% residue transfer) and hard surface and carpet dermal contact but below the target MOE for the following:

- Wearing clothes treated with a fabric spray: ST dermal MOE = less than or equal to **1** using a 100% clothing to skin transfer factor and the MOE is 8 using a 5% clothing to skin transfer factor.
- There are no wipe data available to assess the children's dermal contact to treated decks and/or play sets. Based on hand measurements of workers at the treatment plants, dermal MOEs range from 3 to 13 with considerable uncertainties, and therefore, a wipe study is warranted.

Inhalation

For the residential post-application inhalation exposure and risk assessment, the MOEs were below the target MOE of 100 for the following scenario:

- Humidifier: ST/IT 8-hr Inhalation MOE = **27** for adults and **8** for children; ST/IT 24-hr Inhalation MOE = **11** for adults and **5** for children

Incidental Oral

For the residential post-application incidental oral assessment, the MOEs were above the target MOE of 100 for all scenarios.

Occupational Handler Risk Summary

Dermal

DDAC dermal irritation exposures and risks were not estimated for occupational handler exposures. Instead, dermal irritation exposures and risks will be mitigated using default personal protective equipment requirements based on the toxicity of the end-use product. To minimize dermal exposures, the minimum PPE required for mixers, loaders, and others exposed to end-use products containing concentrations of DDAC that result in classification of category I, II, or III for skin irritation potential will be long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and chemical-resistant apron. Once diluted, if the concentration of DDAC in the diluted solution would result in classification of toxicity category IV for skin irritation potential, then the chemical-resistant gloves and chemical-resistant apron can be eliminated for applicators and others exposed to the dilute. Note that chemical-resistant eyewear will be required if the end-use product is classified as category I or II for eye irritation potential.

Inhalation

For the occupational handler inhalation exposure and risk assessment, the MOEs were above the target MOE of 100 for all scenarios.

A confirmatory inhalation toxicity study may be warranted because inhalation MOEs were below 1,000 for the following scenarios:

- Small process water systems, liquid pour: ST/IT Inhalation MOE = **130**
- Agricultural fogging, mixing and loading: ST/IT Inhalation MOE = **110**
- Medical premises, mopping: ST/IT Inhalation MOE = **280**
- Wood Preservation (non-pressure treatment), blender/sprayer: ST/IT/LT Inhalation MOE = **280**

Occupational Post-Application/Bystander Risk Summary

Dermal

Dermal irritation exposures are assumed to be negligible for all post-application occupational scenarios, except those associated with wood preservation. As with occupational handlers, dermal irritation exposures and risks from post-application activities in a wood preservation treatment facility will be mitigated using default personal protective equipment requirements based on the toxicity of the end-use product. For construction workers handling treated wood the MOEs range from 3 to 13 shortly after application.

Inhalation

For the occupational inhalation post-application exposure and risk assessment, the MOEs were above the target MOE of 100 for all scenarios except for the following scenarios listed below.

- Fogging in a food processing plant: The 8-hr MOE from 2 to 10 hours (2 hour re-entry interval) = **8**.

A confirmatory inhalation toxicity study may be warranted because the inhalation MOE was below 1,000 (additional 10x uncertainty factor is considered because of the lack of an inhalation route-specific toxicological endpoint) for the following scenarios:

- Fogging in a hatchery: The 8-hr MOE from 0 to 8 hours (entering immediately after fogging) = **120**.
- Non-pressure treatment wood preservation, clean-up worker: ST/IT/LT Inhalation MOE = **990**

Data Limitations and Uncertainties:

There are a number of uncertainties associated with this assessment and these have been reiterated from Sections 4.2.3 (residential) and 6.4 (occupational) respectively.

The data limitations and uncertainties associated with the residential handler and post-application exposure assessments include the following:

- Surrogate dermal and inhalation unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study (USEPA, 1999: DP Barcode D247642) or from the Pesticide Handler Exposure Database (USEPA, 1998) (See Appendix B for summaries of these data sources). Most of the CMA data are of poor quality therefore, AD requests that confirmatory monitoring data be generated to support the values used in these assessments.
- The quantities handled/treated were estimated based on information from various sources, including HED's Standard Operating Procedures (SOPs) for Residential Exposure Assessments (USEPA 2000 and 2001). In certain cases, no standard values were available for some scenarios. Assumptions for these scenarios were based on AD estimates and could be further refined from input from registrants.
- Some labels for products which can be used by homeowners in residential settings, as well as by workers in occupational settings, indicate that low pressure sprayers can be used for application of the disinfectant to hard, non-porous surfaces such as floors and walls. A low pressure spray scenario was not assessed for the residential scenario because it is not a typical cleaning method for homeowners.
- In this assessment, incidental ingestion and dermal exposures to treated wood were estimated using DDAC data from an occupational exposure study. The degree of uncertainty (under- or overestimation) associated with using the DDAC hand residue data for dermal and oral exposure from contacting treated lumber are unknown. The amount of residue measured on the test subjects hands is variable and are influenced by the duration of exposure, how often wood is contacted, and the degree of contact (i.e., do the hand residues from the DDAC study mimic a child's play activity on decks and playsets?). A wipe study on treated wood is needed to refine these estimates.
- Available data to assess the levels of DDAC in soil contaminated with DDAC-treated wood do not exist at this time. In addition, leaching data were also not available. Because of this data gap, EPA was not able to accurately predict dermal and incidental ingestion residential post-application exposures to soil contaminated with DDAC-treated wood.

The data limitations and uncertainties associated with the occupational handler and post-application exposure assessments include:

- Surrogate dermal and inhalation unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study (USEPA, 1999: DP Barcode D247642) or from the Pesticide Handler Exposure Database (USEPA, 1998) (See Appendix B for summaries of these data sources). Since the CMA data are of poor quality, the Agency requests that confirmatory data be submitted to support the occupational scenarios assessed in this document.
- Unit exposures are not available for some of the specific scenarios that are prescribed for DDAC, including open loading into oil-well/field environments
  - The CMA data used for oil-well uses are based on open pouring of a material preservative. Although these data are only represented by 2 replicates each, the exposure values are similar to open loading of pesticides in PHED. Furthermore, there are no representative unit exposure data for chemical metering into secondary recovery oil operations. Since the volume of water being treated in secondary recovery operations is so large, the available CMA data cannot be reliably extrapolated because they are based on activities that handle much lower volumes and possibly different techniques. Therefore, it was assumed that if the open pour handling activities for the other oil well operations resulted in MOEs that are not of concern, then the MOEs for the closed system chemical metering into secondary recovery operations would also be not of concern. AD requests that confirmatory data be conducted to show that this is accurate.
- For the wood preservative pressure treatment scenarios, CCA exposure data were used for lack of DDAC-specific exposure data. Limitations and uncertainties associated with the use of these data include:
  - The assumption was made that exposure patterns for workers at treatment facilities using CCA would be similar to exposure patterns for workers at treatment facilities using DDAC, and therefore the exposures could be used as surrogate data for workers that treat wood with DDAC.
  - For environmental modeling, it was assumed that the leaching process from the DDAC treated wood would be similar to that of CCA. However, due to the lack of real data for DDAC -treated wood, it is not possible to verify this assumption.
- The quantities handled/treated were estimated based on information from various sources, including HED's Standard Operating Procedures (SOPs) for Residential Exposure Assessments (USEPA 2000 and 2001) and personal communication with experts. In particular, the use information for oil-well uses and cooling water tower uses are based on personal communication with biocide manufacturers for these types of uses. The individuals contacted have experience in these operations and their estimates are believed to be the best available without undertaking a statistical survey of the uses. In certain cases, no standard values were available for some scenarios. Assumptions for these scenarios were based on AD estimates and could be further refined from input from registrants.
- The percent active ingredient in solution for the pressure treatment of lumber needs to be refined by the registrant. The labels only provided a retention rate. For this assessment, the application rate on the master label was used, which is the same as the application rate for non-pressure treatment of lumber.

APPENDIX J: FIELD SAMPLE IDENTIFICATION CODES

Sample ID Number	Description
AEA04-AS-01-ID-LA	Aerosol worker sample, ME 01, inner dosimeter, lower arms
AEA04-AS-01-ID-UA	Aerosol worker sample, ME 01, inner dosimeter, upper arms
AEA04-AS-01-ID-FT	Aerosol worker sample, ME 01, inner dosimeter, front torso
AEA04-AS-01-ID-RT	Aerosol worker sample, ME 01, inner dosimeter, rear torso
AEA04-AS-01-ID-LL	Aerosol worker sample, ME 01, inner dosimeter, lower legs
AEA04-AS-01-ID-UL	Aerosol worker sample, ME 01, inner dosimeter, upper legs
AEA04-AS-01-OD-LA	Aerosol worker sample, ME 01, outer dosimeter, lower arms
AEA04-AS-01-OD-UA	Aerosol worker sample, ME 01, outer dosimeter, upper arms
AEA04-AS-01-OD-FT	Aerosol worker sample, ME 01, outer dosimeter, front torso
AEA04-AS-01-OD-RT	Aerosol worker sample, ME 01, outer dosimeter, rear torso
AEA04-AS-01-OD-LL	Aerosol worker sample, ME 01, outer dosimeter, lower legs
AEA04-AS-01-OD-UL	Aerosol worker sample, ME 01, outer dosimeter, upper legs
AEA04-AS-01-AR-01	Aerosol worker sample, ME 01, air sampling tube
AEA04-AS-01-FW-01	Aerosol worker sample, ME 01, face/neck wipes
AEA04-AS-01-HW-01	Aerosol worker sample, ME 01, 1st interim hand wash
AEA04-AS-01-HW-02	Aerosol worker sample, ME 01, 2nd interim hand wash
AEA04-AS-01-HW-03	Aerosol worker sample, ME 01, 3rd interim hand wash
AEA04-AS-01-HW-04	Aerosol worker sample, ME 01, 4th interim hand wash
AEA04-AS-01-HW-xx	Aerosol worker sample, ME 01, final hand wash
AEA04-AS-01-RES-01	Aerosol worker sample, ME 01, RespiCon 100 µm
AEA04-AS-01-RES-02	Aerosol worker sample, ME 01, RespiCon 10 µm
AEA04-AS-01-RES-03	Aerosol worker sample, ME 01, RespiCon 2.5 µm
AEA04-AS-02-ID-LA	Aerosol worker sample, ME 02, inner dosimeter, lower arms
AEA04-AS-02-ID-UA	Aerosol worker sample, ME 02, inner dosimeter, upper arms
AEA04-AS-02-ID-FT	Aerosol worker sample, ME 02, inner dosimeter, front torso
AEA04-AS-02-ID-RT	Aerosol worker sample, ME 02, inner dosimeter, rear torso
AEA04-AS-02-ID-LL	Aerosol worker sample, ME 02, inner dosimeter, lower legs
AEA04-AS-02-ID-UL	Aerosol worker sample, ME 02, inner dosimeter, upper legs
AEA04-AS-02-OD-LA	Aerosol worker sample, ME 02, outer dosimeter, lower arms
AEA04-AS-02-OD-UA	Aerosol worker sample, ME 02, outer dosimeter, upper arms
AEA04-AS-02-OD-FT	Aerosol worker sample, ME 02, outer dosimeter, front torso
AEA04-AS-02-OD-RT	Aerosol worker sample, ME 02, outer dosimeter, rear torso
AEA04-AS-02-OD-LL	Aerosol worker sample, ME 02, outer dosimeter, lower legs
AEA04-AS-02-OD-UL	Aerosol worker sample, ME 02, outer dosimeter, upper legs
AEA04-AS-02-AR-01	Aerosol worker sample, ME 02, air sampling tube
AEA04-AS-02-FW-01	Aerosol worker sample, ME 02, face/neck wipes
AEA04-AS-02-HW-01	Aerosol worker sample, ME 02, 1st interim hand wash
AEA04-AS-02-HW-02	Aerosol worker sample, ME 02, 2nd interim hand wash
AEA04-AS-02-HW-03	Aerosol worker sample, ME 02, 3rd interim hand wash
AEA04-AS-02-HW-04	Aerosol worker sample, ME 02, 4th interim hand wash
AEA04-AS-02-HW-xx	Aerosol worker sample, ME 02, final hand wash
AEA04-AS-02-RES-01	Aerosol worker sample, ME 02, RespiCon 100 µm
AEA04-AS-02-RES-02	Aerosol worker sample, ME 02, RespiCon 10 µm
AEA04-AS-02-RES-03	Aerosol worker sample, ME 02, RespiCon 2.5 µm

Exposure Samples (continued)

Sample ID Number	Description
AEA04-AS-03-ID-LA	Aerosol worker sample, ME 03, inner dosimeter, lower arms
AEA04-AS-03-ID-UA	Aerosol worker sample, ME 03, inner dosimeter, upper arms
AEA04-AS-03-ID-FT	Aerosol worker sample, ME 03, inner dosimeter, front torso
AEA04-AS-03-ID-RT	Aerosol worker sample, ME 03, inner dosimeter, rear torso
AEA04-AS-03-ID-LL	Aerosol worker sample, ME 03, inner dosimeter, lower legs
AEA04-AS-03-ID-UL	Aerosol worker sample, ME 03, inner dosimeter, upper legs
AEA04-AS-03-OD-LA	Aerosol worker sample, ME 03, outer dosimeter, lower arms
AEA04-AS-03-OD-UA	Aerosol worker sample, ME 03, outer dosimeter, upper arms
AEA04-AS-03-OD-FT	Aerosol worker sample, ME 03, outer dosimeter, front torso
AEA04-AS-03-OD-RT	Aerosol worker sample, ME 03, outer dosimeter, rear torso
AEA04-AS-03-OD-LL	Aerosol worker sample, ME 03, outer dosimeter, lower legs
AEA04-AS-03-OD-UL	Aerosol worker sample, ME 03, outer dosimeter, upper legs
AEA04-AS-03-AR-01	Aerosol worker sample, ME 03, air sampling tube
AEA04-AS-03-FW-01	Aerosol worker sample, ME 03, face/neck wipes
AEA04-AS-03-HW-01	Aerosol worker sample, ME 03, 1st interim hand wash
AEA04-AS-03-HW-02	Aerosol worker sample, ME 03, 2nd interim hand wash
AEA04-AS-03-HW-03	Aerosol worker sample, ME 03, 3rd interim hand wash
AEA04-AS-03-HW-04	Aerosol worker sample, ME 03, 4th interim hand wash
AEA04-AS-03-HW-xx	Aerosol worker sample, ME 03, final hand wash
AEA04-AS-03-RES-01	Aerosol worker sample, ME 03, RespiCon 100 µm
AEA04-AS-03-RES-02	Aerosol worker sample, ME 03, RespiCon 10 µm
AEA04-AS-03-RES-03	Aerosol worker sample, ME 03, RespiCon 2.5 µm
AEA04-AS-04-ID-LA	Aerosol worker sample, ME 04, inner dosimeter, lower arms
AEA04-AS-04-ID-UA	Aerosol worker sample, ME 04, inner dosimeter, upper arms
AEA04-AS-04-ID-FT	Aerosol worker sample, ME 04, inner dosimeter, front torso
AEA04-AS-04-ID-RT	Aerosol worker sample, ME 04, inner dosimeter, rear torso
AEA04-AS-04-ID-LL	Aerosol worker sample, ME 04, inner dosimeter, lower legs
AEA04-AS-04-ID-UL	Aerosol worker sample, ME 04, inner dosimeter, upper legs
AEA04-AS-04-OD-LA	Aerosol worker sample, ME 04, outer dosimeter, lower arms
AEA04-AS-04-OD-UA	Aerosol worker sample, ME 04, outer dosimeter, upper arms
AEA04-AS-04-OD-FT	Aerosol worker sample, ME 04, outer dosimeter, front torso
AEA04-AS-04-OD-RT	Aerosol worker sample, ME 04, outer dosimeter, rear torso
AEA04-AS-04-OD-LL	Aerosol worker sample, ME 04, outer dosimeter, lower legs
AEA04-AS-04-OD-UL	Aerosol worker sample, ME 04, outer dosimeter, upper legs
AEA04-AS-04-AR-01	Aerosol worker sample, ME 04, air sampling tube
AEA04-AS-04-FW-01	Aerosol worker sample, ME 04, face/neck wipes
AEA04-AS-04-HW-01	Aerosol worker sample, ME 04, 1st interim hand wash
AEA04-AS-04-HW-02	Aerosol worker sample, ME 04, 2nd interim hand wash
AEA04-AS-04-HW-03	Aerosol worker sample, ME 04, 3rd interim hand wash
AEA04-AS-04-HW-04	Aerosol worker sample, ME 04, 4th interim hand wash
AEA04-AS-04-HW-xx	Aerosol worker sample, ME 04, final hand wash

Exposure Samples (continued)

Sample ID Number	Description
AEA04-AS-04-RES-01	Aerosol worker sample, ME 04, RespiCon 100 µm
AEA04-AS-04-RES-02	Aerosol worker sample, ME 04, RespiCon 10 µm
AEA04-AS-04-RES-03	Aerosol worker sample, ME 04, RespiCon 2.5 µm
AEA04-AS-05-ID-LA	Aerosol worker sample, ME 05, inner dosimeter, lower arms
AEA04-AS-05-ID-UA	Aerosol worker sample, ME 05, inner dosimeter, upper arms
AEA04-AS-05-ID-FT	Aerosol worker sample, ME 05, inner dosimeter, front torso
AEA04-AS-05-ID-RT	Aerosol worker sample, ME 05, inner dosimeter, rear torso
AEA04-AS-05-ID-LL	Aerosol worker sample, ME 05, inner dosimeter, lower legs
AEA04-AS-05-ID-UL	Aerosol worker sample, ME 05, inner dosimeter, upper legs
AEA04-AS-05-OD-LA	Aerosol worker sample, ME 05, outer dosimeter, lower arms
AEA04-AS-05-OD-UA	Aerosol worker sample, ME 05, outer dosimeter, upper arms
AEA04-AS-05-OD-FT	Aerosol worker sample, ME 05, outer dosimeter, front torso
AEA04-AS-05-OD-RT	Aerosol worker sample, ME 05, outer dosimeter, rear torso
AEA04-AS-05-OD-LL	Aerosol worker sample, ME 05, outer dosimeter, lower legs
AEA04-AS-05-OD-UL	Aerosol worker sample, ME 05, outer dosimeter, upper legs
AEA04-AS-05-AR-01	Aerosol worker sample, ME 05, air sampling tube
AEA04-AS-05-FW-01	Aerosol worker sample, ME 05, face/neck wipes
AEA04-AS-05-HW-01	Aerosol worker sample, ME 05, 1st interim hand wash
AEA04-AS-05-HW-02	Aerosol worker sample, ME 05, 2nd interim hand wash
AEA04-AS-05-HW-03	Aerosol worker sample, ME 05, 3rd interim hand wash
AEA04-AS-05-HW-04	Aerosol worker sample, ME 05, 4th interim hand wash
AEA04-AS-05-HW-xx	Aerosol worker sample, ME 05, final hand wash
AEA04-AS-05-RES-01	Aerosol worker sample, ME 05, RespiCon 100 µm
AEA04-AS-05-RES-02	Aerosol worker sample, ME 05, RespiCon 10 µm
AEA04-AS-05-RES-03	Aerosol worker sample, ME 05, RespiCon 2.5 µm
AEA04-AS-06-ID-LA	Aerosol worker sample, ME 06, inner dosimeter, lower arms
AEA04-AS-06-ID-UA	Aerosol worker sample, ME 06, inner dosimeter, upper arms
AEA04-AS-06-ID-FT	Aerosol worker sample, ME 06, inner dosimeter, front torso
AEA04-AS-06-ID-RT	Aerosol worker sample, ME 06, inner dosimeter, rear torso
AEA04-AS-06-ID-LL	Aerosol worker sample, ME 06, inner dosimeter, lower legs
AEA04-AS-06-ID-UL	Aerosol worker sample, ME 06, inner dosimeter, upper legs
AEA04-AS-06-OD-LA	Aerosol worker sample, ME 06, outer dosimeter, lower arms
AEA04-AS-06-OD-UA	Aerosol worker sample, ME 06, outer dosimeter, upper arms
AEA04-AS-06-OD-FT	Aerosol worker sample, ME 06, outer dosimeter, front torso
AEA04-AS-06-OD-RT	Aerosol worker sample, ME 06, outer dosimeter, rear torso
AEA04-AS-06-OD-LL	Aerosol worker sample, ME 06, outer dosimeter, lower legs
AEA04-AS-06-OD-UL	Aerosol worker sample, ME 06, outer dosimeter, upper legs
AEA04-AS-06-AR-01	Aerosol worker sample, ME 06, air sampling tube
AEA04-AS-06-FW-01	Aerosol worker sample, ME 06, face/neck wipes
AEA04-AS-06-HW-01	Aerosol worker sample, ME 06, 1st interim hand wash

Exposure Samples (continued)

Sample ID Number	Description
AEA04-AS-06-HW-02	Aerosol worker sample, ME 06, 2nd interim hand wash
AEA04-AS-06-HW-03	Aerosol worker sample, ME 06, 3rd interim hand wash
AEA04-AS-06-HW-04	Aerosol worker sample, ME 06, 4th interim hand wash
AEA04-AS-06-HW-xx	Aerosol worker sample, ME 06, final hand wash
AEA04-AS-06-RES-01	Aerosol worker sample, ME 06, RespiCon 100 µm
AEA04-AS-06-RES-02	Aerosol worker sample, ME 06, RespiCon 10 µm
AEA04-AS-06-RES-03	Aerosol worker sample, ME 06, RespiCon 2.5 µm
AEA04-AS-07-ID-LA	Aerosol worker sample, ME 07, inner dosimeter, lower arms
AEA04-AS-07-ID-UA	Aerosol worker sample, ME 07, inner dosimeter, upper arms
AEA04-AS-07-ID-FT	Aerosol worker sample, ME 07, inner dosimeter, front torso
AEA04-AS-07-ID-RT	Aerosol worker sample, ME 07, inner dosimeter, rear torso
AEA04-AS-07-ID-LL	Aerosol worker sample, ME 07, inner dosimeter, lower legs
AEA04-AS-07-ID-UL	Aerosol worker sample, ME 07, inner dosimeter, upper legs
AEA04-AS-07-OD-LA	Aerosol worker sample, ME 07, outer dosimeter, lower arms
AEA04-AS-07-OD-UA	Aerosol worker sample, ME 07, outer dosimeter, upper arms
AEA04-AS-07-OD-FT	Aerosol worker sample, ME 07, outer dosimeter, front torso
AEA04-AS-07-OD-RT	Aerosol worker sample, ME 07, outer dosimeter, rear torso
AEA04-AS-07-OD-LL	Aerosol worker sample, ME 07, outer dosimeter, lower legs
AEA04-AS-07-OD-UL	Aerosol worker sample, ME 07, outer dosimeter, upper legs
AEA04-AS-07-AR-01	Aerosol worker sample, ME 07, air sampling tube
AEA04-AS-07-FW-01	Aerosol worker sample, ME 07, face/neck wipes
AEA04-AS-07-HW-01	Aerosol worker sample, ME 07, 1st interim hand wash
AEA04-AS-07-HW-02	Aerosol worker sample, ME 07, 2nd interim hand wash
AEA04-AS-07-HW-03	Aerosol worker sample, ME 07, 3rd interim hand wash
AEA04-AS-07-HW-04	Aerosol worker sample, ME 07, 4th interim hand wash
AEA04-AS-07-HW-xx	Aerosol worker sample, ME 07, final hand wash
AEA04-AS-07-RES-01	Aerosol worker sample, ME 07, RespiCon 100 µm
AEA04-AS-07-RES-02	Aerosol worker sample, ME 07, RespiCon 10 µm
AEA04-AS-07-RES-03	Aerosol worker sample, ME 07, RespiCon 2.5 µm
AEA04-AS-08-ID-LA	Aerosol worker sample, ME 08, inner dosimeter, lower arms
AEA04-AS-08-ID-UA	Aerosol worker sample, ME 08, inner dosimeter, upper arms
AEA04-AS-08-ID-FT	Aerosol worker sample, ME 08, inner dosimeter, front torso
AEA04-AS-08-ID-RT	Aerosol worker sample, ME 08, inner dosimeter, rear torso
AEA04-AS-08-ID-LL	Aerosol worker sample, ME 08, inner dosimeter, lower legs
AEA04-AS-08-ID-UL	Aerosol worker sample, ME 08, inner dosimeter, upper legs
AEA04-AS-08-OD-LA	Aerosol worker sample, ME 08, outer dosimeter, lower arms
AEA04-AS-08-OD-UA	Aerosol worker sample, ME 08, outer dosimeter, upper arms
AEA04-AS-08-OD-FT	Aerosol worker sample, ME 08, outer dosimeter, front torso
AEA04-AS-08-OD-RT	Aerosol worker sample, ME 08, outer dosimeter, rear torso
AEA04-AS-08-OD-LL	Aerosol worker sample, ME 08, outer dosimeter, lower legs
AEA04-AS-08-OD-UL	Aerosol worker sample, ME 08, outer dosimeter, upper legs

Exposure Samples (continued)

Sample ID Number	Description
AEA04-AS-08-AR-01	Aerosol worker sample, ME 08, air sampling tube
AEA04-AS-08-FW-01	Aerosol worker sample, ME 08, face/neck wipes
AEA04-AS-08-HW-01	Aerosol worker sample, ME 08, 1st interim hand wash
AEA04-AS-08-HW-02	Aerosol worker sample, ME 08, 2nd interim hand wash
AEA04-AS-08-HW-03	Aerosol worker sample, ME 08, 3rd interim hand wash
AEA04-AS-08-HW-04	Aerosol worker sample, ME 08, 4th interim hand wash
AEA04-AS-08-HW-xx	Aerosol worker sample, ME 08, final hand wash
AEA04-AS-08-RES-01	Aerosol worker sample, ME 08, RespiCon 100 µm
AEA04-AS-08-RES-02	Aerosol worker sample, ME 08, RespiCon 10 µm
AEA04-AS-08-RES-03	Aerosol worker sample, ME 08, RespiCon 2.5 µm
AEA04-AS-09-ID-LA	Aerosol worker sample, ME 09, inner dosimeter, lower arms
AEA04-AS-09-ID-UA	Aerosol worker sample, ME 09, inner dosimeter, upper arms
AEA04-AS-09-ID-FT	Aerosol worker sample, ME 09, inner dosimeter, front torso
AEA04-AS-09-ID-RT	Aerosol worker sample, ME 09, inner dosimeter, rear torso
AEA04-AS-09-ID-LL	Aerosol worker sample, ME 09, inner dosimeter, lower legs
AEA04-AS-09-ID-UL	Aerosol worker sample, ME 09, inner dosimeter, upper legs
AEA04-AS-09-OD-LA	Aerosol worker sample, ME 09, outer dosimeter, lower arms
AEA04-AS-09-OD-UA	Aerosol worker sample, ME 09, outer dosimeter, upper arms
AEA04-AS-09-OD-FT	Aerosol worker sample, ME 09, outer dosimeter, front torso
AEA04-AS-09-OD-RT	Aerosol worker sample, ME 09, outer dosimeter, rear torso
AEA04-AS-09-OD-LL	Aerosol worker sample, ME 09, outer dosimeter, lower legs
AEA04-AS-09-OD-UL	Aerosol worker sample, ME 09, outer dosimeter, upper legs
AEA04-AS-09-AR-01	Aerosol worker sample, ME 09, air sampling tube
AEA04-AS-09-FW-01	Aerosol worker sample, ME 09, face/neck wipes
AEA04-AS-09-HW-01	Aerosol worker sample, ME 09, 1st interim hand wash
AEA04-AS-09-HW-02	Aerosol worker sample, ME 09, 2nd interim hand wash
AEA04-AS-09-HW-03	Aerosol worker sample, ME 09, 3rd interim hand wash
AEA04-AS-09-HW-04	Aerosol worker sample, ME 09, 4th interim hand wash
AEA04-AS-09-HW-xx	Aerosol worker sample, ME 09, final hand wash
AEA04-AS-09-RES-01	Aerosol worker sample, ME 09, RespiCon 100 µm
AEA04-AS-09-RES-02	Aerosol worker sample, ME 09, RespiCon 10 µm
AEA04-AS-09-RES-03	Aerosol worker sample, ME 09, RespiCon 2.5 µm
AEA04-AS-10-ID-LA	Aerosol worker sample, ME 10, inner dosimeter, lower arms
AEA04-AS-10-ID-UA	Aerosol worker sample, ME 10, inner dosimeter, upper arms
AEA04-AS-10-ID-FT	Aerosol worker sample, ME 10, inner dosimeter, front torso
AEA04-AS-10-ID-RT	Aerosol worker sample, ME 10, inner dosimeter, rear torso
AEA04-AS-10-ID-LL	Aerosol worker sample, ME 10, inner dosimeter, lower legs
AEA04-AS-10-ID-UL	Aerosol worker sample, ME 10, inner dosimeter, upper legs
AEA04-AS-10-OD-LA	Aerosol worker sample, ME 10, outer dosimeter, lower arms
AEA04-AS-10-OD-UA	Aerosol worker sample, ME 10, outer dosimeter, upper arms
AEA04-AS-10-OD-FT	Aerosol worker sample, ME 10, outer dosimeter, front torso

Exposure Samples (continued)

Sample ID Number	Description
AEA04-AS-10-OD-RT	Aerosol worker sample, ME 10, outer dosimeter, rear torso
AEA04-AS-10-OD-LL	Aerosol worker sample, ME 10, outer dosimeter, lower legs
AEA04-AS-10-OD-UL	Aerosol worker sample, ME 10, outer dosimeter, upper legs
AEA04-AS-10-AR-01	Aerosol worker sample, ME 10, air sampling tube
AEA04-AS-10-FW-01	Aerosol worker sample, ME 10, face/neck wipes
AEA04-AS-10-HW-01	Aerosol worker sample, ME 10, 1st interim hand wash
AEA04-AS-10-HW-02	Aerosol worker sample, ME 10, 2nd interim hand wash
AEA04-AS-10-HW-03	Aerosol worker sample, ME 10, 3rd interim hand wash
AEA04-AS-10-HW-04	Aerosol worker sample, ME 10, 4th interim hand wash
AEA04-AS-10-HW-xx	Aerosol worker sample, ME 10, final hand wash
AEA04-AS-10-RES-01	Aerosol worker sample, ME 10, RespiCon 100 µm
AEA04-AS-10-RES-02	Aerosol worker sample, ME 10, RespiCon 10 µm
AEA04-AS-10-RES-03	Aerosol worker sample, ME 10, RespiCon 2.5 µm
AEA04-AS-11-ID-LA	Aerosol worker sample, ME 11, inner dosimeter, lower arms
AEA04-AS-11-ID-UA	Aerosol worker sample, ME 11, inner dosimeter, upper arms
AEA04-AS-11-ID-FT	Aerosol worker sample, ME 11, inner dosimeter, front torso
AEA04-AS-11-ID-RT	Aerosol worker sample, ME 11, inner dosimeter, rear torso
AEA04-AS-11-ID-LL	Aerosol worker sample, ME 11, inner dosimeter, lower legs
AEA04-AS-11-ID-UL	Aerosol worker sample, ME 11, inner dosimeter, upper legs
AEA04-AS-11-OD-LA	Aerosol worker sample, ME 11, outer dosimeter, lower arms
AEA04-AS-11-OD-UA	Aerosol worker sample, ME 11, outer dosimeter, upper arms
AEA04-AS-11-OD-FT	Aerosol worker sample, ME 11, outer dosimeter, front torso
AEA04-AS-11-OD-RT	Aerosol worker sample, ME 11, outer dosimeter, rear torso
AEA04-AS-11-OD-LL	Aerosol worker sample, ME 11, outer dosimeter, lower legs
AEA04-AS-11-OD-UL	Aerosol worker sample, ME 11, outer dosimeter, upper legs
AEA04-AS-11-AR-01	Aerosol worker sample, ME 11, air sampling tube
AEA04-AS-11-FW-01	Aerosol worker sample, ME 11, face/neck wipes
AEA04-AS-11-HW-01	Aerosol worker sample, ME 11, 1st interim hand wash
AEA04-AS-11-HW-02	Aerosol worker sample, ME 11, 2nd interim hand wash
AEA04-AS-11-HW-03	Aerosol worker sample, ME 11, 3rd interim hand wash
AEA04-AS-11-HW-04	Aerosol worker sample, ME 11, 4th interim hand wash
AEA04-AS-11-HW-xx	Aerosol worker sample, ME 11, final hand wash
AEA04-AS-11-RES-01	Aerosol worker sample, ME 11, RespiCon 100 µm
AEA04-AS-11-RES-02	Aerosol worker sample, ME 11, RespiCon 10 µm
AEA04-AS-11-RES-03	Aerosol worker sample, ME 11, RespiCon 2.5 µm
AEA04-AS-12-ID-LA	Aerosol worker sample, ME 12, inner dosimeter, lower arms
AEA04-AS-12-ID-UA	Aerosol worker sample, ME 12, inner dosimeter, upper arms
AEA04-AS-12-ID-FT	Aerosol worker sample, ME 12, inner dosimeter, front torso
AEA04-AS-12-ID-RT	Aerosol worker sample, ME 12, inner dosimeter, rear torso
AEA04-AS-12-ID-LL	Aerosol worker sample, ME 12, inner dosimeter, lower legs
AEA04-AS-12-ID-UL	Aerosol worker sample, ME 12, inner dosimeter, upper legs

Exposure Samples (continued)

Sample ID Number	Description
AEA04-AS-12-OD-LA	Aerosol worker sample, ME 12, outer dosimeter, lower arms
AEA04-AS-12-OD-UA	Aerosol worker sample, ME 12, outer dosimeter, upper arms
AEA04-AS-12-OD-FT	Aerosol worker sample, ME 12, outer dosimeter, front torso
AEA04-AS-12-OD-RT	Aerosol worker sample, ME 12, outer dosimeter, rear torso
AEA04-AS-12-OD-LL	Aerosol worker sample, ME 12, outer dosimeter, lower legs
AEA04-AS-12-OD-UL	Aerosol worker sample, ME 12, outer dosimeter, upper legs
AEA04-AS-12-AR-01	Aerosol worker sample, ME 12, air sampling tube
AEA04-AS-12-FW-01	Aerosol worker sample, ME 12, face/neck wipes
AEA04-AS-12-HW-01	Aerosol worker sample, ME 12, 1st interim hand wash
AEA04-AS-12-HW-02	Aerosol worker sample, ME 12, 2nd interim hand wash
AEA04-AS-12-HW-03	Aerosol worker sample, ME 12, 3rd interim hand wash
AEA04-AS-12-HW-04	Aerosol worker sample, ME 12, 4th interim hand wash
AEA04-AS-12-HW-xx	Aerosol worker sample, ME 12, final hand wash
AEA04-AS-12-RES-01	Aerosol worker sample, ME 12, RespiCon 100 µm
AEA04-AS-12-RES-02	Aerosol worker sample, ME 12, RespiCon 10 µm
AEA04-AS-12-RES-03	Aerosol worker sample, ME 12, RespiCon 2.5 µm
AEA04-AS-13-ID-LA	Aerosol worker sample, ME 13, inner dosimeter, lower arms
AEA04-AS-13-ID-UA	Aerosol worker sample, ME 13, inner dosimeter, upper arms
AEA04-AS-13-ID-FT	Aerosol worker sample, ME 13, inner dosimeter, front torso
AEA04-AS-13-ID-RT	Aerosol worker sample, ME 13, inner dosimeter, rear torso
AEA04-AS-13-ID-LL	Aerosol worker sample, ME 13, inner dosimeter, lower legs
AEA04-AS-13-ID-UL	Aerosol worker sample, ME 13, inner dosimeter, upper legs
AEA04-AS-13-OD-LA	Aerosol worker sample, ME 13, outer dosimeter, lower arms
AEA04-AS-13-OD-UA	Aerosol worker sample, ME 13, outer dosimeter, upper arms
AEA04-AS-13-OD-FT	Aerosol worker sample, ME 13, outer dosimeter, front torso
AEA04-AS-13-OD-RT	Aerosol worker sample, ME 13, outer dosimeter, rear torso
AEA04-AS-13-OD-LL	Aerosol worker sample, ME 13, outer dosimeter, lower legs
AEA04-AS-13-OD-UL	Aerosol worker sample, ME 13, outer dosimeter, upper legs
AEA04-AS-13-AR-01	Aerosol worker sample, ME 13, air sampling tube
AEA04-AS-13-FW-01	Aerosol worker sample, ME 13, face/neck wipes
AEA04-AS-13-HW-01	Aerosol worker sample, ME 13, 1st interim hand wash
AEA04-AS-13-HW-02	Aerosol worker sample, ME 13, 2nd interim hand wash
AEA04-AS-13-HW-03	Aerosol worker sample, ME 13, 3rd interim hand wash
AEA04-AS-13-HW-04	Aerosol worker sample, ME 13, 4th interim hand wash
AEA04-AS-13-HW-xx	Aerosol worker sample, ME 13, final hand wash
AEA04-AS-13-RES-01	Aerosol worker sample, ME 13, RespiCon 100 µm
AEA04-AS-13-RES-02	Aerosol worker sample, ME 13, RespiCon 10 µm
AEA04-AS-13-RES-03	Aerosol worker sample, ME 13, RespiCon 2.5 µm
AEA04-AS-14-ID-LA	Aerosol worker sample, ME 14, inner dosimeter, lower arms
AEA04-AS-14-ID-UA	Aerosol worker sample, ME 14, inner dosimeter, upper arms
AEA04-AS-14-ID-FT	Aerosol worker sample, ME 14, inner dosimeter, front torso

Exposure Samples (continued)

Sample ID Number	Description
AEA04-AS-14-ID-RT	Aerosol worker sample, ME 14, inner dosimeter, rear torso
AEA04-AS-14-ID-LL	Aerosol worker sample, ME 14, inner dosimeter, lower legs
AEA04-AS-14-ID-UL	Aerosol worker sample, ME 14, inner dosimeter, upper legs
AEA04-AS-14-OD-LA	Aerosol worker sample, ME 14, outer dosimeter, lower arms
AEA04-AS-14-OD-UA	Aerosol worker sample, ME 14, outer dosimeter, upper arms
AEA04-AS-14-OD-FT	Aerosol worker sample, ME 14, outer dosimeter, front torso
AEA04-AS-14-OD-RT	Aerosol worker sample, ME 14, outer dosimeter, rear torso
AEA04-AS-14-OD-LL	Aerosol worker sample, ME 14, outer dosimeter, lower legs
AEA04-AS-14-OD-UL	Aerosol worker sample, ME 14, outer dosimeter, upper legs
AEA04-AS-14-AR-01	Aerosol worker sample, ME 14, air sampling tube
AEA04-AS-14-FW-01	Aerosol worker sample, ME 14, face/neck wipes
AEA04-AS-14-HW-01	Aerosol worker sample, ME 14, 1st interim hand wash
AEA04-AS-14-HW-02	Aerosol worker sample, ME 14, 2nd interim hand wash
AEA04-AS-14-HW-03	Aerosol worker sample, ME 14, 3rd interim hand wash
AEA04-AS-14-HW-04	Aerosol worker sample, ME 14, 4th interim hand wash
AEA04-AS-14-HW-xx	Aerosol worker sample, ME 14, final hand wash
AEA04-AS-14-RES-01	Aerosol worker sample, ME 14, RespiCon 100 µm
AEA04-AS-14-RES-02	Aerosol worker sample, ME 14, RespiCon 10 µm
AEA04-AS-14-RES-03	Aerosol worker sample, ME 14, RespiCon 2.5 µm
AEA04-AS-15-ID-LA	Aerosol worker sample, ME 15, inner dosimeter, lower arms
AEA04-AS-15-ID-UA	Aerosol worker sample, ME 15, inner dosimeter, upper arms
AEA04-AS-15-ID-FT	Aerosol worker sample, ME 15, inner dosimeter, front torso
AEA04-AS-15-ID-RT	Aerosol worker sample, ME 15, inner dosimeter, rear torso
AEA04-AS-15-ID-LL	Aerosol worker sample, ME 15, inner dosimeter, lower legs
AEA04-AS-15-ID-UL	Aerosol worker sample, ME 15, inner dosimeter, upper legs
AEA04-AS-15-OD-LA	Aerosol worker sample, ME 15, outer dosimeter, lower arms
AEA04-AS-15-OD-UA	Aerosol worker sample, ME 15, outer dosimeter, upper arms
AEA04-AS-15-OD-FT	Aerosol worker sample, ME 15, outer dosimeter, front torso
AEA04-AS-15-OD-RT	Aerosol worker sample, ME 15, outer dosimeter, rear torso
AEA04-AS-15-OD-LL	Aerosol worker sample, ME 15, outer dosimeter, lower legs
AEA04-AS-15-OD-UL	Aerosol worker sample, ME 15, outer dosimeter, upper legs
AEA04-AS-15-AR-01	Aerosol worker sample, ME 15, air sampling tube
AEA04-AS-15-FW-01	Aerosol worker sample, ME 15, face/neck wipes
AEA04-AS-15-HW-01	Aerosol worker sample, ME 15, 1st interim hand wash
AEA04-AS-15-HW-02	Aerosol worker sample, ME 15, 2nd interim hand wash
AEA04-AS-15-HW-03	Aerosol worker sample, ME 15, 3rd interim hand wash
AEA04-AS-15-HW-04	Aerosol worker sample, ME 15, 4th interim hand wash
AEA04-AS-15-HW-xx	Aerosol worker sample, ME 15, final hand wash
AEA04-AS-15-RES-01	Aerosol worker sample, ME 15, RespiCon 100 µm
AEA04-AS-15-RES-02	Aerosol worker sample, ME 15, RespiCon 10 µm
AEA04-AS-15-RES-03	Aerosol worker sample, ME 15, RespiCon 2.5 µm

Exposure Samples (continued)

Sample ID Number	Description
AEA04-AS-16-ID-LA	Aerosol worker sample, ME 16, inner dosimeter, lower arms
AEA04-AS-16-ID-UA	Aerosol worker sample, ME 16, inner dosimeter, upper arms
AEA04-AS-16-ID-FT	Aerosol worker sample, ME 16, inner dosimeter, front torso
AEA04-AS-16-ID-RT	Aerosol worker sample, ME 16, inner dosimeter, rear torso
AEA04-AS-16-ID-LL	Aerosol worker sample, ME 16, inner dosimeter, lower legs
AEA04-AS-16-ID-UL	Aerosol worker sample, ME 16, inner dosimeter, upper legs
AEA04-AS-16-OD-LA	Aerosol worker sample, ME 16, outer dosimeter, lower arms
AEA04-AS-16-OD-UA	Aerosol worker sample, ME 16, outer dosimeter, upper arms
AEA04-AS-16-OD-FT	Aerosol worker sample, ME 16, outer dosimeter, front torso
AEA04-AS-16-OD-RT	Aerosol worker sample, ME 16, outer dosimeter, rear torso
AEA04-AS-16-OD-LL	Aerosol worker sample, ME 16, outer dosimeter, lower legs
AEA04-AS-16-OD-UL	Aerosol worker sample, ME 16, outer dosimeter, upper legs
AEA04-AS-16-AR-01	Aerosol worker sample, ME 16, air sampling tube
AEA04-AS-16-FW-01	Aerosol worker sample, ME 16, face/neck wipes
AEA04-AS-16-HW-01	Aerosol worker sample, ME 16, 1st interim hand wash
AEA04-AS-16-HW-02	Aerosol worker sample, ME 16, 2nd interim hand wash
AEA04-AS-16-HW-03	Aerosol worker sample, ME 16, 3rd interim hand wash
AEA04-AS-16-HW-04	Aerosol worker sample, ME 16, 4th interim hand wash
AEA04-AS-16-HW-xx	Aerosol worker sample, ME 16, final hand wash
AEA04-AS-16-RES-01	Aerosol worker sample, ME 16, RespiCon 100 µm
AEA04-AS-16-RES-02	Aerosol worker sample, ME 16, RespiCon 10 µm
AEA04-AS-16-RES-03	Aerosol worker sample, ME 16, RespiCon 2.5 µm
AEA04-AS-17-ID-LA	Aerosol worker sample, ME 17, inner dosimeter, lower arms
AEA04-AS-17-ID-UA	Aerosol worker sample, ME 17, inner dosimeter, upper arms
AEA04-AS-17-ID-FT	Aerosol worker sample, ME 17, inner dosimeter, front torso
AEA04-AS-17-ID-RT	Aerosol worker sample, ME 17, inner dosimeter, rear torso
AEA04-AS-17-ID-LL	Aerosol worker sample, ME 17, inner dosimeter, lower legs
AEA04-AS-17-ID-UL	Aerosol worker sample, ME 17, inner dosimeter, upper legs
AEA04-AS-17-OD-LA	Aerosol worker sample, ME 17, outer dosimeter, lower arms
AEA04-AS-17-OD-UA	Aerosol worker sample, ME 17, outer dosimeter, upper arms
AEA04-AS-17-OD-FT	Aerosol worker sample, ME 17, outer dosimeter, front torso
AEA04-AS-17-OD-RT	Aerosol worker sample, ME 17, outer dosimeter, rear torso
AEA04-AS-17-OD-LL	Aerosol worker sample, ME 17, outer dosimeter, lower legs
AEA04-AS-17-OD-UL	Aerosol worker sample, ME 17, outer dosimeter, upper legs
AEA04-AS-17-AR-01	Aerosol worker sample, ME 17, air sampling tube
AEA04-AS-17-FW-01	Aerosol worker sample, ME 17, face/neck wipes
AEA04-AS-17-HW-01	Aerosol worker sample, ME 17, 1st interim hand wash
AEA04-AS-17-HW-02	Aerosol worker sample, ME 17, 2nd interim hand wash
AEA04-AS-17-HW-03	Aerosol worker sample, ME 17, 3rd interim hand wash
AEA04-AS-17-HW-04	Aerosol worker sample, ME 17, 4th interim hand wash
AEA04-AS-17-HW-xx	Aerosol worker sample, ME 17, final hand wash

Exposure Samples (continued)

Sample ID Number	Description
AEA04-AS-17-RES-01	Aerosol worker sample, ME 17, RespiCon 100 µm
AEA04-AS-17-RES-02	Aerosol worker sample, ME 17, RespiCon 10 µm
AEA04-AS-17-RES-03	Aerosol worker sample, ME 17, RespiCon 2.5 µm
AEA04-AS-18-ID-LA	Aerosol worker sample, ME 18, inner dosimeter, lower arms
AEA04-AS-18-ID-UA	Aerosol worker sample, ME 18, inner dosimeter, upper arms
AEA04-AS-18-ID-FT	Aerosol worker sample, ME 18, inner dosimeter, front torso
AEA04-AS-18-ID-RT	Aerosol worker sample, ME 18, inner dosimeter, rear torso
AEA04-AS-18-ID-LL	Aerosol worker sample, ME 18, inner dosimeter, lower legs
AEA04-AS-18-ID-UL	Aerosol worker sample, ME 18, inner dosimeter, upper legs
AEA04-AS-18-OD-LA	Aerosol worker sample, ME 18, outer dosimeter, lower arms
AEA04-AS-18-OD-UA	Aerosol worker sample, ME 18, outer dosimeter, upper arms
AEA04-AS-18-OD-FT	Aerosol worker sample, ME 18, outer dosimeter, front torso
AEA04-AS-18-OD-RT	Aerosol worker sample, ME 18, outer dosimeter, rear torso
AEA04-AS-18-OD-LL	Aerosol worker sample, ME 18, outer dosimeter, lower legs
AEA04-AS-18-OD-UL	Aerosol worker sample, ME 18, outer dosimeter, upper legs
AEA04-AS-18-AR-01	Aerosol worker sample, ME 18, air sampling tube
AEA04-AS-18-FW-01	Aerosol worker sample, ME 18, face/neck wipes
AEA04-AS-18-HW-01	Aerosol worker sample, ME 18, 1st interim hand wash
AEA04-AS-18-HW-02	Aerosol worker sample, ME 18, 2nd interim hand wash
AEA04-AS-18-HW-03	Aerosol worker sample, ME 18, 3rd interim hand wash
AEA04-AS-18-HW-04	Aerosol worker sample, ME 18, 4th interim hand wash
AEA04-AS-18-HW-xx	Aerosol worker sample, ME 18, final hand wash
AEA04-AS-18-RES-01	Aerosol worker sample, ME 18, RespiCon 100 µm
AEA04-AS-18-RES-02	Aerosol worker sample, ME 18, RespiCon 10 µm
AEA04-AS-18-RES-03	Aerosol worker sample, ME 18, RespiCon 2.5 µm
AEA04-AS-19-ID-LA	Aerosol worker sample, ME 19, inner dosimeter, lower arms
AEA04-AS-19-ID-UA	Aerosol worker sample, ME 19, inner dosimeter, upper arms
AEA04-AS-19-ID-FT	Aerosol worker sample, ME 19, inner dosimeter, front torso
AEA04-AS-19-ID-RT	Aerosol worker sample, ME 19, inner dosimeter, rear torso
AEA04-AS-19-ID-LL	Aerosol worker sample, ME 19, inner dosimeter, lower legs
AEA04-AS-19-ID-UL	Aerosol worker sample, ME 19, inner dosimeter, upper legs
AEA04-AS-19-OD-LA	Aerosol worker sample, ME 19, outer dosimeter, lower arms
AEA04-AS-19-OD-UA	Aerosol worker sample, ME 19, outer dosimeter, upper arms
AEA04-AS-19-OD-FT	Aerosol worker sample, ME 19, outer dosimeter, front torso
AEA04-AS-19-OD-RT	Aerosol worker sample, ME 19, outer dosimeter, rear torso
AEA04-AS-19-OD-LL	Aerosol worker sample, ME 19, outer dosimeter, lower legs
AEA04-AS-19-OD-UL	Aerosol worker sample, ME 19, outer dosimeter, upper legs
AEA04-AS-19-AR-01	Aerosol worker sample, ME 19, air sampling tube
AEA04-AS-19-FW-01	Aerosol worker sample, ME 19, face/neck wipes
AEA04-AS-19-HW-01	Aerosol worker sample, ME 19, 1st interim hand wash

Exposure Samples (continued)

Sample ID Number	Description
AEA04-AS-19-HW-02	Aerosol worker sample, ME 19, 2nd interim hand wash
AEA04-AS-19-HW-03	Aerosol worker sample, ME 19, 3rd interim hand wash
AEA04-AS-19-HW-04	Aerosol worker sample, ME 19, 4th interim hand wash
AEA04-AS-19-HW-xx	Aerosol worker sample, ME 19, final hand wash
AEA04-AS-19-RES-01	Aerosol worker sample, ME 19, RespiCon 100 µm
AEA04-AS-19-RES-02	Aerosol worker sample, ME 19, RespiCon 10 µm
AEA04-AS-19-RES-03	Aerosol worker sample, ME 19, RespiCon 2.5 µm
AEA04-AS-20-ID-LA	Aerosol worker sample, ME 20, inner dosimeter, lower arms
AEA04-AS-20-ID-UA	Aerosol worker sample, ME 20, inner dosimeter, upper arms
AEA04-AS-20-ID-FT	Aerosol worker sample, ME 20, inner dosimeter, front torso
AEA04-AS-20-ID-RT	Aerosol worker sample, ME 20, inner dosimeter, rear torso
AEA04-AS-20-ID-LL	Aerosol worker sample, ME 20, inner dosimeter, lower legs
AEA04-AS-20-ID-UL	Aerosol worker sample, ME 20, inner dosimeter, upper legs
AEA04-AS-20-OD-LA	Aerosol worker sample, ME 20, outer dosimeter, lower arms
AEA04-AS-20-OD-UA	Aerosol worker sample, ME 20, outer dosimeter, upper arms
AEA04-AS-20-OD-FT	Aerosol worker sample, ME 20, outer dosimeter, front torso
AEA04-AS-20-OD-RT	Aerosol worker sample, ME 20, outer dosimeter, rear torso
AEA04-AS-20-OD-LL	Aerosol worker sample, ME 20, outer dosimeter, lower legs
AEA04-AS-20-OD-UL	Aerosol worker sample, ME 20, outer dosimeter, upper legs
AEA04-AS-20-AR-01	Aerosol worker sample, ME 20, air sampling tube
AEA04-AS-20-FW-01	Aerosol worker sample, ME 20, face/neck wipes
AEA04-AS-20-HW-01	Aerosol worker sample, ME 20, 1st interim hand wash
AEA04-AS-20-HW-02	Aerosol worker sample, ME 20, 2nd interim hand wash
AEA04-AS-20-HW-03	Aerosol worker sample, ME 20, 3rd interim hand wash
AEA04-AS-20-HW-04	Aerosol worker sample, ME 20, 4th interim hand wash
AEA04-AS-20-HW-xx	Aerosol worker sample, ME 20, final hand wash
AEA04-AS-20-RES-01	Aerosol worker sample, ME 20, RespiCon 100 µm
AEA04-AS-20-RES-02	Aerosol worker sample, ME 20, RespiCon 10 µm
AEA04-AS-20-RES-03	Aerosol worker sample, ME 20, RespiCon 2.5 µm
AEA04-AS-21-ID-LA	Aerosol worker sample, ME 21, inner dosimeter, lower arms
AEA04-AS-21-ID-UA	Aerosol worker sample, ME 21, inner dosimeter, upper arms
AEA04-AS-21-ID-FT	Aerosol worker sample, ME 21, inner dosimeter, front torso
AEA04-AS-21-ID-RT	Aerosol worker sample, ME 21, inner dosimeter, rear torso
AEA04-AS-21-ID-LL	Aerosol worker sample, ME 21, inner dosimeter, lower legs
AEA04-AS-21-ID-UL	Aerosol worker sample, ME 21, inner dosimeter, upper legs
AEA04-AS-21-OD-LA	Aerosol worker sample, ME 21, outer dosimeter, lower arms
AEA04-AS-21-OD-UA	Aerosol worker sample, ME 21, outer dosimeter, upper arms
AEA04-AS-21-OD-FT	Aerosol worker sample, ME 21, outer dosimeter, front torso
AEA04-AS-21-OD-RT	Aerosol worker sample, ME 21, outer dosimeter, rear torso
AEA04-AS-21-OD-LL	Aerosol worker sample, ME 21, outer dosimeter, lower legs
AEA04-AS-21-OD-UL	Aerosol worker sample, ME 21, outer dosimeter, upper legs

Exposure Samples (continued)

Sample ID Number	Description
AEA04-AS-21-AR-01	Aerosol worker sample, ME 21, air sampling tube
AEA04-AS-21-FW-01	Aerosol worker sample, ME 21, face/neck wipes
AEA04-AS-21-HW-01	Aerosol worker sample, ME 21, 1st interim hand wash
AEA04-AS-21-HW-02	Aerosol worker sample, ME 21, 2nd interim hand wash
AEA04-AS-21-HW-03	Aerosol worker sample, ME 21, 3rd interim hand wash
AEA04-AS-21-HW-04	Aerosol worker sample, ME 21, 4th interim hand wash
AEA04-AS-21-HW-xx	Aerosol worker sample, ME 21, final hand wash
AEA04-AS-21-RES-01	Aerosol worker sample, ME 21, RespiCon 100 µm
AEA04-AS-21-RES-02	Aerosol worker sample, ME 21, RespiCon 10 µm
AEA04-AS-21-RES-03	Aerosol worker sample, ME 21, RespiCon 2.5 µm
AEA04-AS-22-ID-LA	Aerosol worker sample, ME 22, inner dosimeter, lower arms
AEA04-AS-22-ID-UA	Aerosol worker sample, ME 22, inner dosimeter, upper arms
AEA04-AS-22-ID-FT	Aerosol worker sample, ME 22, inner dosimeter, front torso
AEA04-AS-22-ID-RT	Aerosol worker sample, ME 22, inner dosimeter, rear torso
AEA04-AS-22-ID-LL	Aerosol worker sample, ME 22, inner dosimeter, lower legs
AEA04-AS-22-ID-UL	Aerosol worker sample, ME 22, inner dosimeter, upper legs
AEA04-AS-22-OD-LA	Aerosol worker sample, ME 22, outer dosimeter, lower arms
AEA04-AS-22-OD-UA	Aerosol worker sample, ME 22, outer dosimeter, upper arms
AEA04-AS-22-OD-FT	Aerosol worker sample, ME 22, outer dosimeter, front torso
AEA04-AS-22-OD-RT	Aerosol worker sample, ME 22, outer dosimeter, rear torso
AEA04-AS-22-OD-LL	Aerosol worker sample, ME 22, outer dosimeter, lower legs
AEA04-AS-22-OD-UL	Aerosol worker sample, ME 22, outer dosimeter, upper legs
AEA04-AS-22-AR-01	Aerosol worker sample, ME 22, air sampling tube
AEA04-AS-22-FW-01	Aerosol worker sample, ME 22, face/neck wipes
AEA04-AS-22-HW-01	Aerosol worker sample, ME 22, 1st interim hand wash
AEA04-AS-22-HW-02	Aerosol worker sample, ME 22, 2nd interim hand wash
AEA04-AS-22-HW-03	Aerosol worker sample, ME 22, 3rd interim hand wash
AEA04-AS-22-HW-04	Aerosol worker sample, ME 22, 4th interim hand wash
AEA04-AS-22-HW-xx	Aerosol worker sample, ME 22, final hand wash
AEA04-AS-22-RES-01	Aerosol worker sample, ME 22, RespiCon 100 µm
AEA04-AS-22-RES-02	Aerosol worker sample, ME 22, RespiCon 10 µm
AEA04-AS-22-RES-03	Aerosol worker sample, ME 22, RespiCon 2.5 µm
AEA04-AS-23-ID-LA	Aerosol worker sample, ME 23, inner dosimeter, lower arms
AEA04-AS-23-ID-UA	Aerosol worker sample, ME 23, inner dosimeter, upper arms
AEA04-AS-23-ID-FT	Aerosol worker sample, ME 23, inner dosimeter, front torso
AEA04-AS-23-ID-RT	Aerosol worker sample, ME 23, inner dosimeter, rear torso
AEA04-AS-23-ID-LL	Aerosol worker sample, ME 23, inner dosimeter, lower legs
AEA04-AS-23-ID-UL	Aerosol worker sample, ME 23, inner dosimeter, upper legs
AEA04-AS-23-OD-LA	Aerosol worker sample, ME 23, outer dosimeter, lower arms
AEA04-AS-23-OD-UA	Aerosol worker sample, ME 23, outer dosimeter, upper arms
AEA04-AS-23-OD-FT	Aerosol worker sample, ME 23, outer dosimeter, front torso

Exposure Samples (continued)

Sample ID Number	Description
AEA04-AS-23-OD-RT	Aerosol worker sample, ME 23, outer dosimeter, rear torso
AEA04-AS-23-OD-LL	Aerosol worker sample, ME 23, outer dosimeter, lower legs
AEA04-AS-23-OD-UL	Aerosol worker sample, ME 23, outer dosimeter, upper legs
AEA04-AS-23-AR-01	Aerosol worker sample, ME 23, air sampling tube
AEA04-AS-23-FW-01	Aerosol worker sample, ME 23, face/neck wipes
AEA04-AS-23-HW-01	Aerosol worker sample, ME 23, 1st interim hand wash
AEA04-AS-23-HW-02	Aerosol worker sample, ME 23, 2nd interim hand wash
AEA04-AS-23-HW-03	Aerosol worker sample, ME 23, 3rd interim hand wash
AEA04-AS-23-HW-04	Aerosol worker sample, ME 23, 4th interim hand wash
AEA04-AS-23-HW-xx	Aerosol worker sample, ME 23, final hand wash
AEA04-AS-23-RES-01	Aerosol worker sample, ME 23, RespiCon 100 µm
AEA04-AS-23-RES-02	Aerosol worker sample, ME 23, RespiCon 10 µm
AEA04-AS-23-RES-03	Aerosol worker sample, ME 23, RespiCon 2.5 µm
AEA04-AS-24-ID-LA	Aerosol worker sample, ME 24, inner dosimeter, lower arms
AEA04-AS-24-ID-UA	Aerosol worker sample, ME 24, inner dosimeter, upper arms
AEA04-AS-24-ID-FT	Aerosol worker sample, ME 24, inner dosimeter, front torso
AEA04-AS-24-ID-RT	Aerosol worker sample, ME 24, inner dosimeter, rear torso
AEA04-AS-24-ID-LL	Aerosol worker sample, ME 24, inner dosimeter, lower legs
AEA04-AS-24-ID-UL	Aerosol worker sample, ME 24, inner dosimeter, upper legs
AEA04-AS-24-OD-LA	Aerosol worker sample, ME 24, outer dosimeter, lower arms
AEA04-AS-24-OD-UA	Aerosol worker sample, ME 24, outer dosimeter, upper arms
AEA04-AS-24-OD-FT	Aerosol worker sample, ME 24, outer dosimeter, front torso
AEA04-AS-24-OD-RT	Aerosol worker sample, ME 24, outer dosimeter, rear torso
AEA04-AS-24-OD-LL	Aerosol worker sample, ME 24, outer dosimeter, lower legs
AEA04-AS-24-OD-UL	Aerosol worker sample, ME 24, outer dosimeter, upper legs
AEA04-AS-24-AR-01	Aerosol worker sample, ME 24, air sampling tube
AEA04-AS-24-FW-01	Aerosol worker sample, ME 24, face/neck wipes
AEA04-AS-24-HW-01	Aerosol worker sample, ME 24, 1st interim hand wash
AEA04-AS-24-HW-02	Aerosol worker sample, ME 24, 2nd interim hand wash
AEA04-AS-24-HW-03	Aerosol worker sample, ME 24, 3rd interim hand wash
AEA04-AS-24-HW-04	Aerosol worker sample, ME 24, 4th interim hand wash
AEA04-AS-24-HW-xx	Aerosol worker sample, ME 24, final hand wash
AEA04-AS-24-RES-01	Aerosol worker sample, ME 24, RespiCon 100 µm
AEA04-AS-24-RES-02	Aerosol worker sample, ME 24, RespiCon 10 µm
AEA04-AS-24-RES-03	Aerosol worker sample, ME 24, RespiCon 2.5 µm
AEA04-FF-01-AR-L1	Fortification sample, Day 01, air sampling tube, 1st low level
AEA04-FF-01-AR-L2	Fortification sample, Day 01, air sampling tube, 2nd low level
AEA04-FF-01-AR-L3	Fortification sample, Day 01, air sampling tube, 3rd low level
AEA04-FF-01-AR-H1	Fortification sample, Day 01, air sampling tube, 1st high level
AEA04-FF-01-AR-H2	Fortification sample, Day 01, air sampling tube, 2nd high level
AEA04-FF-01-AR-H3	Fortification sample, Day 01, air sampling tube, 3rd high level

Exposure Samples (continued)

Sample ID Number	Description
AEA04-FF-01-RS-L1	Fortification sample, Day 01, RespiCon filter, 1st low level
AEA04-FF-01-RS-L2	Fortification sample, Day 01, RespiCon filter, 2nd low level
AEA04-FF-01-RS-L3	Fortification sample, Day 01, RespiCon filter, 3rd low level
AEA04-FF-01-RS-H1	Fortification sample, Day 01, RespiCon filter, 1st high level
AEA04-FF-01-RS-H2	Fortification sample, Day 01, RespiCon filter, 2nd high level
AEA04-FF-01-RS-H3	Fortification sample, Day 01, RespiCon filter, 3rd high level
AEA04-FF-01-HW-L1	Fortification sample, Day 01, hand wash, 1st low level
AEA04-FF-01-HW-L2	Fortification sample, Day 01, hand wash, 2nd low level
AEA04-FF-01-HW-L3	Fortification sample, Day 01, hand wash, 3rd low level
AEA04-FF-01-HW-H1	Fortification sample, Day 01, hand wash, 1st high level
AEA04-FF-01-HW-H2	Fortification sample, Day 01, hand wash, 2nd high level
AEA04-FF-01-HW-H3	Fortification sample, Day 01, hand wash, 3rd high level
AEA04-FF-01-FW-L1	Fortification sample, Day 01, face/neck wipe, 1st low level
AEA04-FF-01-FW-L2	Fortification sample, Day 01, face/neck wipe, 2nd low level
AEA04-FF-01-FW-L3	Fortification sample, Day 01, face/neck wipe, 3rd low level
AEA04-FF-01-FW-H1	Fortification sample, Day 01, face/neck wipe, 1st high level
AEA04-FF-01-FW-H2	Fortification sample, Day 01, face/neck wipe, 2nd high level
AEA04-FF-01-FW-H3	Fortification sample, Day 01, face/neck wipe, 3rd high level
AEA04-FF-01-ID-L1	Fortification sample, Day 01, inner dosimeter, 1st low level
AEA04-FF-01-ID-L2	Fortification sample, Day 01, inner dosimeter, 2nd low level
AEA04-FF-01-ID-L3	Fortification sample, Day 01, inner dosimeter, 3rd low level
AEA04-FF-01-ID-H1	Fortification sample, Day 01, inner dosimeter, 1st high level
AEA04-FF-01-ID-H2	Fortification sample, Day 01, inner dosimeter, 2nd high level
AEA04-FF-01-ID-H3	Fortification sample, Day 01, inner dosimeter, 3rd high level
AEA04-FF-01-OD-L1	Fortification sample, Day 01, outer dosimeter, 1st low level
AEA04-FF-01-OD-L2	Fortification sample, Day 01, outer dosimeter, 2nd low level
AEA04-FF-01-OD-L3	Fortification sample, Day 01, outer dosimeter, 3rd low level
AEA04-FF-01-OD-H1	Fortification sample, Day 01, outer dosimeter, 1st high level
AEA04-FF-01-OD-H2	Fortification sample, Day 01, outer dosimeter, 2nd high level
AEA04-FF-01-OD-H3	Fortification sample, Day 01, outer dosimeter, 3rd high level
AEA04-FF-01-AR-C1	Fortification sample, Day 01, air sampling tube, 1st control
AEA04-FF-01-AR-C2	Fortification sample, Day 01, air sampling tube, 2nd control
AEA04-FF-01-HW-C1	Fortification sample, Day 01, hand wash, 1st control
AEA04-FF-01-HW-C2	Fortification sample, Day 01, hand wash, 2nd control
AEA04-FF-01-FW-C1	Fortification sample, Day 01, face/neck wipe, 1st control
AEA04-FF-01-FW-C2	Fortification sample, Day 01, face/neck wipe, 2nd control
AEA04-FF-01-ID-C1	Fortification sample, Day 01, inner dosimeter, 1st control
AEA04-FF-01-ID-C2	Fortification sample, Day 01, inner dosimeter, 2nd control

Exposure Samples (continued)

Sample ID Number	Description
AEA04-FF-01-OD-C1	Fortification sample, Day 01, outer dosimeter, 1st control
AEA04-FF-01-OD-C2	Fortification sample, Day 01, outer dosimeter, 2nd control
AEA04-FF-01-AR-T1	Fortification sample, Day 01, air sampling tube, 1st travel spike
AEA04-FF-01-AR-T2	Fortification sample, Day 01, air sampling tube, 2nd travel spike
AEA04-FF-01-HW-T1	Fortification sample, Day 01, hand wash, 1st travel spike
AEA04-FF-01-HW-T2	Fortification sample, Day 01, hand wash, 2nd travel spike
AEA04-FF-01-FW-T1	Fortification sample, Day 01, face/neck wipe, 1st travel spike
AEA04-FF-01-FW-T2	Fortification sample, Day 01, face/neck wipe, 2nd travel spike
AEA04-FF-01-ID-T1	Fortification sample, Day 01, inner dosimeter, 1st travel spike
AEA04-FF-01-ID-T2	Fortification sample, Day 01, inner dosimeter, 2nd travel spike
AEA04-FF-01-OD-T1	Fortification sample, Day 01, outer dosimeter, 1st travel spike
AEA04-FF-01-OD-T2	Fortification sample, Day 01, outer dosimeter, 2nd travel spike
AEA02-FF-02-AR-L1	Fortification sample, Day 02, air sampling tube, 1st low level
AEA02-FF-02-AR-L2	Fortification sample, Day 02, air sampling tube, 2nd low level
AEA02-FF-02-AR-L3	Fortification sample, Day 02, air sampling tube, 3rd low level
AEA02-FF-02-AR-H1	Fortification sample, Day 02, air sampling tube, 1st high level
AEA02-FF-02-AR-H2	Fortification sample, Day 02, air sampling tube, 2nd high level
AEA02-FF-02-AR-H3	Fortification sample, Day 02, air sampling tube, 3rd high level
AEA04-FF-02-RS-L1	Fortification sample, Day 02, RespiCon filter, 1st low level
AEA04-FF-02-RS-L2	Fortification sample, Day 02, RespiCon filter, 2nd low level
AEA04-FF-02-RS-L3	Fortification sample, Day 02, RespiCon filter, 3rd low level
AEA04-FF-02-RS-H1	Fortification sample, Day 02, RespiCon filter, 1st high level
AEA04-FF-02-RS-H2	Fortification sample, Day 02, RespiCon filter, 2nd high level
AEA04-FF-02-RS-H3	Fortification sample, Day 02, RespiCon filter, 3rd high level
AEA04-FF-02-HW-L1	Fortification sample, Day 02, hand wash, 1st low level
AEA04-FF-02-HW-L2	Fortification sample, Day 02, hand wash, 2nd low level
AEA04-FF-02-HW-L3	Fortification sample, Day 02, hand wash, 3rd low level
AEA04-FF-02-HW-H1	Fortification sample, Day 02, hand wash, 1st high level
AEA04-FF-02-HW-H2	Fortification sample, Day 02, hand wash, 2nd high level
AEA04-FF-02-HW-H3	Fortification sample, Day 02, hand wash, 3rd high level
AEA04-FF-02-FW-L1	Fortification sample, Day 02, face/neck wipe, 1st low level
AEA04-FF-02-FW-L2	Fortification sample, Day 02, face/neck wipe, 2nd low level
AEA04-FF-02-FW-L3	Fortification sample, Day 02, face/neck wipe, 3rd low level
AEA04-FF-02-FW-H1	Fortification sample, Day 02, face/neck wipe, 1st high level
AEA04-FF-02-FW-H2	Fortification sample, Day 02, face/neck wipe, 2nd high level
AEA04-FF-02-FW-H3	Fortification sample, Day 02, face/neck wipe, 3rd high level

Exposure Samples (continued)

Sample ID Number	Description
AEA04-FF-02-ID-L1	Fortification sample, Day 02, inner dosimeter, 1st low level
AEA04-FF-02-ID-L2	Fortification sample, Day 02, inner dosimeter, 2nd low level
AEA04-FF-02-ID-L3	Fortification sample, Day 02, inner dosimeter, 3rd low level
AEA04-FF-02-ID-H1	Fortification sample, Day 02, inner dosimeter, 1st high level
AEA04-FF-02-ID-H2	Fortification sample, Day 02, inner dosimeter, 2nd high level
AEA04-FF-02-ID-H3	Fortification sample, Day 02, inner dosimeter, 3rd high level
AEA04-FF-02-OD-L1	Fortification sample, Day 02, outer dosimeter, 1st low level
AEA04-FF-02-OD-L2	Fortification sample, Day 02, outer dosimeter, 2nd low level
AEA04-FF-02-OD-L3	Fortification sample, Day 02, outer dosimeter, 3rd low level
AEA04-FF-02-OD-H1	Fortification sample, Day 02, outer dosimeter, 1st high level
AEA04-FF-02-OD-H2	Fortification sample, Day 02, outer dosimeter, 2nd high level
AEA04-FF-02-OD-H3	Fortification sample, Day 02, outer dosimeter, 3rd high level
AEA04-FF-02-AR-C1	Fortification sample, Day 02, air sampling tube, 1st control
AEA04-FF-02-AR-C2	Fortification sample, Day 02, air sampling tube, 2nd control
AEA04-FF-02-HW-C1	Fortification sample, Day 02, hand wash, 1st control
AEA04-FF-02-HW-C2	Fortification sample, Day 02, hand wash, 2nd control
AEA04-FF-02-FW-C1	Fortification sample, Day 02, face/neck wipe, 1st control
AEA04-FF-02-FW-C2	Fortification sample, Day 02, face/neck wipe, 2nd control
AEA04-FF-02-ID-C1	Fortification sample, Day 02, inner dosimeter, 1st control
AEA04-FF-02-ID-C2	Fortification sample, Day 02, inner dosimeter, 2nd control
AEA04-FF-02-OD-C1	Fortification sample, Day 02, outer dosimeter, 1st control
AEA04-FF-02-OD-C2	Fortification sample, Day 02, outer dosimeter, 2nd control
AEA04-FF-02-AR-T1	Fortification sample, Day 02, air sampling tube, 1st travel spike
AEA04-FF-02-AR-T2	Fortification sample, Day 02, air sampling tube, 2nd travel spike
AEA04-FF-02-HW-T1	Fortification sample, Day 02, hand wash, 1st travel spike
AEA04-FF-02-HW-T2	Fortification sample, Day 02, hand wash, 2nd travel spike
AEA04-FF-02-FW-T1	Fortification sample, Day 02, face/neck wipe, 1st travel spike
AEA04-FF-02-FW-T2	Fortification sample, Day 02, face/neck wipe, 2nd travel spike
AEA04-FF-02-ID-T1	Fortification sample, Day 02, inner dosimeter, 1st travel spike
AEA04-FF-02-ID-T2	Fortification sample, Day 02, inner dosimeter, 2nd travel spike
AEA04-FF-02-OD-T1	Fortification sample, Day 02, outer dosimeter, 1st travel spike
AEA04-FF-02-OD-T2	Fortification sample, Day 02, outer dosimeter, 2nd travel spike

Exposure Samples (continued)

Sample ID Number	Description
AEA04-FF-03-AR-L1	Fortification sample, Day 03, air sampling tube, 1st low level
AEA04-FF-03-AR-L2	Fortification sample, Day 03, air sampling tube, 2nd low level
AEA04-FF-03-AR-L3	Fortification sample, Day 03, air sampling tube, 3rd low level
AEA04-FF-03-AR-H1	Fortification sample, Day 03, air sampling tube, 1st high level
AEA04-FF-03-AR-H2	Fortification sample, Day 03, air sampling tube, 2nd high level
AEA04-FF-03-AR-H3	Fortification sample, Day 03, air sampling tube, 3rd high level
AEA04-FF-03-RS-L1	Fortification sample, Day 03, RespiCon filter, 1st low level
AEA04-FF-03-RS-L2	Fortification sample, Day 03, RespiCon filter, 2nd low level
AEA04-FF-03-RS-L3	Fortification sample, Day 03, RespiCon filter, 3rd low level
AEA04-FF-03-RS-H1	Fortification sample, Day 03, RespiCon filter, 1st high level
AEA04-FF-03-RS-H2	Fortification sample, Day 03, RespiCon filter, 2nd high level
AEA04-FF-03-RS-H3	Fortification sample, Day 03, RespiCon filter, 3rd high level
AEA04-FF-03-HW-L1	Fortification sample, Day 03, hand wash, 1st low level
AEA04-FF-03-HW-L2	Fortification sample, Day 03, hand wash, 2nd low level
AEA04-FF-03-HW-L3	Fortification sample, Day 03, hand wash, 3rd low level
AEA04-FF-03-HW-H1	Fortification sample, Day 03, hand wash, 1st high level
AEA04-FF-03-HW-H2	Fortification sample, Day 03, hand wash, 2nd high level
AEA04-FF-03-HW-H3	Fortification sample, Day 03, hand wash, 3rd high level
AEA04-FF-03-FW-L1	Fortification sample, Day 03, face/neck wipe, 1st low level
AEA04-FF-03-FW-L2	Fortification sample, Day 03, face/neck wipe, 2nd low level
AEA04-FF-03-FW-L3	Fortification sample, Day 03, face/neck wipe, 3rd low level
AEA04-FF-03-FW-H1	Fortification sample, Day 03, face/neck wipe, 1st high level
AEA04-FF-03-FW-H2	Fortification sample, Day 03, face/neck wipe, 2nd high level
AEA04-FF-03-FW-H3	Fortification sample, Day 03, face/neck wipe, 3rd high level
AEA04-FF-03-ID-L1	Fortification sample, Day 03, inner dosimeter, 1st low level
AEA04-FF-03-ID-L2	Fortification sample, Day 03, inner dosimeter, 2nd low level
AEA04-FF-03-ID-L3	Fortification sample, Day 03, inner dosimeter, 3rd low level
AEA04-FF-03-ID-H1	Fortification sample, Day 03, inner dosimeter, 1st high level
AEA04-FF-03-ID-H2	Fortification sample, Day 03, inner dosimeter, 2nd high level
AEA04-FF-03-ID-H3	Fortification sample, Day 03, inner dosimeter, 3rd high level
AEA04-FF-03-OD-L1	Fortification sample, Day 03, outer dosimeter, 1st low level
AEA04-FF-03-OD-L2	Fortification sample, Day 03, outer dosimeter, 2nd low level
AEA04-FF-03-OD-L3	Fortification sample, Day 03, outer dosimeter, 3rd low level
AEA04-FF-03-OD-H1	Fortification sample, Day 03, outer dosimeter, 1st high level
AEA04-FF-03-OD-H2	Fortification sample, Day 03, outer dosimeter, 2nd high level
AEA04-FF-03-OD-H3	Fortification sample, Day 03, outer dosimeter, 3rd high level
AEA04-FF-03-AR-C1	Fortification sample, Day 03, air sampling tube, 1st control
AEA04-FF-03-AR-C2	Fortification sample, Day 03, air sampling tube, 2nd control
AEA04-FF-03-HW-C1	Fortification sample, Day 03, hand wash, 1st control
AEA04-FF-03-HW-C2	Fortification sample, Day 03, hand wash, 2nd control

Exposure Samples (continued)

Sample ID Number	Description
AEA04-FF-03-FW-C1	Fortification sample, Day 03, face/neck wipe, 1st control
AEA04-FF-03-FW-C2	Fortification sample, Day 03, face/neck wipe, 2nd control
AEA04-FF-03-ID-C1	Fortification sample, Day 03, inner dosimeter, 1st control
AEA04-FF-03-ID-C2	Fortification sample, Day 03, inner dosimeter, 2nd control
AEA04-FF-03-OD-C1	Fortification sample, Day 03, outer dosimeter, 1st control
AEA04-FF-03-OD-C2	Fortification sample, Day 03, outer dosimeter, 2nd control
AEA04-FF-03-AR-T1	Fortification sample, Day 03, air sampling tube, 1st travel spike
AEA04-FF-03-AR-T2	Fortification sample, Day 03, air sampling tube, 2nd travel spike
AEA04-FF-03-HW-T1	Fortification sample, Day 03, hand wash, 1st travel spike
AEA04-FF-03-HW-T2	Fortification sample, Day 03, hand wash, 2nd travel spike
AEA04-FF-03-FW-T1	Fortification sample, Day 03, face/neck wipe, 1st travel spike
AEA04-FF-03-FW-T2	Fortification sample, Day 03, face/neck wipe, 2nd travel spike
AEA04-FF-03-ID-T1	Fortification sample, Day 03, inner dosimeter, 1st travel spike
AEA04-FF-03-ID-T2	Fortification sample, Day 03, inner dosimeter, 2nd travel spike
AEA04-FF-03-OD-T1	Fortification sample, Day 03, outer dosimeter, 1st travel spike
AEA04-FF-03-OD-T2	Fortification sample, Day 03, outer dosimeter, 2nd travel spike
AEA04-FF-04-AR-L1	Fortification sample, Day 04, air sampling tube, 1st low level
AEA04-FF-04-AR-L2	Fortification sample, Day 04, air sampling tube, 2nd low level
AEA04-FF-04-AR-L3	Fortification sample, Day 04, air sampling tube, 3rd low level
AEA04-FF-04-AR-H1	Fortification sample, Day 04, air sampling tube, 1st high level
AEA04-FF-04-AR-H2	Fortification sample, Day 04, air sampling tube, 2nd high level
AEA04-FF-04-AR-H3	Fortification sample, Day 04, air sampling tube, 3rd high level
AEA04-FF-04-RS-L1	Fortification sample, Day 04, RespiCon filter, 1st low level
AEA04-FF-04-RS-L2	Fortification sample, Day 04, RespiCon filter, 2nd low level
AEA04-FF-04-RS-L3	Fortification sample, Day 04, RespiCon filter, 3rd low level
AEA04-FF-04-RS-H1	Fortification sample, Day 04, RespiCon filter, 1st high level
AEA04-FF-04-RS-H2	Fortification sample, Day 04, RespiCon filter, 2nd high level
AEA04-FF-04-RS-H3	Fortification sample, Day 04, RespiCon filter, 3rd high level
AEA04-FF-04-HW-L1	Fortification sample, Day 04, hand wash, 1st low level
AEA04-FF-04-HW-L2	Fortification sample, Day 04, hand wash, 2nd low level
AEA04-FF-04-HW-L3	Fortification sample, Day 04, hand wash, 3rd low level
AEA04-FF-04-HW-H1	Fortification sample, Day 04, hand wash, 1st high level
AEA04-FF-04-HW-H2	Fortification sample, Day 04, hand wash, 2nd high level
AEA04-FF-04-HW-H3	Fortification sample, Day 04, hand wash, 3rd high level

Exposure Samples (continued)

Sample ID Number	Description
AEA04-FF-04-FW-L1	Fortification sample, Day 04, face/neck wipe, 1st low level
AEA04-FF-04-FW-L2	Fortification sample, Day 04, face/neck wipe, 2nd low level
AEA04-FF-04-FW-L3	Fortification sample, Day 04, face/neck wipe, 3rd low level
AEA04-FF-04-FW-H1	Fortification sample, Day 04, face/neck wipe, 1st high level
AEA04-FF-04-FW-H2	Fortification sample, Day 04, face/neck wipe, 2nd high level
AEA04-FF-04-FW-H3	Fortification sample, Day 04, face/neck wipe, 3rd high level
AEA04-FF-04-ID-L1	Fortification sample, Day 04, inner dosimeter, 1st low level
AEA04-FF-04-ID-L2	Fortification sample, Day 04, inner dosimeter, 2nd low level
AEA04-FF-04-ID-L3	Fortification sample, Day 04, inner dosimeter, 3rd low level
AEA04-FF-04-ID-H1	Fortification sample, Day 04, inner dosimeter, 1st high level
AEA04-FF-04-ID-H2	Fortification sample, Day 04, inner dosimeter, 2nd high level
AEA04-FF-04-ID-H3	Fortification sample, Day 04, inner dosimeter, 3rd high level
AEA04-FF-04-OD-L1	Fortification sample, Day 04, outer dosimeter, 1st low level
AEA04-FF-04-OD-L2	Fortification sample, Day 04, outer dosimeter, 2nd low level
AEA04-FF-04-OD-L3	Fortification sample, Day 04, outer dosimeter, 3rd low level
AEA04-FF-04-OD-H1	Fortification sample, Day 04, outer dosimeter, 1st high level
AEA04-FF-04-OD-H2	Fortification sample, Day 04, outer dosimeter, 2nd high level
AEA04-FF-04-OD-H3	Fortification sample, Day 04, outer dosimeter, 3rd high level
AEA04-FF-04-AR-C1	Fortification sample, Day 04, air sampling tube, 1st control
AEA04-FF-04-AR-C2	Fortification sample, Day 04, air sampling tube, 2nd control
AEA04-FF-04-HW-C1	Fortification sample, Day 04, hand wash, 1st control
AEA04-FF-04-HW-C2	Fortification sample, Day 04, hand wash, 2nd control
AEA04-FF-04-FW-C1	Fortification sample, Day 04, face/neck wipe, 1st control
AEA04-FF-04-FW-C2	Fortification sample, Day 04, face/neck wipe, 2nd control
AEA04-FF-04-ID-C1	Fortification sample, Day 04, inner dosimeter, 1st control
AEA04-FF-04-ID-C2	Fortification sample, Day 04, inner dosimeter, 2nd control
AEA04-FF-04-OD-C1	Fortification sample, Day 04, outer dosimeter, 1st control
AEA04-FF-04-OD-C2	Fortification sample, Day 04, outer dosimeter, 2nd control
AEA04-FF-04-AR-T1	Fortification sample, Day 04, air sampling tube, 1st travel spike
AEA04-FF-04-AR-T2	Fortification sample, Day 04, air sampling tube, 2nd travel spike
AEA04-FF-04-HW-T1	Fortification sample, Day 04, hand wash, 1st travel spike
AEA04-FF-04-HW-T2	Fortification sample, Day 04, hand wash, 2nd travel spike
AEA04-FF-04-FW-T1	Fortification sample, Day 04, face/neck wipe, 1st travel spike
AEA04-FF-04-FW-T2	Fortification sample, Day 04, face/neck wipe, 2nd travel spike
AEA04-FF-04-ID-T1	Fortification sample, Day 04, inner dosimeter, 1st travel spike

Exposure Samples (continued)

Sample ID Number	Description
AEA04-FF-04-ID-T2	Fortification sample, Day 04, inner dosimeter, 2nd travel spike
AEA04-FF-04-OD-T1	Fortification sample, Day 04, outer dosimeter, 1st travel spike
AEA04-FF-04-OD-T2	Fortification sample, Day 04, outer dosimeter, 2nd travel spike
AEA04-FF-05-AR-L1	Fortification sample, Day 05, air sampling tube, 1st low level
AEA04-FF-05-AR-L2	Fortification sample, Day 05, air sampling tube, 2nd low level
AEA04-FF-05-AR-L3	Fortification sample, Day 05, air sampling tube, 3rd low level
AEA04-FF-05-AR-H1	Fortification sample, Day 05, air sampling tube, 1st high level
AEA04-FF-05-AR-H2	Fortification sample, Day 05, air sampling tube, 2nd high level
AEA04-FF-05-AR-H3	Fortification sample, Day 05, air sampling tube, 3rd high level
AEA04-FF-05-RS-L1	Fortification sample, Day 05, RespiCon filter, 1st low level
AEA04-FF-05-RS-L2	Fortification sample, Day 05, RespiCon filter, 2nd low level
AEA04-FF-05-RS-L3	Fortification sample, Day 05, RespiCon filter, 3rd low level
AEA04-FF-05-RS-H1	Fortification sample, Day 05, RespiCon filter, 1st high level
AEA04-FF-05-RS-H2	Fortification sample, Day 05, RespiCon filter, 2nd high level
AEA04-FF-01-RS-H3	Fortification sample, Day 05, RespiCon filter, 3rd high level
AEA04-FF-05-HW-L1	Fortification sample, Day 05, hand wash, 1st low level
AEA04-FF-05-HW-L2	Fortification sample, Day 05, hand wash, 2nd low level
AEA04-FF-05-HW-L3	Fortification sample, Day 05, hand wash, 3rd low level
AEA04-FF-05-HW-H1	Fortification sample, Day 05, hand wash, 1st high level
AEA04-FF-05-HW-H2	Fortification sample, Day 05, hand wash, 2nd high level
AEA04-FF-05-HW-H3	Fortification sample, Day 05, hand wash, 3rd high level
AEA04-FF-05-FW-L1	Fortification sample, Day 05, face/neck wipe, 1st low level
AEA04-FF-05-FW-L2	Fortification sample, Day 05, face/neck wipe, 2nd low level
AEA04-FF-05-FW-L3	Fortification sample, Day 05, face/neck wipe, 3rd low level
AEA04-FF-05-FW-H1	Fortification sample, Day 05, face/neck wipe, 1st high level
AEA04-FF-05-FW-H2	Fortification sample, Day 05, face/neck wipe, 2nd high level
AEA04-FF-05-FW-H3	Fortification sample, Day 05, face/neck wipe, 3rd high level
AEA04-FF-05-ID-L1	Fortification sample, Day 05, inner dosimeter, 1st low level
AEA04-FF-05-ID-L2	Fortification sample, Day 05, inner dosimeter, 2nd low level
AEA04-FF-05-ID-L3	Fortification sample, Day 05, inner dosimeter, 3rd low level
AEA04-FF-05-ID-H1	Fortification sample, Day 05, inner dosimeter, 1st high level
AEA04-FF-05-ID-H2	Fortification sample, Day 05, inner dosimeter, 2nd high level
AEA04-FF-05-ID-H3	Fortification sample, Day 05, inner dosimeter, 3rd high level
AEA04-FF-05-OD-L1	Fortification sample, Day 05, outer dosimeter, 1st low level
AEA04-FF-05-OD-L2	Fortification sample, Day 05, outer dosimeter, 2nd low level
AEA04-FF-05-OD-L3	Fortification sample, Day 05, outer dosimeter, 3rd low level
AEA04-FF-05-OD-H1	Fortification sample, Day 05, outer dosimeter, 1st high level
AEA04-FF-05-OD-H2	Fortification sample, Day 05, outer dosimeter, 2nd high level
AEA04-FF-05-OD-H3	Fortification sample, Day 05, outer dosimeter, 3rd high level

Exposure Samples (continued)

Sample ID Number	Description
AEA04-FF-05-AR-C1	Fortification sample, Day 05, air sampling tube, 1st control
AEA04-FF-05-AR-C2	Fortification sample, Day 05, air sampling tube, 2nd control
AEA04-FF-05-HW-C1	Fortification sample, Day 05, hand wash, 1st control
AEA04-FF-05-HW-C2	Fortification sample, Day 05, hand wash, 2nd control
AEA04-FF-05-FW-C1	Fortification sample, Day 05, face/neck wipe, 1st control
AEA04-FF-05-FW-C2	Fortification sample, Day 05, face/neck wipe, 2nd control
AEA04-FF-05-ID-C1	Fortification sample, Day 05, inner dosimeter, 1st control
AEA04-FF-05-ID-C2	Fortification sample, Day 05, inner dosimeter, 2nd control
AEA04-FF-05-OD-C1	Fortification sample, Day 05, outer dosimeter, 1st control
AEA04-FF-05-OD-C2	Fortification sample, Day 05, outer dosimeter, 2nd control
AEA04-FF-05-AR-T1	Fortification sample, Day 05, air sampling tube, 1st travel spike
AEA04-FF-05-AR-T2	Fortification sample, Day 05, air sampling tube, 2nd travel spike
AEA04-FF-05-HW-T1	Fortification sample, Day 05, hand wash, 1st travel spike
AEA04-FF-05-HW-T2	Fortification sample, Day 05, hand wash, 2nd travel spike
AEA04-FF-05-FW-T1	Fortification sample, Day 05, face/neck wipe, 1st travel spike
AEA04-FF-05-FW-T2	Fortification sample, Day 05, face/neck wipe, 2nd travel spike
AEA04-FF-05-ID-T1	Fortification sample, Day 05, inner dosimeter, 1st travel spike
AEA04-FF-05-ID-T2	Fortification sample, Day 05, inner dosimeter, 2nd travel spike
AEA04-FF-05-OD-T1	Fortification sample, Day 05, outer dosimeter, 1st travel spike
AEA04-FF-05-OD-T2	Fortification sample, Day 05, outer dosimeter, 2nd travel spike
AEA04-FF-06-AR-L1	Fortification sample, Day 06, air sampling tube, 1st low level
AEA04-FF-06-AR-L2	Fortification sample, Day 06, air sampling tube, 2nd low level
AEA04-FF-06-AR-L3	Fortification sample, Day 06, air sampling tube, 3rd low level
AEA04-FF-06-AR-H1	Fortification sample, Day 06, air sampling tube, 1st high level
AEA04-FF-06-AR-H2	Fortification sample, Day 06, air sampling tube, 2nd high level
AEA04-FF-06-AR-H3	Fortification sample, Day 06, air sampling tube, 3rd high level
AEA04-FF-06-RS-L1	Fortification sample, Day 06, RespiCon filter, 1st low level
AEA04-FF-06-RS-L2	Fortification sample, Day 06, RespiCon filter, 2nd low level
AEA04-FF-06-RS-L3	Fortification sample, Day 06, RespiCon filter, 3rd low level
AEA04-FF-06-RS-H1	Fortification sample, Day 06, RespiCon filter, 1st high level
AEA04-FF-06-RS-H2	Fortification sample, Day 06, RespiCon filter, 2nd high level
AEA04-FF-06-RS-H3	Fortification sample, Day 06, RespiCon filter, 3rd high level
AEA04-FF-06-HW-L1	Fortification sample, Day 06, hand wash, 1st low level
AEA04-FF-06-HW-L2	Fortification sample, Day 06, hand wash, 2nd low level

Exposure Samples (continued)

Sample ID Number	Description
AEA04-FF-06-HW-L3	Fortification sample, Day 06, hand wash, 3rd low level
AEA04-FF-06-HW-H1	Fortification sample, Day 06, hand wash, 1st high level
AEA04-FF-06-HW-H2	Fortification sample, Day 06, hand wash, 2nd high level
AEA04-FF-06-HW-H3	Fortification sample, Day 06, hand wash, 3rd high level
AEA04-FF-06-FW-L1	Fortification sample, Day 06, face/neck wipe, 1st low level
AEA04-FF-06-FW-L2	Fortification sample, Day 06, face/neck wipe, 2nd low level
AEA04-FF-06-FW-L3	Fortification sample, Day 06, face/neck wipe, 3rd low level
AEA04-FF-06-FW-H1	Fortification sample, Day 06, face/neck wipe, 1st high level
AEA04-FF-06-FW-H2	Fortification sample, Day 06, face/neck wipe, 2nd high level
AEA04-FF-06-FW-H3	Fortification sample, Day 06, face/neck wipe, 3rd high level
AEA04-FF-06-ID-L1	Fortification sample, Day 06, inner dosimeter, 1st low level
AEA04-FF-06-ID-L2	Fortification sample, Day 06, inner dosimeter, 2nd low level
AEA04-FF-06-ID-L3	Fortification sample, Day 06, inner dosimeter, 3rd low level
AEA04-FF-06-ID-H1	Fortification sample, Day 06, inner dosimeter, 1st high level
AEA04-FF-06-ID-H2	Fortification sample, Day 06, inner dosimeter, 2nd high level
AEA04-FF-06-ID-H3	Fortification sample, Day 06, inner dosimeter, 3rd high level
AEA04-FF-06-OD-L1	Fortification sample, Day 06, outer dosimeter, 1st low level
AEA04-FF-06-OD-L2	Fortification sample, Day 06, outer dosimeter, 2nd low level
AEA04-FF-06-OD-L3	Fortification sample, Day 06, outer dosimeter, 3rd low level
AEA04-FF-06-OD-H1	Fortification sample, Day 06, outer dosimeter, 1st high level
AEA04-FF-06-OD-H2	Fortification sample, Day 06, outer dosimeter, 2nd high level
AEA04-FF-06-OD-H3	Fortification sample, Day 06, outer dosimeter, 3rd high level
AEA04-FF-06-AR-C1	Fortification sample, Day 06, air sampling tube, 1st control
AEA04-FF-06-AR-C2	Fortification sample, Day 06, air sampling tube, 2nd control
AEA04-FF-06-HW-C1	Fortification sample, Day 06, hand wash, 1st control
AEA04-FF-06-HW-C2	Fortification sample, Day 06, hand wash, 2nd control
AEA04-FF-06-FW-C1	Fortification sample, Day 06, face/neck wipe, 1st control
AEA04-FF-06-FW-C2	Fortification sample, Day 06, face/neck wipe, 2nd control
AEA04-FF-06-ID-C1	Fortification sample, Day 06, inner dosimeter, 1st control
AEA04-FF-06-ID-C2	Fortification sample, Day 06, inner dosimeter, 2nd control
AEA04-FF-06-OD-C1	Fortification sample, Day 06, outer dosimeter, 1st control
AEA04-FF-06-OD-C2	Fortification sample, Day 06, outer dosimeter, 2nd control
AEA04-FF-06-AR-T1	Fortification sample, Day 06, air sampling tube, 1st travel spike
AEA04-FF-06-AR-T2	Fortification sample, Day 06, air sampling tube, 2nd travel spike
AEA04-FF-06-HW-T1	Fortification sample, Day 06, hand wash, 1st travel spike
AEA04-FF-06-HW-T2	Fortification sample, Day 06, hand wash, 2nd travel spike

Exposure Samples (continued)

Sample ID Number	Description
AEA04-FF-06-FW-T1	Fortification sample, Day 06, face/neck wipe, 1st travel spike
AEA04-FF-06-FW-T2	Fortification sample, Day 06, face/neck wipe, 2nd travel spike
AEA04-FF-06-ID-T1	Fortification sample, Day 06, inner dosimeter, 1st travel spike
AEA04-FF-06-ID-T2	Fortification sample, Day 06, inner dosimeter, 2nd travel spike
AEA04-FF-06-OD-T1	Fortification sample, Day 06, outer dosimeter, 1st travel spike
AEA04-FF-06-OD-T2	Fortification sample, Day 06, outer dosimeter, 2nd travel spike
AEA04-FF-07-AR-L1	Fortification sample, Day 07, air sampling tube, 1st low level
AEA04-FF-07-AR-L2	Fortification sample, Day 07, air sampling tube, 2nd low level
AEA04-FF-07-AR-L3	Fortification sample, Day 07, air sampling tube, 3rd low level
AEA04-FF-07-AR-H1	Fortification sample, Day 07, air sampling tube, 1st high level
AEA04-FF-07-AR-H2	Fortification sample, Day 07, air sampling tube, 2nd high level
AEA04-FF-07-AR-H3	Fortification sample, Day 07, air sampling tube, 3rd high level
AEA04-FF-07-RS-L1	Fortified sample, Day 07, RespiCon filter, 1st low level
AEA04-FF-07-RS-L2	Fortified sample, Day 07, RespiCon filter, 2nd low level
AEA04-FF-07-RS-L3	Fortified sample, Day 07, RespiCon filter, 3rd low level
AEA04-FF-07-RS-H1	Fortified sample, Day 07, RespiCon filter, 1st high level
AEA04-FF-07-RS-H2	Fortified sample, Day 07, RespiCon filter, 2nd high level
AEA04-FF-07-RS-H3	Fortified sample, Day 07, RespiCon filter, 3rd high level
AEA04-FF-07-HW-L1	Fortification sample, Day 07, hand wash, 1st low level
AEA04-FF-07-HW-L2	Fortification sample, Day 07, hand wash, 2nd low level
AEA04-FF-07-HW-L3	Fortification sample, Day 07, hand wash, 3rd low level
AEA04-FF-07-HW-H1	Fortification sample, Day 07, hand wash, 1st high level
AEA04-FF-07-HW-H2	Fortification sample, Day 07, hand wash, 2nd high level
AEA04-FF-07-HW-H3	Fortification sample, Day 07, hand wash, 3rd high level
AEA04-FF-07-FW-L1	Fortification sample, Day 07, face/neck wipe, 1st low level
AEA04-FF-07-FW-L2	Fortification sample, Day 07, face/neck wipe, 2nd low level
AEA04-FF-07-FW-L3	Fortification sample, Day 07, face/neck wipe, 3rd low level
AEA04-FF-07-FW-H1	Fortification sample, Day 07, face/neck wipe, 1st high level
AEA04-FF-07-FW-H2	Fortification sample, Day 07, face/neck wipe, 2nd high level
AEA04-FF-07-FW-H3	Fortification sample, Day 07, face/neck wipe, 3rd high level
AEA04-FF-07-ID-L1	Fortification sample, Day 07, inner dosimeter, 1st low level
AEA04-FF-07-ID-L2	Fortification sample, Day 07, inner dosimeter, 2nd low level
AEA04-FF-07-ID-L3	Fortification sample, Day 07, inner dosimeter, 3rd low level
AEA04-FF-07-ID-H1	Fortification sample, Day 07, inner dosimeter, 1st high level
AEA04-FF-07-ID-H2	Fortification sample, Day 07, inner dosimeter, 2nd high level
AEA02-FF-07-ID-H3	Fortification sample, Day 07, inner dosimeter, 3rd high level
AEA04-FF-07-OD-L1	Fortification sample, Day 07, outer dosimeter, 1st low level

Exposure Samples (continued)

Sample ID Number	Description
AEA04-FF-07-OD-L2	Fortification sample, Day 07, outer dosimeter, 2nd low level
AEA04-FF-07-OD-L3	Fortification sample, Day 07, outer dosimeter, 3rd low level
AEA04-FF-07-OD-H1	Fortification sample, Day 07, outer dosimeter, 1st high level
AEA04-FF-07-OD-H2	Fortification sample, Day 07, outer dosimeter, 2nd high level
AEA04-FF-07-OD-H3	Fortification sample, Day 07, outer dosimeter, 3rd high level
AEA04-FF-07-AR-C1	Fortification sample, Day 07, air sampling tube, 1st control
AEA04-FF-07-AR-C2	Fortification sample, Day 07, air sampling tube, 2nd control
AEA04-FF-07-HW-C1	Fortification sample, Day 07, hand wash, 1st control
AEA04-FF-07-HW-C2	Fortification sample, Day 07, hand wash, 2nd control
AEA04-FF-07-FW-C1	Fortification sample, Day 07, face/neck wipe, 1st control
AEA04-FF-07-FW-C2	Fortification sample, Day 07, face/neck wipe, 2nd control
AEA04-FF-07-ID-C1	Fortification sample, Day 07, inner dosimeter, 1st control
AEA04-FF-07-ID-C2	Fortification sample, Day 07, inner dosimeter, 2nd control
AEA04-FF-07-OD-C1	Fortification sample, Day 07, outer dosimeter, 1st control
AEA04-FF-07-OD-C2	Fortification sample, Day 07, outer dosimeter, 2nd control
AEA04-FF-07-AR-T1	Fortification sample, Day 07, air sampling tube, 1st travel spike
AEA04-FF-07-AR-T2	Fortification sample, Day 07, air sampling tube, 2nd travel spike
AEA04-FF-07-HW-T1	Fortification sample, Day 07, hand wash, 1st travel spike
AEA04-FF-07-HW-T2	Fortification sample, Day 07, hand wash, 2nd travel spike
AEA04-FF-07-FW-T1	Fortification sample, Day 07, face/neck wipe, 1st travel spike
AEA04-FF-07-FW-T2	Fortification sample, Day 07, face/neck wipe, 2nd travel spike
AEA04-FF-07-ID-T1	Fortification sample, Day 07, inner dosimeter, 1st travel spike
AEA04-FF-07-ID-T2	Fortification sample, Day 07, inner dosimeter, 2nd travel spike
AEA04-FF-07-OD-T1	Fortification sample, Day 07, outer dosimeter, 1st travel spike
AEA04-FF-07-OD-T2	Fortification sample, Day 07, outer dosimeter, 2nd travel spike
AEA04-FF-08-AR-L1	Fortification sample, Day 08, air sampling tube, 1st low level
AEA04-FF-08-AR-L2	Fortification sample, Day 08, air sampling tube, 2nd low level
AEA04-FF-08-AR-L3	Fortification sample, Day 08, air sampling tube, 3rd low level
AEA04-FF-08-AR-H1	Fortification sample, Day 08, air sampling tube, 1st high level
AEA04-FF-08-AR-H2	Fortification sample, Day 08, air sampling tube, 2nd high level
AEA04-FF-08-AR-H3	Fortification sample, Day 08, air sampling tube, 3rd high level
AEA04-FF-08-RS-L1	Fortification sample, Day 08, RespiCon filter, 1st low level
AEA04-FF-08-RS-L2	Fortification sample, Day 08, RespiCon filter, 2nd low level
AEA04-FF-08-RS-L3	Fortification sample, Day 08, RespiCon filter, 3rd low level

Exposure Samples (continued)

Sample ID Number	Description
AEA04-FF-08-RS-H1	Fortification sample, Day 08, RespiCon filter, 1st high level
AEA04-FF-08-RS-H2	Fortification sample, Day 08, RespiCon filter, 2nd high level
AEA04-FF-08-RS-H3	Fortification sample, Day 08, RespiCon filter, 3rd high level
AEA04-FF-08-HW-L1	Fortification sample, Day 08, hand wash, 1st low level
AEA04-FF-08-HW-L2	Fortification sample, Day 08, hand wash, 2nd low level
AEA04-FF-08-HW-L3	Fortification sample, Day 08, hand wash, 3rd low level
AEA04-FF-08-HW-H1	Fortification sample, Day 08, hand wash, 1st high level
AEA04-FF-08-HW-H2	Fortification sample, Day 08, hand wash, 2nd high level
AEA04-FF-08-HW-H3	Fortification sample, Day 08, hand wash, 3rd high level
AEA04-FF-08-FW-L1	Fortification sample, Day 08, face/neck wipe, 1st low level
AEA04-FF-08-FW-L2	Fortification sample, Day 08, face/neck wipe, 2nd low level
AEA04-FF-08-FW-L3	Fortification sample, Day 08, face/neck wipe, 3rd low level
AEA04-FF-08-FW-H1	Fortification sample, Day 08, face/neck wipe, 1st high level
AEA04-FF-08-FW-H2	Fortification sample, Day 08, face/neck wipe, 2nd high level
AEA04-FF-08-FW-H3	Fortification sample, Day 08, face/neck wipe, 3rd high level
AEA04-FF-08-ID-L1	Fortification sample, Day 08, inner dosimeter, 1st low level
AEA04-FF-08-ID-L2	Fortification sample, Day 08, inner dosimeter, 2nd low level
AEA04-FF-08-ID-L3	Fortification sample, Day 08, inner dosimeter, 3rd low level
AEA04-FF-08-ID-H1	Fortification sample, Day 08, inner dosimeter, 1st high level
AEA04-FF-08-ID-H2	Fortification sample, Day 08, inner dosimeter, 2nd high level
AEA04-FF-08-ID-H3	Fortification sample, Day 08, inner dosimeter, 3rd high level
AEA04-FF-08-OD-L1	Fortification sample, Day 08, outer dosimeter, 1st low level
AEA04-FF-08-OD-L2	Fortification sample, Day 08, outer dosimeter, 2nd low level
AEA04-FF-08-OD-L3	Fortification sample, Day 08, outer dosimeter, 3rd low level
AEA04-FF-08-OD-H1	Fortification sample, Day 08, outer dosimeter, 1st high level
AEA04-FF-08-OD-H2	Fortification sample, Day 08, outer dosimeter, 2nd high level
AEA04-FF-08-OD-H3	Fortification sample, Day 08, outer dosimeter, 3rd high level
AEA04-FF-08-AR-C1	Fortification sample, Day 08, air sampling tube, 1st control
AEA04-FF-08-AR-C2	Fortification sample, Day 08, air sampling tube, 2nd control
AEA04-FF-08-HW-C1	Fortification sample, Day 08, hand wash, 1st control
AEA04-FF-08-HW-C2	Fortification sample, Day 08, hand wash, 2nd control
AEA04-FF-08-FW-C1	Fortification sample, Day 08, face/neck wipe, 1st control
AEA04-FF-08-FW-C2	Fortification sample, Day 08, face/neck wipe, 2nd control
AEA04-FF-08-ID-C1	Fortification sample, Day 08, inner dosimeter, 1st control
AEA04-FF-08-ID-C2	Fortification sample, Day 08, inner dosimeter, 2nd control
AEA04-FF-08-OD-C1	Fortification sample, Day 08, outer dosimeter, 1st control
AEA04-FF-08-OD-C2	Fortification sample, Day 08, outer dosimeter, 2nd control

Exposure Samples (continued)

Sample ID Number	Description
AEA04-FF-08-AR-T1	Fortification sample, Day 08, air sampling tube, 1st travel spike
AEA04-FF-08-AR-T2	Fortification sample, Day 08, air sampling tube, 2nd travel spike
AEA04-FF-08-HW-T1	Fortification sample, Day 08, hand wash, 1st travel spike
AEA04-FF-08-HW-T2	Fortification sample, Day 08, hand wash, 2nd travel spike
AEA04-FF-08-FW-T1	Fortification sample, Day 08, face/neck wipe, 1st travel spike
AEA04-FF-08-FW-T2	Fortification sample, Day 08, face/neck wipe, 2nd travel spike
AEA04-FF-08-ID-T1	Fortification sample, Day 08, inner dosimeter, 1st travel spike
AEA04-FF-08-ID-T2	Fortification sample, Day 08, inner dosimeter, 2nd travel spike
AEA04-FF-08-OD-T1	Fortification sample, Day 08, outer dosimeter, 1st travel spike
AEA04-FF-08-OD-T2	Fortification sample, Day 08, outer dosimeter, 2nd travel spike
AEA04-FF-09-AR-L1	Fortification sample, Day 09, air sampling tube, 1st low level
AEA04-FF-09-AR-L2	Fortification sample, Day 09, air sampling tube, 2nd low level
AEA04-FF-09-AR-L3	Fortification sample, Day 09, air sampling tube, 3rd low level
AEA04-FF-09-AR-H1	Fortification sample, Day 09, air sampling tube, 1st high level
AEA04-FF-09-AR-H2	Fortification sample, Day 09, air sampling tube, 2nd high level
AEA04-FF-09-AR-H3	Fortification sample, Day 09, air sampling tube, 3rd high level
AEA04-FF-09-RS-L1	Fortification sample, Day 09, RespiCon filter, 1st low level
AEA04-FF-09-RS-L2	Fortification sample, Day 09, RespiCon filter, 2nd low level
AEA04-FF-09-RS-L3	Fortification sample, Day 09, RespiCon filter, 3rd low level
AEA04-FF-09-RS-H1	Fortification sample, Day 09, RespiCon filter, 1st high level
AEA04-FF-09-RS-H2	Fortification sample, Day 09, RespiCon filter, 2nd high level
AEA04-FF-09-RS-H3	Fortification sample, Day 09, RespiCon filter, 3rd high level
AEA04-FF-09-HW-L1	Fortification sample, Day 09, hand wash, 1st low level
AEA04-FF-09-HW-L2	Fortification sample, Day 09, hand wash, 2nd low level
AEA04-FF-09-HW-L3	Fortification sample, Day 09, hand wash, 3rd low level
AEA04-FF-09-HW-H1	Fortification sample, Day 09, hand wash, 1st high level
AEA04-FF-09-HW-H2	Fortification sample, Day 09, hand wash, 2nd high level
AEA04-FF-09-HW-H3	Fortification sample, Day 09, hand wash, 3rd high level
AEA04-FF-09-FW-L1	Fortification sample, Day 09, face/neck wipe, 1st low level
AEA04-FF-09-FW-L2	Fortification sample, Day 09, face/neck wipe, 2nd low level
AEA04-FF-09-FW-L3	Fortification sample, Day 09, face/neck wipe, 3rd low level
AEA04-FF-09-FW-H1	Fortification sample, Day 09, face/neck wipe, 1st high level
AEA04-FF-09-FW-H2	Fortification sample, Day 09, face/neck wipe, 2nd high level
AEA04-FF-09-FW-H3	Fortification sample, Day 09, face/neck wipe, 3rd high level
AEA04-FF-09-ID-L1	Fortification sample, Day 09, inner dosimeter, 1st low level
AEA04-FF-09-ID-L2	Fortification sample, Day 09, inner dosimeter, 2nd low level
AEA04-FF-09-ID-L3	Fortification sample, Day 09, inner dosimeter, 3rd low level

Exposure Samples (continued)

Sample ID Number	Description
AEA04-FF-09-ID-H1	Fortification sample, Day 09, inner dosimeter, 1st high level
AEA04-FF-09-ID-H2	Fortification sample, Day 09, inner dosimeter, 2nd high level
AEA04-FF-09-ID-H3	Fortification sample, Day 09, inner dosimeter, 3rd high level
AEA04-FF-09-OD-L1	Fortification sample, Day 09, outer dosimeter, 1st low level
AEA04-FF-09-OD-L2	Fortification sample, Day 09, outer dosimeter, 2nd low level
AEA04-FF-09-OD-L3	Fortification sample, Day 09, outer dosimeter, 3rd low level
AEA04-FF-09-OD-H1	Fortification sample, Day 09, outer dosimeter, 1st high level
AEA04-FF-09-OD-H2	Fortification sample, Day 09, outer dosimeter, 2nd high level
AEA04-FF-09-OD-H3	Fortification sample, Day 09, outer dosimeter, 3rd high level
AEA04-FF-09-AR-C1	Fortification sample, Day 09, air sampling tube, 1st control
AEA04-FF-09-AR-C2	Fortification sample, Day 09, air sampling tube, 2nd control
AEA04-FF-09-HW-C1	Fortification sample, Day 09, hand wash, 1st control
AEA04-FF-09-HW-C2	Fortification sample, Day 09, hand wash, 2nd control
AEA04-FF-09-FW-C1	Fortification sample, Day 09, face/neck wipe, 1st control
AEA04-FF-09-FW-C2	Fortification sample, Day 09, face/neck wipe, 2nd control
AEA04-FF-09-ID-C1	Fortification sample, Day 09, inner dosimeter, 1st control
AEA04-FF-09-ID-C2	Fortification sample, Day 09, inner dosimeter, 2nd control
AEA04-FF-09-OD-C1	Fortification sample, Day 09, outer dosimeter, 1st control
AEA04-FF-09-OD-C2	Fortification sample, Day 09, outer dosimeter, 2nd control
AEA04-FF-09-AR-T1	Fortification sample, Day 09, air sampling tube, 1st travel spike
AEA04-FF-09-AR-T2	Fortification sample, Day 09, air sampling tube, 2nd travel spike
AEA04-FF-09-HW-T1	Fortification sample, Day 09, hand wash, 1st travel spike
AEA04-FF-09-HW-T2	Fortification sample, Day 09, hand wash, 2nd travel spike
AEA04-FF-09-FW-T1	Fortification sample, Day 09, face/neck wipe, 1st travel spike
AEA04-FF-09-FW-T2	Fortification sample, Day 09, face/neck wipe, 2nd travel spike
AEA04-FF-09-ID-T1	Fortification sample, Day 09, inner dosimeter, 1st travel spike
AEA04-FF-09-ID-T2	Fortification sample, Day 09, inner dosimeter, 2nd travel spike
AEA04-FF-09-OD-T1	Fortification sample, Day 09, outer dosimeter, 1st travel spike
AEA04-FF-09-OD-T2	Fortification sample, Day 09, outer dosimeter, 2nd travel spike

Background Check Samples

AEA04-BG-01-AR-R1-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 1, Sample 1
AEA04-BG-01-AR-R1-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 1, Sample 2
AEA04-BG-01-AR-R2-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 2, Sample 1
AEA04-BG-01-AR-R2-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 2, Sample 2
AEA04-BG-01-AR-R3-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 3, Sample 1
AEA04-BG-01-AR-R3-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 3, Sample 2
AEA04-BG-01-AR-R4-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 4, Sample 1
AEA04-BG-01-AR-R4-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 4, Sample 2
AEA04-BG-01-AR-R5-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 5, Sample 1
AEA04-BG-01-AR-R5-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 5, Sample 2
AEA04-BG-01-AR-R6-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 6, Sample 1
AEA04-BG-01-AR-R6-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 6, Sample 2
AEA04-BG-01-AR-R7-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 7, Sample 1
AEA04-BG-01-AR-R7-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 7, Sample 2
AEA04-BG-01-AR-R8-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 8, Sample 1
AEA04-BG-01-AR-R8-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 8, Sample 2
AEA04-BG-01-AR-R9-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 9, Sample 1
AEA04-BG-01-AR-R9-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 9, Sample 2
AEA04-BG-01-AR-R10-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 10, Sample 1
AEA04-BG-01-AR-R10-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 10, Sample 2
AEA04-BG-01-AR-R11-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 11, Sample 1
AEA04-BG-01-AR-R11-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 11, Sample 2
AEA04-BG-01-AR-R12-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 12, Sample 1
AEA04-BG-01-AR-R12-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 12, Sample 2

AEA04-BG-01-AR-R13-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 13, Sample 1
AEA04-BG-01-AR-R13-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 13, Sample 2
AEA04-BG-01-AR-R14-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 14, Sample 1
AEA04-BG-01-AR-R14-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 14, Sample 2
AEA04-BG-01-AR-R15-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 15, Sample 1
AEA04-BG-01-AR-R15-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 15, Sample 2
AEA04-BG-01-AR-R16-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 16, Sample 1
AEA04-BG-01-AR-R16-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 16, Sample 2
AEA04-BG-01-AR-R17-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 17, Sample 1
AEA04-BG-01-AR-R17-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 17, Sample 2
AEA04-BG-01-AR-R18-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 18, Sample 1
AEA04-BG-01-AR-R18-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 18, Sample 2
AEA04-BG-01-AR-R19-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 19, Sample 1
AEA04-BG-01-AR-R19-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 19, Sample 2
AEA04-BG-01-AR-R20-1	Background sample, ME 01, air sampling tube, Hotel/Motel Room 20, Sample 1
AEA04-BG-01-AR-R20-2	Background sample, ME 01, air sampling tube, Hotel/Motel Room 20, Sample 2

Antimicrobial Exposure Assessment Task Force II (AEATF II)

AEROSOL APPLICATION SCENARIO: RATIONALE FOR STUDY DESIGN

July 13, 2009

TABLE OF CONTENTS

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Deleted: 5
Deleted: 7
Deleted: 8
Deleted: 9
Deleted: 10
Deleted: 11
Deleted: 12
Deleted: 13
Deleted: 15
Deleted: 18
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Deleted: 23
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Deleted: 27
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AEROSOL APPLICATION SCENARIO: RATIONALE FOR STUDY DESIGN

1. Introduction

This document summarizes the rationale for critical elements of the design of the AEATF II aerosol application exposure monitoring study. Aerosol application represents an exposure scenario being addressed as part of the overall AEATF II antimicrobial exposure assessment program. This study is being conducted to determine potential dermal and inhalation antimicrobial chemical exposures associated with the use of hand-held, pressurized aerosol cans. The resulting data will likely improve the completeness and accuracy of the database used by the U.S. Environmental Protection Agency (EPA) to assess potential exposures to antimicrobial chemicals used in aerosol products. The results of the study will provide EPA with data on exposure that has been made a condition of re-registration for a number of antimicrobials. Results from the study may reduce uncertainty about the range of exposure experienced by consumers and workers handling antimicrobials. The ability to accurately predict exposure may allow other chemical classes of antimicrobials to also be considered for registration based on exposure estimates generated from the data to be produced by this study.

2. Scenario Definition

An antimicrobial handling scenario is a set of related tasks, pesticide formulations, equipment, engineering controls, and worker and/or consumer practices. For the purposes of the AEATF II antimicrobial exposure assessment Program, the **aerosol application scenario** is defined as the hand-held pressurized aerosol-based application of a label-specified end-use formulation containing an antimicrobial chemical. This includes the task of actual aerosol spraying for purposes of air and surface odor elimination, sanitizing, or disinfecting. The aerosol application scenario involves application according to typical practices, e.g., spraying surfaces from a distance of approximately 6-10 inches in a manner to apply enough formulation to provide an adequate amount for cleaning. Hard surface applications are typically sprayed until visibly "thoroughly" wet per label direction. No wiping will be conducted as part of this application scenario. Surface applications are typically made in smooth, sweeping, overlapping patterns. Examples of "representative" spray application techniques that this scenario is expected to capture include horizontal spraying moving upward and downward from the starting point to hard surfaces such as laminate, tile, porcelain, glass, and metal). The ready-to-use (i.e., no mixing or loading procedures are involved) pressurized aerosol represents a common application method in residential (consumer) settings, and is also used in institutional settings, as an alternative to "dilutable" products, such as an end-use solution filled into a trigger sprayer. The aerosol application scenario is being used to address potential exposures to hand-held spray products in general, including surface disinfecting sprays, air

sanitizers, and foaming aerosols. The pressurized disinfecting aerosol spray was selected to represent this group of spray products because it is a commonly used product type, the application process (spray nozzle actuation) is similar across all aerosol product types, and the surface application rates, normalized to mass of formulation per surface area are comparable across product types (e.g., aerosol foam active ingredient application rates range from 0.002 to 0.007 mg/cm^2, and disinfecting aerosol spray application rates range from 0.0007 to 0.003 mg/cm^2) (Aklam, et al., 2006). Appendix A provides additional documentation supporting the selection of the disinfecting aerosol spray. This documentation includes the results of a non-human subject application parameter study which was needed to facilitate appropriate selection of a surrogate, representative product to be used in the aerosol scenario exposure monitoring study. Based on the nozzle size, amount of material dispensed per unit time, air concentrations, and aerosol characteristics, across products in the four major aerosol categories (hard surface disinfecting sprays, hard surface foaming aerosols, soft surface sprays, air fresheners), *Clorox Commercial Solutions® Clorox® Disinfecting Spray (*EPA Reg. No. 67619-03), was selected as a representative, albeit conservative surrogate and a product most likely to produce measurable exposures for purposes of the aerosol application study. Appendix A describes how the product chosen for this study ranks with respect to commonly available antimicrobial-containing aerosols sold by the major manufacturers of these products. Specific characteristics examined were nozzle size, particle size generated, ejection rate, and a high percentage of non-volatile active ingredient for which there was an existing analytical method. In addition to the predilection for this product to produce measurable exposure under normal use conditions, the particular choice of location and intensity of use will likely produce high end measurements of exposure (see Section 5.4).

In practice, aerosol application may or may not involve follow-on tasks, such as wiping the sprayed surface. Some aerosol products are considered "leave-on" sprays that do not require post-spray wiping. Only the actual aerosol spray application is covered by this scenario. Applicator exposure associated with wiping is being addressed in another AEATF II scenario. Therefore, in the case of the aerosol application scenario, the applicator's exposure during a single workday would arise only from the task of application (spraying) of the product (i.e., not from post-application wiping, such as a potable water rinse and wipe, following aerosol application to a food preparation surface). The distribution of daily exposures for the aerosol application scenario will directly characterize the handler's daily exposure to the antimicrobial expected from "leave-on" spray applications. Characterization of exposures resulting from the combination of aerosol and wipe applications would require exposure information from the wiping scenario as well. The actual approach used to combine exposures from two or more scenarios would naturally depend on the particular needs of each regulatory (or other) user of the antimicrobial database. For example, if only the arithmetic mean exposure of a combined aerosol and wipe application is needed for a risk assessment, then the sum of the two separate arithmetic means (i.e., one for the aerosol scenario and one for the ready to use wipe scenario) can always be used. Any other statistics will depend on what assumptions users wish to make about the correlation in exposure between two tasks performed by the same applicator. If perfect (i.e., 100%) correlation

is assumed, percentiles can be summed to get a combined percentile. If the tasks are assumed to be independent, then pseudo MEs for an aerosol-plus-wipe combination can always be generated by combining every possible aerosol application ME with every possible wipe scenario ME. More sophisticated users will likely employ Monte Carlo simulation methods to accommodate other between-task correlations. Because there are multiple reasonable approaches and because regulatory objectives and required degrees of conservatism vary considerably among potential database users, AEATF II does not recommend any one particular method.

The AEATF II study restricts the aerosol application scenario to professional applicators only. This focus on professional applicators is a practical necessity, given that consumer handlers are typically involved in much shorter task durations where very low exposures are anticipated (see section 5.3). Such low exposures would likely be at or below the limits of quantification/detection of the analytical method. As a result, because of the higher range of daily amount of product used (i.e., pounds of active ingredient handled) and longer application task durations, professional aerosol applicator exposure is expected to be greater, on the average, than that of consumers. This amount of product handled per task, and per day is an important consideration, given that dermal exposure levels normalized to amount handled from other ready-to-use products (e.g., hand-held pressurized aerosols) have typically been observed to be higher than other products whose application may result in more direct interaction, including mixing and loading tasks, with the pesticide formulation (e.g., mixing, loading and application of manual, low pressure sprayers) (EPA 1998). Exceptions to this generalization would be ready-to-use products that may involve direct contact with end-use formulation, e.g., direct handling of ready-to-use wipe products that are impregnated with end-use formulation.

Thus, the AEATF II exposure data for pressurized aerosol spray application of antimicrobial pesticides would be 'conservative' (i.e., would over-predict) if used to describe consumer application exposure. However, it would be reasonable for regulatory agencies using the data to assume that exposure levels for consumer applicators, when normalized for the amount of active ingredient handled, are not greater than those for professional applicators.

3. Existing Aerosol Application Exposure Data

3.1 PHED Studies

Since 1992 the EPA has conducted professional and consumer mixer/loader and applicator exposure and risk assessments relying primarily on the exposure data in Pesticide Handlers Exposure Database (PHED). PHED version 1.01 was initially released in February 1992, followed by PHED version 1.1 in February 1995. PHED version 1.1 was described by the Agency as an incremental improvement over the 1.01 version (Pesticide Handlers Exposure Database, User's Guide Version 1.1, Health Canada, U.S. Environmental Protection Agency, American Crop Protection Association,

February 1995). PHED does include two studies conducted using aerosol application methods. Relevant characteristics of these studies are summarized in Table 1.

Table 1: Summary of Aerosol Application Studies in PHED

Study	Study 456	Study 521
Active Ingredient:	Insecticide	Insecticide
Type of Use:	Residential Crack/Crevice	Residential Crack/Crevice
Aerosol Spray:	15 oz cans (4.33 g ai/can)	16 oz cans (5.54 g ai/can)
Monitoring Events (ME):	15	15
Product Applied:	1 can/ME	1 can/ME
Different Houses Used:	15 (1/ME)	15 (1/ME)
Different Subjects Used:	3 (5 houses/subject)	5 (3 houses/subject)
Location:	Kansas City, MO	Vero Beach, FL
Type of Glove Used:	Chemical Resistant	None
Analytical Grade(s)	A (hands), C (dermal, inhalation)	A (hands, dermal, inhalation)

Unfortunately, these studies have limitations that reduce their value for an antimicrobial-oriented generic database. Both of these studies involved aerosol application for indoor residential insecticide (crack and crevice) treatment. The exposures typical for this product use may not be applicable to antimicrobials. Although both studies monitored application in different houses, the same subjects were used for multiple MEs. Lastly, every ME within a study applied an identical amount of product. Thus, there is no variation in amount of a.i. handled within a study and very little difference between the two studies.

Study 456 has additional problems: All subjects in this study wore chemical resistant gloves, a practice that is not typical for aerosol application of antimicrobials. In addition, both the dermal and inhalation exposure data from study 456 have only an analytical quality grade of C. To support the registration of a pesticide, the data should have an analytical grade of A or B. As a result, study 456 is rarely considered in regulatory exposure assessments.

PHED study 521 meets some of the AEATF II acceptance criteria for evaluating existing data. Although acknowledging that these data are of limited value, the EPA does use this study for antimicrobial exposure assessments. However, because the aerosol

product was not an antimicrobial product and there was a lack of diversity with respect to amount of AI handled (and an associated range of duration of product spraying), additional data are needed. It is also noteworthy that descriptions of study 521 or 456 provided in PHED do not include particle size distribution documentation.

3.2 CMA Study

In addition to PHED, another source of existing data being used by regulatory agencies in the case of antimicrobials is the *Chemical Manufacturers Association Antimicrobial Exposure Assessment Study* directed by Dr. William Popendorf at the University of Iowa (Popendorf et al. 1992). In total, the CMA study obtained both dermal and inhalation exposure measurements for 88 separate monitoring events (MEs) using nine different application methods (pour liquid, pump, pour solid, place solid, aerosol spray, high pressure spray, low pressure spray, mop and wipe). For aerosol (pressurized canisters), trigger-sprayed aerosol, and wiping applications, exposures to the active ingredients ortho phenyl phenol (OPP) and ortho benzyl p-chlorophenol (OBPCP) were measured.

In the CMA study aerosol application (for the purpose of disinfecting) resulted in only five MEs with measurable exposures. Only hand exposures were detectable for these MEs. MEs were conducted in different rooms distributed over a dental office, private residences, and public buildings. The applicators were dental office employees, professional housekeeping staff, or members of the general population. All applications were made using products contained in aerosol spray cans. The application duration, only a fraction of which involved actual aerosol spraying, ranged from 9 to 260 minutes.

Based on EPA's review (Mostaghimi 1995), CMA's study data met some regulatory agency requirements, but were lacking in other areas. In particular, the following areas of the CMA study were found to be lacking:

1) Good laboratory practice, especially in the area of providing quality assurance, was not always followed closely.

2) A majority of extraction efficiencies were below the minimum level suggested in EPA guidelines. Perhaps more importantly, the percent field recoveries (which represent the amount recovered under actual conditions encountered in the study) of many of the chemicals were lower than the minimum needed to assess exposure.

3) Flow volume of the air sampling equipment resulted in most of the inhalation exposure data being less than detection; and

4) None of the application method/end use settings had the minimum number of replicates (i.e., 15) recommended in EPA's guidelines. ('Replicate' is an historical term for monitoring event, or ME.)

The EPA concluded that the limited number of replicates combined with poor recovery data severely limits the conclusions that can be made from CMA's study. In many Re-registration Eligibility Decisions (REDs) issued during 2005 and 2006, EPA has stated that "the risk assessment noted deficiencies in the surrogate dermal and inhalation exposure data available from the Chemical Manufacturers Association (CMA) database. Therefore, the Agency is requiring confirmatory data to support the uses assessed with the CMA exposure data within this risk assessment." The limitations identified by EPA in the CMA's study data were also echoed by regulatory agencies in California (Powell et al., 1995) and Canada (Worgan and Rozario, 1993). All note that the exposure data cannot be used as generic data for all antimicrobials because recoveries were low, precision of the measurements were not established, and CMA did not establish the validity of generalizing the information among applications and end-use settings.

4. The AEATF II Aerosol Application Monitoring Study

The AEATF II program, as described in the Governing Document (2008), intends to develop a database of exposure monitoring data that can be used to support practical regulatory decisions about future exposures for different (including currently nonexistent) active ingredients and their associated products. The database needs to address a variety of exposure scenarios for which no or limited data currently exist. The aerosol application scenario is an important component of the AEATF II program and the focus of this study. As noted in the previous section, existing monitoring data for this scenario are considered inadequate.

The primary purpose of the aerosol application monitoring study is to develop more accurate information on worker exposures to antimicrobials. These data will consist of dermal and inhalation exposure estimates derived from monitoring subjects under conditions that broadly represent those expected for the future application of arbitrary antimicrobial pesticides.

Although this study will use only a single active ingredient, AEATF II and regulatory agencies generally recognize two important principles that allow such exposure results to be generalized to a larger set of conditions:

1. Dermal and inhalation exposure to antimicrobial chemicals are considered generic (i.e., independent of the particular active ingredient used). This *generic principle* permits use of a single surrogate active ingredient to predict exposure for other active ingredients.
2. The *principle of proportionality* of exposure to appropriate measures of active ingredient contact potential. For example, if measured exposure is E_1 when the amount of active ingredient handled (AaiH) is H_1, then the predicted exposure when AaiH is H_2 is just $E_2 = H_2(E_1/H_1)$.

Consequently, AEATF II anticipates the resulting database will contain sufficient data to support exposure assessments for aerosol application for a number of antimicrobial active ingredients over a range of AaiH levels.

An applicator-day is defined as a single professional applicator and a single day on which he/she performs the scenario-specific task as described in Section 2 above. Each possible applicator-day is implicitly associated with a set of application conditions that includes, but is not limited to, applicator behavior, formulation type, location, and environmental conditions. Therefore, the aerosol application scenario can be viewed as the collection (or 'population') of all possible applicator-days that conform to the scenario definition. The basic experimental unit for this scenario is a monitoring event (or ME). During a monitoring event, AEATF II researchers will collect dermal and inhalation exposure information from a worker while he/she performs aerosol application. Each ME is designed to represent a single applicator-day and its corresponding exposure potential. Therefore, the set of N MEs obtained for the aerosol application scenario are designed to characterize future aerosol application scenario applicator-days. The primary challenge is that for the aerosol application scenario (as is true for all AEATF II scenarios) only a small number of expensive experimentally-obtained monitoring events are feasible.

4.1 General Method: Random Sampling and Diversity Selection

Potential monitoring events could be identified by obtaining a random sample of applicator-days from within some well-defined population of professional applicators and from among the days on which they plan aerosol application of antimicrobial chemicals. Each selected applicator (that agrees to participate) would then be monitored for exposure in the workplace location (or locations) on the day selected. In this case, each ME corresponds to an actually-occurring applicator-day and the application conditions would not be under any experimental control. This pure random sampling approach would be an observational study since no subject is intentionally exposed to chemicals.

For the aerosol application scenario this pure random sampling approach is neither practical nor desirable. Because aerosol-spray products are more expensive than those with a trigger sprayer, the routine use of these aerosol products by professionals tends to be limited. Consequently, identifying a population of aerosol application days from which to select a random sample would be quite difficult. Even if identified, a random sample from this population would not be expected to include applicator days with larger amounts of product use unless the sample sizes are very large. Because the cost of monitoring events is very high, large sample sizes are not feasible. Thus, capturing the possible range of amount used is unlikely and the predominance of the lower application amounts would be associated with a high degree of non-detects on dosimetry garments (this was observed with the CMA study and PHED data discussed in section 3 above). Finally, many antimicrobial products that janitors use contain ADBAC, so it would not be possible for a purely observational study to separate aerosol

application exposure from the other types of ADBAC application (e.g. mop, wipe, trigger spray, etc.) exposure.

A sample of N professional applicators will still be randomly selected. However, the selected workers will not be observed during one of their scheduled antimicrobial aerosol application days. Rather, the N randomly selected workers will be randomly assigned to a set of N synthetic aerosol application-day conditions. As described in Section 5, the MEs using these synthetic applicator-day conditions will be conducted in rooms within vacant commercial lodging facility buildings (e.g., hotels, motels with kitchenette or full kitchen) or, if motels with full kitchens are not available, in unoccupied apartments that are within non-vacant commercial lodging facility buildings. Obviously, many ME conditions will be associated with the particular subject assigned (e.g., aerosol application behaviors). Those conditions not associated with the subject, however, will be constructed or selected to exhibit diversity in factors expected to influence exposure. In particular, some MEs will be conducted in different buildings and use differing amounts of antimicrobial product.

It is important to emphasize that although a random sample of observational MEs are not being obtained from a population of all possible (i.e., current or future) aerosol applicator-days, the data will in most instances be treated by users of the database as if it were such a random sample. That is, simple descriptive statistics such as means and percentiles will be used to characterize the diversity of exposure in this set of MEs. Users will not usually view these MEs as a set of N experimental units assigned to N fixed 'design points'. As is always the case, extrapolation from this set of MEs to a set of future aerosol applicator-days for regulatory purposes depends on the objective and requires subject matter expertise.

4.2 Restriction of Study to Fresno County, California

All MEs for the aerosol application monitoring study will be conducted in rooms inside vacant buildings (or inside non-occupied rooms within non-vacant buildings) in Fresno County, CA. This particular geographic area was selected given its proximity to the analytical laboratory. Fresno County also contains a moderately large metropolitan area and offers a population of over 500,000 persons. Consequently, there is a substantial janitorial population whose members are potentially acceptable for monitoring activities.

The use of a single geographic area is based on the premise that the type and variety of indoor janitorial aerosol application tasks being performed throughout one geographical area will not differ substantially from a similar array of tasks being performed at sites in another geographical area. That is, the variation in exposure associated with aerosol application inside of buildings throughout Fresno County, CA would not be expected to differ substantially if another metropolitan area was used or multiple cities over the country were spanned. This premise is supported by the Popendorf et al. (1992) antimicrobial exposure monitoring study which concluded that variability in dermal and

inhalation exposures across workers was primarily influenced by the application method and by implication, each individual worker's implementation of that application method (i.e., their work practices and behavior), rather than the location or setting in which the application method is performed. This implies that monitoring multiple subjects and capturing diversity in indoor aerosol application conditions that might influence behavior is more important than geographic diversity.

Geographic differences in exposure that have been observed in some agricultural cohorts are not expected for aerosol applications. For example, in harvesters, climatic conditions that influence the degree of dustiness, the rate of dissipation of foliar pesticide residues, or the amount of perspiration may influence exposure. Those differences cannot really be considered regional, but rather environmental. In the case of janitorial services conducted indoors, the environmental conditions are constrained by heating, ventilating and air conditioning systems that control dustiness, temperature, humidity and airflow. Therefore, these conditions are expected to be similar throughout the country.

Limited standardization of janitorial practices is another factor that is expected to lessen the importance of geographic area. The janitorial business is supported by organizations (e.g., International Sanitary Supply Association; www.issa.com) and companies (e.g., JohnsonDiversey; www.johnsondiversey.com; JohnsonDiversey offers a "Power Tools" training series) that supply training and guidance on issues such as duration of a particular job function, the types of supplies that are required and how to use equipment and supplies most efficiently. This helps to insure that janitorial work tasks are conducted somewhat uniformly across the country. By examining the documentation supporting training and use of janitorial supplies, the AEATF II found no evidence of regional work differences.

Lastly, there is increased efficiency, convenience, and cost savings associated with the use of a single location near the analytical laboratory. The use of buildings located over multiple cities would be especially costly. The cost of selecting both buildings and subjects would increase at least in proportion to the number of geographic locations due to field team logistics and resources required. For the reasons outlined above, there would appear to be little benefit from such an increase in cost.

5. Construction of Monitoring Events

As noted above a combination of random sampling and diversity selection is being used by the AEATF II to obtain N monitoring events (MEs) for the aerosol application study. In the AEATF II approach, instances of possible handler-day conditions under the scenario are synthetically constructed and handler-day exposures measured. Although application conditions are synthetic, actual applicators will have been randomly sampled from among professional applicator volunteers recruited from janitorial services located in Fresno County California. Each of N professional applicators will be randomly

assigned to one of the N synthetic applicator-days. Each combination of applicator and set of synthetic application-day conditions comprises a single monitoring event (ME).

The synthetic application-day conditions are either purposively or randomly chosen in such a manner that the MEs capture diversity likely in the aerosol application scenario. The approach used by the AEATF II achieves diversity by:

1. Using multiple sites (i.e., facilities/dates) within the study area (Fresno Co., CA) rather than conducting all monitoring at a single site;
2. Varying the levels of potential AI contact among MEs within each site.
3. Using a different subject for every ME.

Diversifying these three 'meta-characteristics' (site, AI contact level, and subject) indirectly varies many known and unknown application-conditions. Additional diversification by varying minor ME application-conditions (e.g., different configurations of aerosol surfaces) may also be added but is not a formal part of the design.

The resulting set N MEs provides a diverse set of applicator-days that mimic the diversity likely within the actual aerosol application scenario. The AEATF II has determined, in consultation with the U.S. EPA, Health Canada, and California EPA, that this combination of random sampling and diversity selection is appropriate considering the regulatory purpose of the data and feasibility. As described below, a diversity selection approach is one that can be purposive or can be coupled with random choice elements when feasible to reduce intentional selection bias. The AEATF II Governing Document (2008) describes diversity selection more generally in the context of the AEATF II antimicrobial exposure assessment program.

5.1 Random Sample of Professional Applicators

The most important single meta-characteristic that is formally varied when constructing MEs is the applicator. These are professional workers with experience in performing aerosol applications, who are available and consent to perform these tasks under the synthetic application-day conditions of the study. Although these applicators will be a random sample from an existing population of workers, they can be equally viewed as just another component of the synthetic ME being constructed to predict a single instance of a future day's exposure to an arbitrary antimicrobial pesticide. Each selected worker provides his/her unique set of behaviors to the aerosol application task. A random sample of applicator-days could, in theory, contain two or more days with the same worker. However, the random sampling method used for this study permits only one monitoring event per worker in order to capture a larger diversity of application behaviors.

The applicators will all be professional janitorial workers in the Fresno County, CA metropolitan area. Flyers and/or advertisements soliciting subjects will be posted at all cooperating janitorial service providers in the area and in selected local print media (all

materials will have been reviewed and approved for use by the IRB). Callers responding to flyers and/or media advertisements who are interested in participating in the study may be scheduled for Informed Consent meetings at the volunteer's convenience. It is not necessary to wait until the recruiting period is closed before enrollments begin. These individuals will then be contacted and screened, individuals who meet the study requirements will be recruited until the required number of applicators is obtained. As a precaution, more applicators are selected than are expected to be needed. Individuals who are enrolled to participate in the study will then be randomly ordered and assigned a subject identification sequence number (SISN). This random sample of workers is then allocated to MEs by SISN.

The recruitment process will terminate when sufficient subjects have been recruited for the study, i.e., have agreed to participate and signed the ICFs. If fewer than the required number of subjects has been recruited during the open recruitment period, the enrollment period will be extended in 7 days increments, until at least the minimum number of subjects and alternates have been enrolled into the study.

This process results in a simple random sample of qualifying subjects from the volunteer pool. Note, however, that this is not technically the same as a random sample from the existing population of professional janitorial workers. By definition, volunteers are self-selected and could, in theory, have different characteristics than non-volunteers. Such fine distinctions have little relevance in this case, however, because this is not an observational study of existing applicator-days. Because workers are randomly assigned to synthetic application-day conditions, the resulting MEs are still considered synthetic applicator-days. Thus, any type of random sampling of just one ME component (e.g., applicator in this case) provides no statistical advantage other than reduction of selection bias.

5.2 Selection of Monitoring Sites

Monitoring will always be conducted within vacant lodging facility buildings or vacant areas and rooms within otherwise occupied buildings. The purpose in conducting these studies in vacant or unoccupied areas in buildings/areas is to be free from personal interferences with non-subjects and the potential contamination from other sources of a commonly-used active ingredient (i.e., ADBAC). It also makes it easier to design monitoring events that focus on aerosol application only as opposed to the broad range of janitorial activities a subject might engage in that could also involve the active ingredient. Using vacant or unoccupied areas in buildings also offers greater control of the scheduling of monitoring events.

Each combination of facility (building or building complex) and monitoring period (i.e., dates) is termed a 'site'. Diversity is induced by requiring that the N monitoring events occur at N_C different sites over the Fresno County metropolitan area. As noted above, environmental conditions (e.g., temperature, humidity, air exchange rates) may be similar between facilities and at different times. On the other hand, buildings and dates

might still be surrogates for other confounding factors that could cause systematic differences in exposure. Conceivable confounding factors might be architectural differences in room size, construction materials and configuration, and dirtiness or organic loading levels on surfaces to be cleaned. Temporal separation of sites tends to average out subtle 'study effect' correlations that can result when the same research personnel, equipment, and area-wide environmental conditions are involved.

Obviously, between-site diversity is maximized if every ME for a scenario occurs at a different site (i.e., N_C=N). However, there are practical efficiencies to be gained by conducting multiple MEs (i.e., N_M) per site. Consequently the aerosol study achieves a balance by using multiple sites with multiple MEs per site. Any correlation resulting from having multiple MEs/site can be overcome, at least partially, by also increasing within-site diversity. Thus, facilities are preferred if they provide diverse indoor room and area configurations, e.g., individual offices, bathrooms, kitchen areas, dining areas.

For the AEATF II Monitoring Program, the term cluster is defined as the set of MEs for a scenario associated with the same building (or building complex) and span of days during which exposure monitoring occurs. In contrast, the term site refers to the physical facility and temporal monitoring period considered together as a unit (the temporal aspect of a site is not always emphasized but is important nevertheless). A total of N_C sites are required for the aerosol scenario. Each site will be used for a single cluster of N_M aerosol application MEs. The set of different sites should posses the following general design characteristics:

1. Each site must be located in a different facility (i.e., building or building complex).
2. The configuration of rooms actually used for MEs at the different sites should differ in ways that might influence exposure.

For purposes of the aerosol application study, the available space in each facility must also be large enough and have bathrooms and/or food preparation areas (e.g., kitchens or 'kitchenettes') that provide relevant and adequate surface areas for aerosol treatment. Commercial lodging facilities (e.g., hotels, motels with kitchenettes or full kitchen, and/or if needed, small apartments) are buildings that are most likely to provide an adequate amount of relevant aerosol application surface area for the monitoring events, e.g., bathroom sinks and fixtures, toilets and fixtures, bathtubs and fixtures, shower stalls and fixtures, bathroom counter tops, kitchen sinks and fixtures, kitchen countertops, and trash cans. While other building types, such as offices (e.g., medical suites) and meeting locations (e.g., universities) represent locations where disinfecting aerosols may be applied, and provide diversity in architecture and floor plan, these categories are less likely to provide the number of separate rooms and surface areas needed for the range of amount of aerosol to be sprayed.

A random sampling approach will be used to select N_C acceptable facilities. First, a list of all properties that meet the following criteria will be compiled:

- The property is commercially advertised on YellowPages.com or similar listings under "hotel, or motel " in "Fresno County, California," and;

- The property is at least partially within the boundaries of Fresno County, California; and

This list of commercial lodging facilities will then be randomized. Next, these properties will be investigated in (random) order until N_C qualifying facilities have been found. To qualify, the properties must meet the following general criteria:

- The facility management is willing to cooperate in the study and provide the necessary number of units with bathrooms and/or food preparation areas (FPAs).
- The configuration of available and ME-suitable rooms provides acceptable diversity of application surfaces (e.g., horizontal and vertical surfaces, kitchens, bathrooms, sinks, countertops, toilets).
- There is a functional HVAC system
- Electric service is on or available for a short period (i.e., less than 32 days).
- The property does not require specialized cleaning or maintenance prior to use.

In addition to these criteria, an acceptable facility must also fall into one of N_C different building/room categories (see Section 6.5). To insure diversity among the selected sites, only a single facility will be selected from each category. Properties will be investigated (in random order) until the first N_C acceptable facilities are found.

This procedure results in a (stratified) random sample of N_C acceptable and diverse facilities from the population of all such qualified facilities in Fresno County, California. Monitoring activities are then scheduled purposively for each facility.

5.3 Varying Amount of Product Applied

Another key diversity meta-parameter used to construct synthetic application-day conditions is the amount of active ingredient handled (AaiH). All MEs in the study will apply the same active ingredient at the same concentration using a different number of 19-oz (538 g) aerosol cans. Consequently, AaiH will be directly proportional to of the total amount of product (i.e., number of cans) sprayed during the monitoring period. To properly diversify the amount of product sprayed, some reasonable estimate for the expected range of this meta-parameter among professional applicators is needed. Data on the total amount of product applied are unavailable. Consequently, the expected range must be inferred indirectly from existing data on components of total workday product use.

Table 2 summarizes information on the average amount of formulated aerosol or trigger spray product applied to various surfaces in bathrooms and kitchens during observed cleaning events. These data were obtained from an observational study of actual product use by consumers (Aklam et al., 2006).

Table 2: The amount of product formulation (aerosol and trigger sprays) applied (g) for bathroom and kitchen surfaces.

Location	Type of Surface	N	Mean Amount Sprayed, g
Bathroom	Counter	12	10.16
	Sink	6	9.04
	Toilet	15	11.91
	Tub/Shower/Shower Door	15	93.31
	Wastebasket	3	3.67
Kitchen	Counter	13	41.50
	Sink	9	22.14
	Wastebasket	4	34.95

Each row in Table 2 only characterizes cleaning events for individual surface types, not the entire room. The mean amount of product applied if an entire room were treated can be approximated by assuming that a bathroom or a kitchen contains one surface of each surface type listed in Table 2. The resulting two room totals are shown in Table 3 along with the amount averaged over both room types. This overall average of 113 grams/room represents the mean total amount of product used in a 'generic' or 'typical' room treated on a given workday.

Table 3: The estimated average total amount of product formulation applied (g) when treating either the entire bathroom or the entire kitchen.

Room Type	Mean Amount of Product Used (g/room)
Bathroom	128.1
Kitchen	99.59
Generic Room[1]	113.3

[1] A 'typical' average amount of product used per room per day based on bathrooms and kitchens.

Obviously, 113 grams represents only the mean amount of product applied per room by a residential consumer. The actual amount will vary from room to room, from day to day, and from person to person. However, this amount is not expected to vary independently. There will certainly be some degree of correlation for all rooms cleaned by the same individual. More importantly a negative correlation is expected to exist between the total number of rooms per workday and the amount of product used per

room. That is, when a larger number of rooms are treated, there could be a tendency to spend less time, and apply less product, per room.

Logically, on days when antimicrobials are used, at least one room will be treated. In this case 113 grams of product would be used on average. This translates to 21% of the 19 oz (538 g) canister that will be used for this study. Given the negative correlation between number of rooms/day and amount/room, this lower bound should probably be larger than the generic room average. (i.e., more than the 'average' amount of product might be sprayed on surfaces when only a single room is cleaned). In addition, for the AEATF II aerosol study, the analytical method LOQ sets a practical lower limit on the amount of product that should be used for an ME. Obviously it is desirable to obtain actual measurements, rather than non-detects, beneath normal work clothing. For this scenario, it is felt that a practical lower bound of one canister (i.e., 538 grams) per ME will achieve detectable levels of active ingredients on dosimetry matrices.

Information about the upper limit on number of rooms/day is based completely on inferences about the professional housekeeping population. Aerosol products used by professionals are in smaller, specialty business venues, such as medical offices and specialty hotels. Thus, while consumers may treat only a single kitchen and one or two bathrooms on a single day, this number in institutional settings such as hospitals is expected to be much larger. According to JohnsonDiversey Inc. (personal communication with AEATF II, September 19, 2008), information from multiple sources[1] indicate that a single individual at a hospital would typically clean from 15 to 20 hospital patient rooms per day. However, aerosol use is more likely at medical and dental offices and specialty lodging facilities than in hospitals. In these settings JohnsonDiversey Inc. feels that the typical range would extend below 15 rooms per day. Consequently, 20 rooms/day would appear to be a reasonable upper bound for professional aerosol applicators.

As noted above, when such a large number of rooms are cleaned per day, it is very likely that the mean amount of product applied per room will be less than the 'overall average' of 113 grams. However, using 20 rooms/day and 113 grams of product per room should still provide a conservative upper bound for total product applied per day by professional cleaners. This approximation gives a maximum of 2,260 grams of product (113 g/room x 20 rooms/day), or about 4.2 19-oz canisters (2,260 g / 538 g per canister), per day.

Thus, these results suggest that reasonable diversity in AaiH among MEs could be obtained by varying the number of 19-oz canisters applied between 1 and 4. This will be accomplished by dividing this range into N_M intervals, or strata, of amount of product

[1] JohnsonDiversey's expert opinion was based in part on information from the following sources: 1) the American Hospital Association (http://www.aha.org/aha_app/index.jsp), the American Society for Health Care Environmental Services (http://www.ashes.org/ashes_app/index.jsp), and the U.S. EPA's Environmental Best Practices for Health Care Facilities (JCAHO Environment of Care Standards 1.3,2.3,4.0, November 2005).

(i.e., number of canisters) sprayed (see Section 6.5). Each of the N_M MEs at a site will be assigned to one of these product use intervals.

5.4 Potential Sources of ME Bias

As noted above, a practical study goal is that the set of aerosol application MEs represents a diversity of potential applicator-day conditions that might impact exposure. To the extent this is achieved, the set of MEs will tend to exhibit greater variation in log-exposure than would an actual population of all possible applicator-days. Because applicator-day exposures are expected to be distributed lognormally, greater variation of log-exposure implies greater positive skewness of non-transformed exposure. Consequently, statistics that are sensitive to positive skewness (e.g., arithmetic mean and upper percentiles) might be biased upwards.

It is also important to recognize that some degree of potential overestimation bias is inherent in any study if the exposures measured on the inner dosimeters from MEs are less than limit of quantitation (LOQ). This is more likely to occur when the amount of product applied is smaller, although AEATF is making every effort to obtain measurable exposures for all MEs.

Another potential source of inherent potential overestimation bias in the study design described in this document and the associated protocol is reusing the same rooms for multiple applicators. The residue remaining from a prior day's use might represent a significant source of dermal contamination for subsequent users.

Other potential sources of potential overestimation bias result from characterizing all aerosol exposure from situations having higher-than-average exposure potential such as:

- spraying in an enclosed space (e.g., shower enclosure),
- spraying above and below the chest height,
- spraying near air exhaust vents, or
- walking into spray mist sprayed overhead.

For most regulatory users of these data, however, potential overestimation of exposure will likely be of little concern because it would still be inherently protective of workers. The AEATF does not foresee significant sources of underestimation bias for exposure estimates derived from data resulting from the proposed study.

6. Sample Size Determination

For the most part, sample sizes can only be determined using statistical theory alone when either

1. There is assumed random sampling from a population and the goal is to estimate some characteristic of that population; or

2. There is assumed randomization of experimental units to treatments and the goal is only to compare or contrast treatments in some manner; 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 'naturally' random (although such natural residual randomness may 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 three 'random' situations above as a reference model. The random reference model is constructed so that it reflects important aspects of the actual situation. The sample size that is appropriate for the reference model is then used for the actual study design. The use of a random reference model is not, however, a claim that the pure situation described by the reference model actually occurs.

This random reference model approach is used to determine sample sizes for the aerosol application scenario. The aerosol application study will utilize a combination of random sampling, randomization, and diversity selection methods. While this methodology contains some elements of all three pure situations above, none apply completely. The ultimate goal of this study is to construct synthetic MEs that can be used to characterize the diversity of future daily exposures to antimicrobials through aerosol application. Hence, the study objectives are more closely aligned with the random sampling situation (1) above. As a result, a reference model for random sampling will be used for the determination of sample size.

6.1 Reference Sampling Model

In a general sense, the aerosol application study involves selecting N_C buildings and then conducting N_M MEs within each building. This results in a total of $N=N_C \times N_M$ monitoring events. The simplest reference model would be one that treats the N MEs as a simple random sample of N independent applicator-days from a population of future applicator-days. However, if there is a correlation between MEs conducted in the same building, the sample sizes calculated from this reference model will be too small. A better reference model would accommodate this simple type of ME correlation. More complicated reference models that incorporate specific aspects of the sampling and random assignments could also be proposed. However, such models would be of little practical value since they would require estimates for many parameters for which no information is available.

For the aerosol application study, therefore, random nested sampling will be used as a reasonable reference model for the combination of random sampling, randomization, and diversity selection actually used. This reference model assumes that:

1. Exposure, normalized by the amount of active ingredient handled, is lognormally distributed with a known geometric standard deviation (GSD). Equivalently, the logarithm of normalized exposure is normally distributed with known standard deviation Log GSD.

2. There are N_C clusters (i.e., sites) and N_M MEs per cluster. The total number of MEs is, therefore, $N=N_C \times N_M$.

3. There is a possible within-cluster (i.e., within-site) correlation of log normalized exposure. This is referred to as the intra-cluster correlation, or just the ICC.

6.2 Benchmark Objective

Benchmark objectives specify accuracy goals that must be achieved within the framework of the reference sampling model when sample size is adequate. In this study, 'sample size' means both the number of clusters (N_C) and the number of MEs per cluster (N_M).

For the aerosol application study, the benchmark objective is that (when the reference model is true) sample estimates of the arithmetic mean and 95th percentile of normalized exposure are accurate to within 3-fold 95% of the time. The EPA, in discussion with AEATF II, determined that this benchmark is sufficient for regulatory purposes.

6.3 Expected Variation in Normalized Exposure

Some idea of the variability of normalized exposure is necessary in order to determine the sample size that meets the benchmark objective. In terms of the reference nested-random sampling model, the variation structure is determined by the geometric standard deviation (GSD) and the intra-cluster correlation (ICC). GSD measures the total relative variation between future applicator-days of normalized exposure. The ICC describes how similar within-site exposures are with respect to the total variation in (normalized exposure). An ICC of zero means that MEs within the same cluster are no more similar than are MEs in different clusters. At the other extreme, ICC=1 means that all MEs in the same cluster have identical exposure.

As noted previously, the CMA study (Popendorf et al. 1992) provides the only directly relevant existing data for the aerosol application of antimicrobial pesticides. This study, however, provides just five aerosol applicator monitoring events spread over three

different facilities. Although only hand exposures were detectable, these data can provide a crude estimate of total relative variation (GSD). However, the numbers of facilities and MEs per facility are too small to provide a useful estimate of ICC.

Although obtained for crack and crevice insecticide applications, PHED study 521 can provide normalized dermal exposure data for 15 hand-held aerosol monitoring events collected from 15 different residential houses. For this measure, there were no significant differences among the five subjects ($p=0.1833$). Thus, it is reasonable to treat these as 15 independent MEs for the purpose of estimating total relative variation. As was the case for the CMA study, these data can provide no estimate of ICC since each ME was conducted in a different house.

In addition to the two aerosol studies discussed above, exposure data from additional, non-aerosol application sources are also available (Table 4): The CMA study provided data for mopping applications (6 MEs) and for wiping applications (6 MEs). As is the case for aerosol, both mopping and wiping application are repetitive-motion tasks. Although the magnitude of the normalized exposures for mopping, wiping, and aerosol application are not expected to be the same, the relative variation for repetitive-motion activities might be expected to be driven primarily by variation in subject behavior. If so, then these four sets of data might have a common geometric standard deviation and a more robust estimate of GSD can be obtained by using all of this information.

The feasibility of using the normalized dermal exposure results from the two aerosol data sets or from all four 'repetitive task' data sets together to estimate relative total variation for the aerosol study was first evaluated. Only dermal exposure was considered given that it was associated with higher exposures, i.e., was found to be the primary route of exposure in these studies. Levene's test for equal variability among groups (Glazer, 1983) was applied to the $\log_e$-transformed, normalized dermal exposure values. These results are summarized in Table 5. Although the log-scale standard deviations (SD) ranged from 0.62 to 1.61 there was no significant difference ($p > 0.05$) in relative variability among the four data sets. A common-variance ANOVA model gave a pooled log-scale SD of 0.74 for the two aerosol studies and 1.05 for all four repetitive-motion studies. The corresponding estimates of geometric standard deviation (GSD = exp SD) would then be 2.1 and 2.9, respectively. These two GSD values are considered in the determination of sample size in the next section.

None of these studies can provide an indication of the expected magnitude of the within-cluster correlation (ICC) in normalized exposure resulting from aerosol application. Much of the variation resulting from such a repetitive task is expected to track the variation in worker behaviors and within-facility diversity. In contrast, small variation in indoor environmental conditions (surface types and configurations, temperature, humidity, air exchange rate) is expected across indoor locations (e.g., building types) in which the monitoring events take place. This would suggest an intra-cluster correlation (ICC) near zero. A central tendency ICC value across many outdoor agricultural exposure scenarios, where moderate levels of within-site correlation are

expected, is 0.3 (AHETF, 2007, Appendix C). This represents a likely upper-bound for most indoor antimicrobial exposure scenarios.

Table 4: Source (Study)-Specific Normalized Dermal Exposure Values for each Monitoring Event

Source (Study)	Monitoring Event ID	Normalized Dermal Exposure (µg / lbs ai handled)
CMA (Aerosol, Hands)[1]	47	126,263
	79	48,913
	80	666,667
	87	413,043
	90	340,909
PHED (Aerosol, Study 521)[2]	521-A-1	2,180,000
	521-A-2	657,000
	521-A-3	365,000
	521-B-4	488,000
	521-B-5	459,000
	521-B-6	199,000
	521-C-7	815,000
	521-C-8	1,140,000
	521-C-9	1,720,000
	521-D-10	1,020,000
	521-D-11	521,000
	521-D-12	384,000
	521-E-13	683,000
	521-E-14	617,000
	521-E-15	410,000
CMA (Mop)[3]	1	20,855
	5	22,186
	7	503,250
	9	16,656
	10	34,394
	11	37,088
CMA (Wipe)[4]	2	4,313,916
	6	1,747,115
	8	1,058,688
	61	49,252
	62	471,758
	73	2,570,922

[1] Monitoring events corresponded to separate individuals each treating a different room. Rooms were spread over multiple buildings. Dermal residues were only detectable on hands. Three monitoring events that yielded non-detectable residues for all body parts were excluded.
[2] Monitoring events corresponded to three separate evaluations of 5 different individuals. Each of the 15 monitoring events occurred in a different house.
[3] Monitoring events corresponded to separate individuals treating a different room (over a variety of locations).
[4] Monitoring events corresponded to individuals treating a different room. Rooms were spread over multiple buildings. Two monitoring events that yielded non-detectable residues for all body parts were excluded.

Table 5: Estimates of the Variation in Total Normalized Dermal Exposure from Existing Studies.

Study	N	Standard Deviation of Log_e Normalized Exposure
PHED (Aerosol, Study 521)	15	0.62
CMA (Aerosol-Hands)	5	1.05
CMA (Wipe)	6	1.61
CMA (Mop)	6	1.26
Common Relative Variation Models:[1]		
PHED and CMA Aerosol Studies only:		
Common SD of Log_e Exposure		0.74
Common GSD of Exposure[2]		2.1
All 4 Repetitive Task Studies:		
Common SD of Log_e Exposure		1.05
Common GSD of Exposure[2]		2.9

[1]Assuming a separate mean for each study, but a common standard deviation on the log scale.
[2]Geometric standard deviation = exp(SD).

6.4 Determination of Sample Size

A Monte Carlo simulation approach was used to examine the impact of number of clusters (N_C) and number of MEs per cluster (N_M) on accuracy of the arithmetic mean and 95th percentile for the reference model. For each examination 10,000 random data sets were generated using the reference nested-random sampling model and assumed values of the total GSD and the intracluster correlation (ICC). From each simulated set, estimates of the arithmetic mean and 95th percentile were calculated.

The fold relative accuracies (*fRA*) for the mean and 95th percentile were also computed. If θ is the parameter of interest and T is the corresponding calculated statistic, then fold relative accuracy is defined as:

(1) $$fRA = \text{Maximum of } T/\theta \text{ and } \theta/T$$

Fold relative accuracy simply expresses how far T is from θ in a relative sense. The result is 10,000 random values of *fRA*. The empirical 95th percentile of these 10,000 *fRA* values, fRA_{95}, is the quantity of interest. By definition, T is within (fRA_{95})-fold of θ, 95% of the time. Thus, if 3-fold accuracy is desired, fRA_{95} should be approximately equal to 3. (Note that for historical reasons, the EPA and others sometimes refer to fRA_{95} as the 'K-factor'.) The simulation procedures and the definition of fold relative accuracy are the same as those used for the AHETF monitoring program (AHETF, 2007, Appendix C). This simulation method and its theoretical basis are described in greater detail in the AHETF documentation.

For a configuration of N_C=3 clusters (i.e., sites or buildings), Table 6 shows the sample size necessary to achieve 3-fold relative accuracy with GSD=2.1 or GSD=2.9 and an intra-cluster correlations (ICC) as high as 0.3. For the aerosol-only GSD of 2.1, only 2 MEs per cluster are needed giving a total of N=6 MEs for the aerosol scenario. However, when the more robust repetitive-motion task GSD of 2.9 is used, 6 MEs per cluster are required giving N=18 MEs for the scenario. Given the sensitivity of the sample size to GSD and the belief that the repetitive-motion GSD is a better indicator of the expected true relative variation for this scenario, the AEATF II prefers to assume GSD=2.9 for the purposes of determining sample size. As also shown in Table 6, smaller, and perhaps more likely, ICCs will yield accuracies much better than 3-fold.

Table 6: Relative accuracy profile when there are N_C=3 clusters (sites) and the number of monitoring events per cluster (N_M) is chosen to give 3-fold accuracy or better at ICC=0.3.

ICC	95% Bound on Relative Accuracy (fRA_{95}) or "K-factor"			
	Aerosol Studies GSD of 2.1 N_M=2 MEs per cluster		Repetitive Task Studies GSD of 2.9 N_M=6 MEs per cluster	
	Arithmetic Mean	95th Percentile	Arithmetic Mean	95th Percentile
0	2.0	2.6	1.9	2.2
0.1	2.0	2.7	2.1	2.4
0.2	2.1	2.8	2.3	2.7
0.3	2.1	3.0	2.5	3.0

It is also possible to obtain equivalent accuracies with different configurations of N_C and N_M. For example, when GSD=2.9 the three configurations listed in Table 7 are essentially equivalent. Although they may be statistically equivalent, the configuration with fewer clusters and more MEs per cluster (and more total MEs) is actually more cost effective and also permits a greater diversity in amount of product applied within each cluster. Thus, a design of 3 sites and 6 MEs per site appears reasonable if the reference model is assumed. By analogy, this configuration will be used for the aerosol application study as well.

Table 7: Practically equivalent configurations of clusters and MEs per cluster when ICC=0.3.

Number of Clusters, N_C	MEs per Cluster, N_M	Total MEs, N	fRA_{95} for 95th Percentile	
			ICC=0	ICC=0.3
3	6	18	2.2	3.0
4	4	16	2.2	2.8
6	2	12	2.6	2.8

6.5 Building/Room Categories and Product Use Intervals

The scenario design in Section 6.4 indicated that NC=3 clusters are required. As discussed in Section 5.2 each of these three clusters of MEs should be conducted at a monitoring site that can be generally described as a qualifying commercial lodging facility (i.e., hotel, motel with kitchenette or full kitchen). MEs will be conducted in available bathrooms and, if present, food preparation areas within the facility. A food preparation area (or FPA) is defined as a room containing a stove/oven, refrigerator, and food preparation sink.

A simple random sample of qualifying facilities could be selected. However, this might result in two or more monitoring sites with similar configurations of ME-appropriate rooms. Although valid, greater diversity among monitoring sites can be obtained if each of the three clusters is conducted in a somewhat different room configuration. Consequently, for the aerosol application study the AEATF II will consider only the following three building/room configuration categories:

A. Hotels/motels with 20 or more available units containing full kitchens

B. Hotels/motels with 20 or more available units containing kitchenettes

C. Hotels/motels with 20 or more bathroom-only units.

These three categories were chosen because they vary with respect to bathroom and FPA (i.e., kitchen or 'kitchenette') configurations which might be expected to impact exposure potential differently. Although other, equally acceptable, classifications could be proposed, this one is considered both intuitive and logistically practical.

As described in Section 5.2 above, one facility will be randomly selected from each category. It is important to emphasize that this study is not concerned with testing whether average exposure differences exist between the three different configuration categories. Nor would it be especially relevant if true exposure differences actually do not exist, on the average, between these categories. Rather, the purpose of the patterned randomization is simply to reduce the likelihood that the three selected monitoring sites will be too similar by chance.

The scenario design also requires N_M=6 MEs within each cluster. As noted in Section 5.3, each of these MEs will require an amount of product in the range of 1 to 4 19oz cans. Thus, a reasonable approach is to require that the six MEs have applicators apply product amounts somewhere within the following six ranges:

A. 1 to 1.5 cans	B. 1.5 to 2 cans	C. 2 to 2.5 cans
D. 2.5 to 3 cans	E. 3 to 3.5 cans	F. 3.5 to 4 cans

Ranges for the different product application volumes are used since partial can amounts are difficult to control exactly without impacting the behavior of an applicator. Actual product levels are not randomly assigned within each interval. Rather, each applicator will be asked to stop applying when the ME observer estimates that the amount applied is somewhere in the target interval assigned to the ME.

The N=18 randomly sampled professional applicators will be randomly assigned to the N=18 combinations of building/room configuration category and application volume illustrated in Table 8. This provides a diverse set of MEs with respect to three meta-parameters: (1) applicator, (2) types of rooms, and (3) product volume applied.

Table 8: The structure of the N=18 MEs proposed for the aerosol application study

Number of 19 oz cans applied per ME	Building/room configuration category		
	Motel with bathrooms and Full Kitchen FPAs	Hotel/motel units with bathrooms and Kitchenette FPAs	Hotel/motel units with bathrooms only
1 to 1.5	●	●	●
1.5 to 2	●	●	●
2 to 2.5	●	●	●
2.5 to 3	●	●	●
3 to 3.5	●	●	●
3.5 to 4	●	●	●

It is reasonable to ask if it would be simpler to abandon the attempt to structure diversity in building/room configuration and application volume. One might simply select three facilities at random from among the qualifying facilities in Fresno County. In addition, six application volumes anywhere between 1 and 4 cans could also be randomly selected. Table 9 illustrates possible consequences of such an unstructured approach. Because facility selection was completely at random, one category was missed and two monitoring sites in another category (motel with full kitchen) were selected by chance. This still provides some diversity, but not as much as provided by the stronger diversity selection approach in Table 8. The randomly selected application volumes cover all but the 1 to 1.5 can amounts. But there is no balance within each facility and some of the intervals are more heavily represented than others.

Table 9: A structure of the N=18 MEs generated by randomly selecting building and product amount

Number of 19 oz cans applied per ME	Building/room configuration category			
	Motel with bathrooms and full kitchen		Hotel/motel units with bathrooms and kitchenette FPAs	Hotel/motel units with bathrooms only
1 to 1.5				
1.5 to 2	●●●	●		
2 to 2.5		●●●		●●●●
2.5 to 3				●●
3 to 3.5	●	●●		
3.5 to 4	●●			

Table 9 illustrates only one example of the possible random configurations that could be generated. However, the lack of diversity shown by this configuration is rather typical of other randomly generated configurations. In general, when sample sizes are relatively small, random selection is less likely to produce a diverse set of MEs. Although neither of the approaches shown in Tables 8 and 9 can yield a true random sample of future applicator days, it is felt that the diversity selection approach (Table 8) will be better able to characterize the future applicator-day diversity in exposure. On balance, therefore, the AEATF II considers that constructing MEs with the greater diversity shown in Table 8 is well worth the additional effort.

It should be noted that the ME design illustrated in Table 8 has the superficial appearance of a fixed-effect treatment structure with two fixed factors: building/room configuration category and application volume. In such an experimental framework this could be thought of as 18 experimental units (applicators) assigned to 18 design points (combinations of category and amount). However, regulatory agencies and most other users of these data will prefer to view these MEs not as a fixed-factor 'comparative' experiment, but merely as a set of N=18 synthetic applicator-days that characterize the diversity of exposures possible for the aerosol application scenario. This 'diversity characterization' objective was envisioned by AEATF II when determining sample size. A statistical comparison of exposure between building types or between application volumes was not envisioned as an objective for the purpose of sample size determination. However, statistically sophisticated users of these data are always free to analyze such aspects of the exposure data if they so desire.

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APPENDIX A

Study Rationale
Product Selection Justification

July 13, 2009

RATIONALE FOR STUDY

1. Introduction

This document is designed to provide relevant information and rationale for the conduct of the subject study. Prior to initiation of protocol development, an effort was made to check for existing data that could be utilized / substituted to estimate exposure from use of antimicrobial aerosol products both in household and commercial/institutional settings. Additionally, the information collected would also provide a valuable tool in selection of the product/s and study design for estimating exposure from use of pressurized aerosol cans.

2. Literature Review

A literature search revealed that very little data existed on exposure to pressurized aerosol products. The most relevant articles were selected and a summary of those reports/publications is provided as part of the justification for the conduct of the subject study and its application in the proposed study design and product selection.

2.1. Berger-Preiss et al. (2005):

This study was conducted in response to the EU Directive 98/8/EC, to estimate inhalation and dermal exposure during spray applications of biocides. The study involved an extensive survey of published and unpublished literature regarding use of biocides and categorized the information according to the uses e.g., greenhouses, indoor pest control, stables, wood preservatives and antifouling agents. Measurements were performed at selected workplaces during disinfection operations in food and feed areas; pest control operations for private, public and veterinary hygiene; wood preservative and anti-fouling agents. In order to compare literature results regarding influence of parameters relevant to exposure (e.g., spraying equipment, nozzle size, direction of application), model experiments were conducted in 60 m^3 rooms. The sprayers used in the model experiment were Frowein "Spray Boss" with various nozzle sizes (low pressure); Wagner (airless sprayer); and a cold fogging apparatus which represented the range of equipment used in the work place. In the extensive literature survey conducted by the authors, only one reference regarding use of aerosol cans for indoor and/or green house pest control was available.

The research literature survey of work place measurements were mostly related to agrochemicals, wood protection, and paint with high or low pressure aerosol generation. The inhalation exposure monitoring data was mostly from green houses, including re-entry type of studies for worker safety using stationary sampling or personal pumps. The results from work place measurements and model experiments revealed the following:

- Particle size distribution was the most important parameter and was dependent on the nozzle size of the sprayer
- Fine particles stayed suspended longer and gave higher inhalation exposure

- Inhalation exposure was lowest when spraying direction was downward
- Inhalation exposures was higher during overhead spraying
- Highest inhaled dose rates were measured during fogging
- Sprayers' distance from the sprayed object was of minor importance
- Higher pressure spraying led to higher exposure
- Spraying of higher application volumes (amount of active material) per time led to an increased inhalation exposure
- Air concentrations were higher without ventilation
- Dermal exposures were very much dependent on the spraying direction and apparatus
- Spraying the upper part of the wall, the head, upper arms and thighs had most exposure (with Spray Boss) and exposure was lower during fogging and horizontal spraying and also lower during spraying of the lower part of the wall
- Dermal exposures varied by a factor of 10 and were dependent on the behavior of the user
- Model experiments were predictive of the field measurements
- Aqueous solutions gave higher concentrations compared to higher vapor pressure solvent based solutions
- No major differences between stationary sampling or personal pumps, with slightly higher trend with the personal pump

The study does not provide exposure data which is directly applicable to the cleaning and disinfecting aerosol products in cans represented by the Task Force membership. However, the study provides useful information in selecting the product/s and in study design. Based on this information one can conclude that a product which will have a higher number of particles in the inhalable range (fine spray), used in multi-directional orientation, in confined spaces and with relatively low vapor pressure will provide the greatest exposure.

2.2. Marquart et al. (2003)

This publication is a review of available literature on the subject and discusses various determinants influencing exposure and use of the information in developing models for risk assessment. Inhalation and dermal exposures are complex processes and determinants of exposure depend on exposure scenario. In the aerosol spraying process the most important exposure determinants are:

- Spray volume i.e., amount of liquid sprayed
- Area treated
- Orientation of worker in relation to application or orientation of the spray applicator
- Proximity of the worker to the source i.e., distance from the application surface
- Spray pressure is related to particle size distribution; and deposition velocity is important for both inhalation and dermal exposure from use of aerosols
- Type of surface

- Worker habits

The publication does not provide data that can be directly substituted for estimating inhalation and dermal exposure from use of aerosol products. However, the information available supports the arguments, made subsequently, for product selection in the proposed study and provides guidance in study design. In the proposed study the most influential determinants for inhalation and dermal exposure will be considered both in the selection of the product and study design.

2.3. Nazaroff et al. (2006)

This was an extensive study undertaken for the California Air Resources Board (ARB) to determine the exposure from air contaminants produced by indoor use of consumer products for cleaning and as air fresheners. The study focused on the volatile organic components that contributed to production of photochemical smog including indoor reactive chemistry. The main emphasis was on the terpene-ozone reaction.

The indoor household products were identified by a shelf survey of five retail outlets in Northern California and by literature review on air pollutants. The product list included disinfectants, general-purpose degreasers, general-purpose cleaners, wood cleaners, furniture maintenance products, spot removers, multi-purpose solvents and air fresheners. From the list, six products (one from each group) were selected to study emissions and concentrations of the primary constituents in simulated-use experiments in room-sized research chambers. Experiments were also conducted in a bench-scale chamber under controlled conditions to study the reactivity of volatiles with ozone. The test atmosphere was analyzed for various components and particle size distribution was measured only up to four micrometers for the aerosol products. The data was analyzed for its relevance to humans.

The study concluded that inhalation exposure to air pollutants can be expected to occur under some circumstances during the use of common household cleaning products.
In this elaborate study on exposure to household products no effort was made to determine the concentration of the active ingredients in air and the focus was on the volatile liquids and gases. Therefore, the data is not directly applicable to estimate exposure to the aerosol products represented by the Task Force membership.

2.4. PHED and CMA Studies

These studies have been discussed in detail previously in the Scenario Design Document and will not be considered further.

2.5. Conclusions from the Existing Data

From the review of the relevant literature, it can be concluded:

- The existing information does provide useful general information on the behavior of the aerosol products and identifies variables which are most influential in

defining inhalation and dermal exposure by use of aerosols.

- The data are very limited and do not fully represent the use patterns and exposure scenarios of the products represented by the Task Force and therefore, are not suitable for estimating the inhalation and /or dermal exposures by use of aerosol cans.
- The available knowledge could be helpful in the proposed study design and selection of the product.

The proposed study can be designed to provide exposure data most suitable for use in the risk assessment of the aerosol biocide products in cans.

2.6. Relevance of Existing Data to the Study Goals

As discussed above in the conclusions the data cannot be directly used to assess the inhalation or dermal exposure associated with use of pressurized aerosol cans, but has relevance in defining the parameters that contribute to and influence the degree of exposure. The main goal of the study is to generate data using a product with high exposure potential and covering the most influential variables associated with inhalation and dermal exposure. The data generated can then be used in risk assessments for most exposure scenarios resulting from use of aerosol cans.

2.6.1. Most Influential Variables Effecting Exposure

The most influential variables described in the existing data and relevant for the current study design and selection of the representative product (test material) are:

- Amount of material used
- Release rate
- Particle size distribution
  - Nozzle technology
  - Pressure in the can
  - Temperature / humidity
- Surface on which product is used
- Orientation of the can during use

These influential variables are considered and discussed in more detail in the following section - rationale for selection of the test substance for the study.

3.0 RATIONALE FOR SELECTION OF TEST SUBSTANCE

Test substance selection was based on the hypothesis that a representative product /products could be selected and data generated with the following characteristics:

- Serve as a surrogate for most pressurized aerosol use categories
- Use pattern represents high end exposure – a conservative scenario
- Use scenario covers most influential variables of exposure
- Has a stable active ingredient with a low Limit of Quantification
- Results can be extrapolated to most antimicrobial aerosol products

In order to meet the above **criteria for product selection**, the following information was considered:

1. Survey of the products represented by the AEATF II
    a. Product profile including aerosol characteristics, release rate, nozzle size and use scenarios
    b. Consideration of influential variables
2. Identify product categories based on use scenarios
3. Conduct of a pilot/ method development study using a representative product from each category
4. Identify product to serve as surrogate to meet criteria for the study design and product selection

3.1 Antimicrobial Products Represented by AEATF II

3.1.1 Survey of products For selection of the surrogate product/s, an informal survey of the Task Force Membership, representing the number and type of aerosol products was conducted, and the following 18 products marketed by 9 major companies were identified. Table 1 presents details on the product use and other associated characteristics. It should be noted that the number of products represented by these companies are sold under various brand names in retail stores either by the companies or their customers and cover a vast range of antimicrobial aerosol products sold on the market. Therefore, the product representation covers the range of use categories both for household and commercial/institutional applications.

Table 1– Products Represented by the Task Force Membership

Product name	Company Name	Use Scenario	Spray Type
Lysol Brand Disinfectant Spray; Lysol Brand IC Disinfectant Spray; Professional Lysol Brand Disinfectant Spray; (EPA Reg--Biosol)	Reckitt Benckiser	Hard surface disinfectant & sanitizer; Soft surface sanitizer	Fine spray
EPA Reg. name: Lysol Brand foaming Disinfectant Basin Tub & Tile Cleaner II; Sold under several other names	Reckitt Benckiser	Hard surface cleaner & disinfectant	Foaming Spray
Lysol Brand Disinfectant Spray (Lysol Neutra Air)	Reckitt Benckiser	Disinfectant air treatment	Fine Spray
Clorox Disinfecting Spray	Clorox Services Company	Spot treatment; surface disinfectant (hard nonporous surfaces); other	Fine Spray
Raid Ant & Roach Killer Germ Fighter	S.C. Johnson & Son, Inc.	Other--Insecticide with antimicrobial agent (0.1%)	Fine Spray
Oust Air Sanitizer	S.C. Johnson & Son, Inc.	Disinfectant/sanitizer (Air)	Fine Spray
Oust Surface Disinfectant & Air Sanitizer	S.C. Johnson & Son, Inc.	Disinfectant/sanitizer	Fine Spray
Antibacterial Scrubbing Bubbles Bathroom Cleaner	S.C. Johnson & Son, Inc.	Foaming aerosol products	Foaming spray
Envy Multipurpose Cleaner	JohnsonDiversey Inc.	Disinfectant/sanitizer; Cleaning--industrial, institutional	Foaming Spray
Endbac II	JohnsonDiversey Inc.	Disinfectant/sanitizer; Cleaning--industrial, institutional	Foaming Spray
Aerosol Surface Disinfectant	Stepan Company	Surface disinfectant	Fine Spray
Aerosol Detergent/ Disinfectant	Stepan Company	Surface cleaner/disinfectant	Fine Spray
Aerosol SDAS	Stepan Company	Surface sanitizer/ disinfectant; air freshener, air sanitizer	Fine Spray
Staphene Spray	Steris Corporation	Surface disinfectant air sanitizer	Fine Spray
Asepti-Steryl	Ecolab, Inc.	Hard surface hospital disinfectant	Fine Spray
Asepticare	Ecolab, Inc.	Hard surface hospital disinfectant	Fine Spray
Febreze Air Effects/Swiffer Furniture Polish	Proctor and Gamble	Air freshener and furniture polish	Fine Spray
Withheld	International Paint	Anti-fouling agent	Fine–coarse Spray

The concentration of the AI(s) is available on request. The main active ingredients found in these products are shown in Table 2:

Table 2 – Active Ingredients in Products Shown in Table 1

Active Ingredient (AI)	No. Products
• Octyl decyl dimethyl ammonium chloride (ODAC)	2
• Dioctyl dimethyl ammonium chloride (DODAC)	2
• Didecyl dimethyl ammonium chloride (DDAC)	2
• Alkyl dimethyl benzyl ammonium saccharinate (ADBAS)	1
• Dimethyl benzyl ammonium chlorides (DBAs)	1
• Alkyl dimethyl benzyl ammonium chloride (ADBAC)	10
• Alkyl dimethyl ethylbenzyl ammonium chloride (ADEBAC)	5
• BTC 2125M	3
• Ethanol (EtOH)	5
• 2-phenylphenol	1
• o-benzyl-p-chlorophenol (OBPC)	1
• p-tertiary amylphenol (TAP)	1

3.1.2 Consideration of Most Influential Criteria/Variables in Product Selection

Particle size distribution, Release rate and Nozzle technology

It is well known, as summarized previously, that particle size and amount of product released/unit time are some of the influential variables impacting dermal and inhalation exposure from use of aerosol products. The particle size and the release rate are related to and controlled by the nozzle characteristics (size or orifice diameter and technology) along with various other parameters. Therefore, nozzle characteristics were also considered in justifying the product selection for the aerosol exposure study.

In the aerosol spray applications, it is desirable to deliver a spray of small particles (>10-200 µm) with somewhat uniform diameter and most of the products have particle sizes less than 200 µm (Table 3). The actuator or nozzle design (orifice size or diameter and taper) is one of the parameters that influence the particle size, release rate and hence exposure to the user. The release rate and particle size are also limited by the container pressure and container characteristics (e.g., size or surface to volume ratio, container material including plastic, steel or aluminum) and fluid properties including surface tension and viscosity (Shieh et al. 2008). There are numerous variations on the combination of nozzle size and design, container pressure and size which are used in controlling the average droplet size and release rate for an aerosol product (Lionstar

Corporation; Giles et al. 2005). The aerosol cans are generally made of metal and plastic and the propellant pressure ranges from 40 to 60 PSI based on the material. The can sizes range from 2.5 to 19 ounces.

Release rates/Nozzle technology

Table 3 provides Release rates and nozzle sizes for the aerosol products. The data show that the release rates range from 0.66 g/second – 2.8 g/second and the nozzle sizes range from 0.013 – 0.03 inches and most of the nozzles sizes were ~0.02". (It should be noted that the information provided in Table 3 on the aerosol generation technology used by the companies is propriety in nature and the products are coded for public release of this information. However, the EPA will be provided with complete information). As mentioned previously, the release rate and particle size is dependent on the combination of nozzle technology and can characteristics. Aerosol can sizes range from 2.5 -19 oz and are pressurized at 40-60 PSI with the propellant of choice. The pressure is limited by the material used that allows safe use of the cans. One can conclude that release rate and particle size distribution are controlled by combination of nozzle technology and can pressure. Therefore, the release rates and particle size have a limited range. The exposure to the biocide is not only related to the release rate, it is also associated with the concentration of the biocide in the product. Data in Table 4 show that at similar release rates (1.36 g/s vs.1.3 g/s for the *Clorox Disinfectant Spray vs. Lysol Brand Disinfectant Spray)*, the concentration of the active ADBAC was 17.2 mg vs. 6.7 mg for *Clorox Disinfectant Spray vs. Lysol Brand Disinfectant Spray* respectively. Therefore, in selecting the product for the study, concentration of active ingredient in the product is an important consideration. *Clorox Disinfectant* Spray had the highest % of actives among the products listed in Table 1.

(Note: When release rates were not available from the companies, the data was experimentally generated in the laboratory according to the method described in the pilot study).

Particle size distribution:

Particle size information was collected during the survey on the products listed in Table 1 and when this information was not supplied by the company, it was generated in the laboratory according to the method described in the pilot study report (see section 4.3). The particle size distribution data on each of the 18 products is provided in Table 3. The data show that particle size distribution ranged from 16 -164 µm depending on the product type and method of particle size determination. The hard surface fine spray products, had particle size distribution 40-157 µm with *Clorox Disinfectant Spray* having the lowest particle size distribution. The surface disinfectants which are also used as air fresheners/sanitizers and air treatment products had particle size range of 16-87 µm and most of them had the smallest nozzle size. The foaming spray products had particle size distribution of 24-164 µm. The lower particle sizes of 24-34 µm is for the products where data was generated in the laboratory. This is attributed to the difference in methodology by which data was generated and the phenomenon where larger particles impacted on the target surface and were not captured and only small particles were collected.

Surface and Orientation:
A hard target surface with a vertical and over head orientation of the spray can was considered the most conservative scenario (highest exposure use) and is expected to give the most bounce back from the spray that increases the air concentration in the breathing zone and dermal deposition.

Temperature and humidity:
The particle size distribution is influenced by the humidity and temperature. The exposure monitoring study is planned to be conducted in the hotels/motels or apartment buildings where ambient environmental conditions will be consistent during the study duration.

Amount of material and exposure duration:
The exposure is also dependent on the amount and duration of material used. This is discussed in detail on pages 14-16 of the Scenario Design Document.

Behavior of the User
The exposure is highly dependent on the behavior of the individual user. Observations will be made to document the work practices of the MEs.

Table 3. Nozzle Size, Release Rate and Particle size Distribution of the Antimicrobial Aerosol Products.

Product Number	Use Scenario	Type of Spray	Nozzle Size"	Spray Rate g/s	Particle size µm*
1	Spot treatment; surface disinfectant (hard nonporous surfaces); other	Fine Spray	0.02	1.36**	40**
2	Hard surface disinfectant & sanitizer; soft surface sanitizer	Fine Spray	0.02	1.1-1.6	150
3	Hard surface hospital disinfectant	Fine Spray	0.018	1.46**	58-157
4	Hard surface hospital disinfectant	Fine Spray	0.02	0.98**	34-90
5	Other--Insecticide with antimicrobial	Fine Spray	0.027	2.0-2.8	125-147
6	surface cleaner,/disinfectant	Fine Spray	0.03	1.56**	85.0
7	Surface disinfectant	Fine Spray	0.03	1.3	85.0
8	Surface disinfectant, air sanitizer	Fine Spray	0.03	0.1.3**	85.0
9	Surface sanitizer/disinfectant, air freshener	Fine Spray	0.016"	0.6-0.8	16**
10	Disinfectant/air sanitizer	Fine Spray	0.016	0.8 g/s @ 100% fill	35
11	Air sanitizer	Fine Spray	0.022	0.8-1.2 1.0 g/s avg	35 avg
12	Air freshener and furniture polisher	Fine Spray	0.013	1.1g/s	85
13	Disinfectant Spray – air treatment	Fine Spray	0.02	0.95-1.45	87
14	Foaming aerosol bathroom cleaner	Foaming spray	0.016"	1.8-2.4	97-164
15	Disinfectant/sanitizer; Cleaning--industrial, institutional	Foaming Spray	0.02	2.26**	24**
16	Disinfectant/sanitizer; Cleaning--industrial, institutional	Foaming Spray	0.02	0.66**	49**
17	Surface cleaner & disinfectant	Foaming Spray	0.02	1.8-2.2	34**
18	Anti-fouling agents in paints	Fine Spray	0.018	1.17	variable

* = Particle size was typically supplied as the median diameter or the 95% confidence interval on the mean; otherwise a range is provided; ** = Based on data from pilot study; avg =Average; [1] = The particle size varies based on the pigment and/or use scenario (5-2000 µm).

July 13, 2009

3.1.2 Categories of the Products

The products represented by the AEATF II could be divided into four major use categories:

1. Hard- surface disinfectant fine sprays
2. Foaming aerosol products – coarse spray
3. Soft surface disinfectants
4. Air fresheners

The nozzle size and associated information (particle size, release rate) on the four use categories is summarized in Table 3 and discussed below (note: if a product is used for more than one category, it was counted for each category):

1. **Hard- surface disinfectants (fine spray)** – The nozzle size for these 11 products ranged from 0.016 - 0.03″. Out of the 11 products, 4 are also used as air sanitizers/fresheners. A majority of the hard surface disinfectant products (1-8) have the nozzle size of 0.018 - 0.03″ and the release rates ranged from 0.98 – 2.8 g/second with a majority of the products having rates from 1.3 -1.56 g/second. Product 5, which has the highest release rate of up to 2.8 g/second, is a combination product with an insecticide.

   The products which are also used as air fresheners/sanitizers have nozzle sizes of 0.013″ to 0.016″ with one product (#8) having a nozzle size of 0.03″. The release rates for these products ranged from 0.6-1.3 g/second with product #8 having the highest rate.

   The particle size distribution of the products ranges from 16-157 µm. The largest particle sizes were for product #5 and the smallest for product #9 which is also a combination hard surface spray and air freshener. For a majority of these products the median diameter was >80 µm.

2. **Foaming aerosol products** – The nozzle sizes of the four products were 0.02″ except for one product having nozzle size of 0.016″. However, the release rates for all the products were within 1.8-2.4 g/second except for product #16 with a nominal rate of 0.66 g/second and the particle size ranged from 33-164µm.

3. **Soft surface disinfectants** – All the soft surface disinfectants are also used as hard surface disinfectants and the data is covered under that category.

4. **Air Fresheners/sanitizers** – The nozzle size for 6 air freshener/sanitizer products ranged from 0.013-0.03″ with the majority having a nozzle size of < 0.02″. The release rate ranged from 0.6-1.2 g/s and the median particle size ranged from 16-85µm.

(Note: for some of the products where data was not supplied by the company, it was generated in the laboratory and there may be slight differences in the particle size distribution data due to differences in measurement technology).

Product #18 represents use of antimicrobials as antifouling agents in paints. The nozzle size for this product was 0.018" with a release rate of 1.17 g/second. The particle size distribution is generally variable based on the pigment used in the paint and if the paint is for artwork or household or outdoor use. The particle sizes can vary from 5-2000µm. The nozzle size and release rate show that paint aerosol cans are within the hard surface fine category. Exposure to antimicrobials in paint products was not considered in study design as these aerosol paint cans are often used with exposure mitigating measures.

As discussed previously the particle size and release rates are controlled by the nozzle technology and pressure in the can; and a causal relationship between nozzle sizes, release rates and particle size distribution cannot be made. However, the data indicate that over a broad range of products and use categories the nozzle sizes, and release rates fall within a limited range.

From the above information it can be concluded:

- A majority (83%) of the aerosol products fall into the hard surface disinfectants or cleaners category. About 60% having fine spray and 22% foaming spray and:
  - Would represent the highest use potential.
  - Hard surface fine spay products, with extensive use and potential for bounce back would represent the highest inhalation and dermal exposure scenario.
  - The foaming spray products may represent high end use, but due to their foaming action upon reaching the surface the bounce back effect is diminished and the inhalation and dermal exposure are limited.
- One third (33%) of the products are used as air fresheners/sanitizers alone or are part of the hard surface sanitizer category. These products have fine spray and are sprayed in room air space and have highest inhalation exposure potential. However, the air freshener products are only used for a short duration (5-10 seconds) and overall exposure is limited and would be much lower than the hard surface disinfectants and cleaners.
- Only a few of the products from the hard surface, fine spray category are also used as soft surface disinfectants/sanitizers and exposure potential for this use is lower due to decreased bounce back and absorption by the surface.
- It can be concluded that hard surface disinfectants/cleaners with fine spray would represent overall high end exposure and can serve as a surrogate for other use scenarios for inhalation and dermal exposure estimations.

The selection process was further streamlined by conduct of a pilot/method development study where one representative and commonly used product was selected from each category. The test substances for this preliminary investigation were chosen based on the fact that the majority of the products are commonly used in commercial and household settings and a large percentage (Table 2) contain an environmentally

stable active ingredient (specifically the 14 Carbon chain-length ADBAC or 14C ADBAC) for which a sensitive validated analytical method exists.

4. Conduct of A Pilot / Method Development Study

4.1 Objectives

A preliminary non-GLP investigation was conducted on the above mentioned 4 products for development of methods which would further streamline the selection of product/products to be used in the definitive study. The main objectives of the preliminary/method development phase were:

1. Cover a range of aerosol products, nozzle sizes and release rates.
2. Determine the volume/amount sprayed per unit time to establish the detection limits and determine the anticipated air concentration of the product near the breathing zone of the user.
3. Characterize the aerosol spray (particle size distribution) produced by the selected products.
4. Develop the method for subsequent sampling in the exposure monitoring study.
5. Compare the results of the products and select product/products for the exposure monitoring study.

4.2 Products Selected for the Pilot Study

The following products with active ingredients were selected:

1. Hard surface disinfectant fine spray (Nozzle 0.02"; Release rate 1.36 g/s)

   Clorox Disinfecting Spray (DDAC, ADBAC, ODAC, DODAC, Ethanol)

2. Foaming aerosol product (Nozzle 0.016"; Release rate 1.8-2.4 g/s)

   Antibacterial Scrubbing Bubbles Bathroom Cleaner (ADBAC)

3. Soft surface disinfectant (Nozzle 0.02"; Release rate 1.1-1.6 g/s)

   *Lysol Brand Disinfectant Spray (*ADBAS, Ethanol)

4. Air freshener (Nozzle 0.03"; Release rate 1.3 g/s)

   Stepan Aerosol SDAS (ADBAC)

4.3 Study Design Overview

Release rate:

Four or five cans of each product were discharged for 10 seconds each after shaking. The cans were weighed before and after discharge to determine the mass emitted in 10

seconds. Similarly, for the products in Table 1 when such data was not volunteered, 10 second samples (4-6) were taken and the average of the samples was used in estimating the release rate.

Design considerations:
The preliminary investigation was conducted in an environmental chamber (8x16x16 feet and having temperature and airflow controls) at the Golden Pacific Laboratories, in Fresno, California. It is well known and as discussed in Section 1.2, the exposure to aerosol products can be influenced by environmental conditions and orientation/behavior of the user. Therefore, the most important variables influencing the air concentrations and exposure were considered in comparing the products and the following parameters were selected for the preliminary investigations:

Orientation of the aerosol can and surface – A hard target surface with a vertical orientation of the spray can was considered the most conservative scenario and expected to give the most bounce back from the spray and increase the air concentration in the breathing zone and hence increased potential inhalation and dermal exposure.
Distance from the surface – The distance between the surface and spray can was six inches representing the lower bound of ranges indicated on labels of each surface applied product.
Room temperature – Room temperature of 72° F was selected as the ambient temperature of a household or institutional setting where most of the aerosol products are used.
Airflow – Airflow rates vary from a mean of 0.6 ACH (Air Change per Hour) for household environments to 10-16 for institutional environments (EPA, 2001). For the preliminary exploratory study, an air flow of 0.6 ACH was selected to represent the more conservative scenario.

All products except the air freshener were sprayed against a hard surface for 10 seconds from a distance of 6 inches and height of about 5 feet at three different location in the in the room (three replicates). The air freshener was applied in the air at about 6 feet height. For each replicate (Spray location) samples for air concentration were taken concurrently using both OVS and IOM tubes (for comparison and subsequent selection). The IOM and OVS tubes are commonly used for collecting both volatiles and particulate matter in the breathing zone. Particle size distribution was determined using a RespiCon 3-stage Impactor with particle size cuts at 2.5, 10.0 and 100 µm (RespiCon™ Particle Sampler - Model 8522, TSI Inc.). Samples were collected by placing sampling tubes/samplers on a laboratory stand at about five feet height representing the breathing zone and position of the user. The sampling tubes/samplers were placed facing the wall where test material was applied, again simulating the exposure position of the user. For the air freshener the sampling stand was placed under the area where test substance was applied. The amount sprayed per unit time (10 seconds) was determined from four to five replicates per product by weight difference of the aerosol cans before and after application. All samples were collected using personal air pumps drawing 2 L/min and 3.2 L/min, for IOM/OVS and Respicon,

respectively. All samples were analyzed for C14 ADBAC, the active ingredient (AI) common in the selected products using HPLC MS/MS. The environmental chamber was vented prior to each product use.

4.4 Results

- **Amount Dispensed Per Unit Time**

The average amount of each product (average of 4 to 5 samples) dispensed in 10 seconds is provided in Table 4. All products except for *Antibacterial Scrubbing Bubbles (hard surface)* were similar with regard to mean emission rate of total product. The emission rate for the *Stepan Aerosol SDAS (air Freshener)* was rather erratic. The results clearly indicate that the *Clorox Disinfecting Spray* (hard surface fine Spray) consistently emits the highest amount of AI per unit time and represents the greatest potential for aerosol exposures on either a time or can-used basis. This is attributable to *Clorox Disinfecting Spray* having the highest percentage of the active ingredient compared to other products.

Table 4: Amount of Product Dispensed per Unit Time

Product(Labeled Application Site)	Product Dispensed per 10 sec (g)					Mean (g)	Fraction C14 ADBAC	C14 ADBAC Dispensed (mg)
Clorox Disinfecting Spray (hard surface)	13.6	13.3	13.8	13.8		13.6	0.00126	17.2
Antibacterial Scrubbing Bubbles (hard surface)	18.8	18.9	18.7	18.8		18.8	0.00066	12.4
Lysol Brand Disinfecting Spray (soft surface)	12.6	12.5	13.0	12.4		12.6	0.00053	6.7
Stepan Aerosol SDAS (air freshener)	13.0	22.5	15.6	4.9	9.1	13.0	0.0006	7.8

- **Air Concentration (Amount of ADBAC)**

The 10 second spray duration was sufficient for detecting the test substance in the air samples. Results for the air concentration measurements are summarized in Table 5 and Figure 1. The results indicate that *Clorox Disinfecting Spray* (hard surface fine Spray) and *Stepan Aerosol SDAS* (Air Freshener) produced comparable air concentrations of the AI (14C ADBAC) and were higher than *Antibacterial Scrubbing Bubbles Bathroom Cleaner or* Lysol *Brand Disinfectant Spray* (soft surface spray). Of these four product types, the *Clorox Disinfecting Spray* and/or *Stepan Aerosol SDAS* represent the use pattern scenarios with potentially highest exposure and could be selected as surrogate for representing the exposure to use of aerosol products if one assumed that they are used for comparable durations.

- **Selection of Sampling Tube**

There was no apparent difference in air concentrations when the samples were taken by either the IOM or OVS tubes, suggesting that either of these commonly used air sampling tubes could be used in subsequent exposure monitoring. For the main study

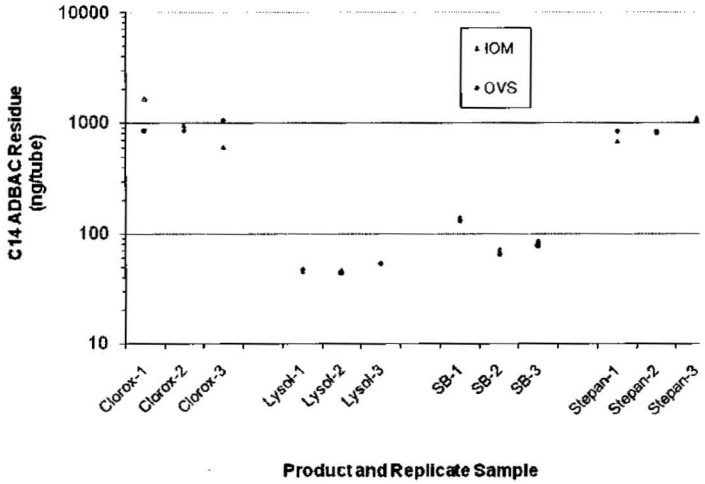
the OVS tubes were selected for collection of air samples to measure potentially inspirable air concentrations.

Table 5: Comparison of C14 ADBAC Air Concentration Measurement Methods

Product	Sampling Tube	C14 ADBAC Residue (ng/tube)				
		Replicate Spray 1	Replicate Spray 2	Replicate Spray 3	Arithmetic Mean	Geometric Mean
Clorox Disinfecting Spray (hard surface)	OVS	865	862	1063	930	925
	IOM	1652	967	615	1078	994
Antibacterial Scrubbing Bubbles (hard surface)	OVS	132	65	77	91	87
	IOM	143	72	88	101	97
Lysol Brand Disinfecting Spray (soft surface)	OVS	48	44	54	49	48
	IOM	46	47	55	49	49
Stepan Aerosol SDAS (air freshener)	OVS	840	847	1043	910	905
	IOM	692	826	1113	877	860

The data from Table 5 have been summarized graphically in Figure 1.

Figure 1: Relative Mass Trapped by Co-Located IOM and OVS Samplers



- **Particle Size Distribution**

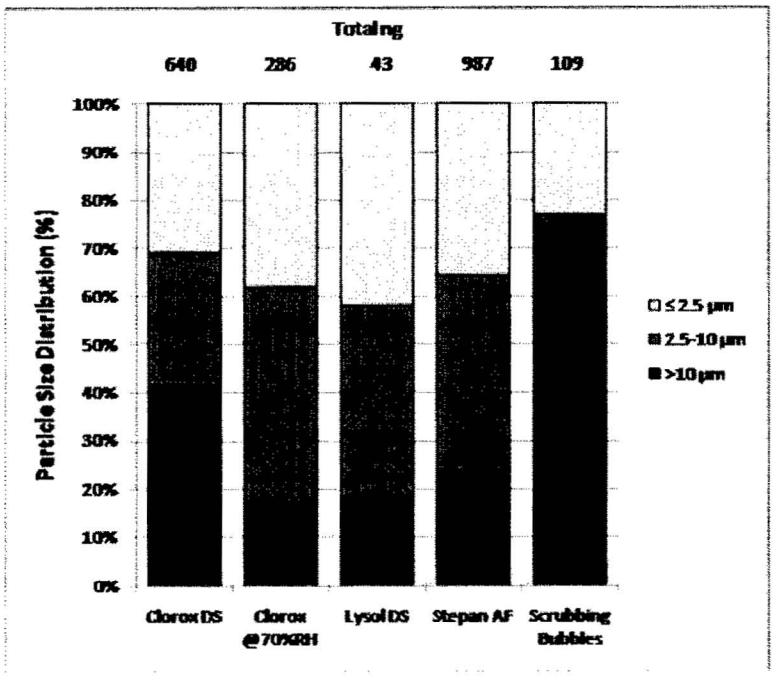
The particle size distribution results (Table 6 and Figure 2) show clear differences in the four product categories. The *Clorox Disinfectant Spray* (hard surface) had about 31% of the suspended particle mass ≤ 2.5 µm (respirable range) with total inhalable mass of 640 ng. The *Antibacterial Scrubbing Bubbles Bathroom Cleaner* (hard surface) had ~23 % of the mass with particle sizes ≤ 2.5 µm and total inhalable mass of 109 ng, indicating that large particles were impacted on the surface and converted into foam/bubbles and only a very small fraction was suspended in air. The *Lysol Brand Disinfectant Spray* (soft surface spray) produced the highest percentage of particles ≤2.5 µm (42%), but the total mass collected (43 ng) was the lowest representing the least potential for dermal and overall exposure. The inhalation exposure would be further reduced when the product is used on soft surfaces due to minimum bounce from the soft surface, typical of aerosol behavior (Pauluhn, 2003). The air freshener, *Stepan Aerosol SDAS* had the highest suspended inspirable particulate mass (987ng) and intermediate percentage (36%) of particle mass ≤ 2.5 µm. As discussed previously, the amount used is substantially lower and the overall exposure will be lower than the other products; the *Clorox Disinfectant Spray* represents the most conservative scenario. The 2.5 µm particle size is of particular interest, because this is the size targeted for delivery to laboratory animals during inhalation toxicity testing.

Table 6: Respicon C14 ADBAC Residue in ng/stage (% on the stage)

Product	Respicon 2.5 µm Respirable	Respicon 10 µm Thoracic	Respicon 100 µm Inhalable	Total Inspirable (ng)
Clorox Disinfecting Spray (hard surface)	196 (30.6)	179 (28.0)	265 (41.4)	640
Antibacterial Scrubbing Bubbles (hard surface)	25 (23.0)	3 (2.7)	81 (74.3)	109
Lysol Brand Disinfecting Spray (soft surface)	18 (41.9)	17 (39.5)	8 (18.6)	43
Stepan Aerosol SDAS (air freshener)	351 (35.6)	399 (40.4)	237 (24.0)	987

The IOM, OVS and Respicon samplers each captures approximately the same total mass of suspended particles in air. However, as a fraction of the total mass emitted from the spray can, they collect from ~0.001 to 0.01%. This collection selectivity reflects the nature of particles that remain suspended in air for more than a few seconds, and in this case specifically those particles that remain suspended after collision with a hard surface. It also reflects the fact that air collectors designed to sample inspirable particles don't pick up the vast majority of mass that is transiently in the air following emission from the nozzle. This also has very significant implications when comparing MMAD in Table 3, because different methodologies were employed for measuring particle size. Laser spectrometry allows characterization of the entire spectrum of particle sizes emitted into the air, while the Respicon sampler picks up a maximum particle size of 100 µm.

Figure 2. Particle Size Distribution Captured by Respicon



July 13, 2009

5 Conclusions

The results of the pilot study clearly show that based on nozzle size, amount of material dispensed per unit time, air concentrations, and aerosol characteristics, the hard surface disinfectant product, i.e., *Clorox Disinfecting Spray (*EPA Reg. No. 67619-03), represents the high-end exposure scenario and the product most likely to produce measurable exposure and would therefore serve as the surrogate for the study entitled "Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using a Pressurized Aerosol Can for Indoor Uses". Taking type of surface and the inspirable mass into consideration, the *Clorox Disinfecting Spray* (hard surface fine Spray) and *Stepan Aerosol SDAS* (Air Freshener) represent uses with the most inhalation and/or dermal exposure potential. The Air Freshener seemed to have comparable inspirable mass to the hard surface spray. However, as mentioned previously, the total mass of the active ingredient dispensed per unit time for the *Clorox Disinfecting Spray* is more than double the *Stepan Aerosol SDAS* (17.2/6.7 mg, Table 4) and dermal exposure will likely be higher for the *Clorox Disinfecting Spray*. Additionally, the hard surface spray product will be used to a much greater extent in a day, especially in commercial use, than the air freshener. Based on the available data, the *Clorox Disinfecting Spray* (hard surface fine spray) would represent a high end conservative choice for exposure monitoring studies.
The selected product would also meet objectives of the study and test material selection criteria, i.e.:

- Serve as surrogate for most aerosol use categories
- Use pattern represents high end exposure – a conservative scenario
- Use scenario covers most influential variables of exposure
    - Highest % of AI
    - Nozzle size of majority of the aerosol products
    - Particle size distribution representative of fine spray
    - Used for hard surface and confined spaces
- Having stable active ingredient
- Results can be extrapolated to most products on the market

6. References

Berger-Preiss, E., Boehncke, A., Könnecker, G., Mangelsdorf, I., Holthenrich, D., and Koch, W. (2005). Inhalation and dermal exposure during spray application of biocides-Fraunhofer Institute of Toxicology and Experimental Medicine. Internl J Hygiene and Environ Health 208: 357-372

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LionstarCorp Ltd, 35 Fairfield Rise, Wollaston, Stourbridge, West Midlands DY8 3PQ UK.

Marquart, D.H., Brouwer, J.H., Gijsbers, J., Links, L.H.M., Warren, N. and Van Hemmen, J.J. (2003). Determinants Of Dermal Exposure Relevant for Exposure Modeling in Regulatory Risk Assessment. Ann Occ. Hygiene 47: 599-607

Nazaroff, W.W.,Beverly K. Coleman, Hugo Destaillats, Alfred T. Hodgson, DeLing Liu, Melissa M. Lunden, Brett C. Singer, and Charles J. Weschler. (2006). Indoor Air Chemistry: Cleaning Agents, Ozone and Toxic Air Contaminants; University of California Berkeley, CA; Environmental Energy Technologies Division, Lawrence Berkeley National Laboratory, Berkeley, CA 94720 (Final Report: Contract No. 01-336)

The Pesticide Handlers Exposure Database (PHED, version 1.1). – Two Studies involving the Monitoring of dermal and inhalation exposure during the use of a pressurized aerosol container

Popendorf, W., Selim, M., and Kross, B.C. (1992). Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. University of Iowa, Institute of Agricultural Medicine and Occupational Health. Iowa City, Iowa

Shieh, Doris S., Huitt, Daniel A., Kennedy, Timothy James and De Gopegui, Ricardo Ruiz (2008). Compressed gas propellants in plastic aerosols. United States Patent 7448517.

Pauluhn, J. (2003). Inhalation Toxicity of Pesticides in *Encyclopedia of Agrochemicals*. Eds. J.R. Plimmer, D.W. Gammon, N.N. Ragsdale, and T. Roberts. Wiley Interscience, NY.pp. 893-91.

PROFESSIONAL JANITORS WANTED

Seeking volunteers for a study evaluating exposure to cleaning products while using a commonly used aerosol product. Volunteers will be compensated a total of $120 for their inconvenience.

Please contact Sami Selim at 559-824-1535 (English) or

Noé Galván at 559-917-9119 (English/Spanish)

for more information.

Study sponsored by the Antimicrobial Exposure Assessment Task Force administered by the American Chemistry Council, and directed by Golden Pacific Laboratories of Fresno, CA. 559-275-9091

CERTIFICATE OF COMPLETION

This is to certify that Sami Selim, Ph.D., has completed

Investigator Training for Medical Research

April 26, 2007
Las Vegas, Nevada

Jointly sponsored by

University of Rochester School of Medicine and Dentistry,
Strong Memorial Hospital
and
Western Institutional Review Board (WIRB)

Angela J. Bowen, M.D.
President, WIRB

John C. Schneider, BS
Course Director

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Site Operations and SOPs

April 27, 2007
Las Vegas, Nevada

Jointly sponsored by

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Western Institutional Review Board (WIRB)

Angela J. Bowen, M.D.
President, WIRB

John C. Schneider, BS
Course Director

Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that **Natan Chavez** successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: 07/07/2009

Certification Number: 253804

Part 2 Request (Crespo, 7/17/09, 7:04 AM) to Initial Submission for a Readable Version of the Label for Translation

Megan Boatwright

From: Yesenia Crespo [YCrespo@iirb.com]
Sent: Friday, July 17, 2009 7:04 AM
To: Megan Boatwright
Subject: FW: Submission Package for 070270
Attachments: advertisement.pdf; certificates of training.pdf; AEATF Aerosol Study Protocol 071409.doc; AEATF Aerosol Study Scenario Design 071309.doc; Study Setup Form - 070270.doc; Submission Letter - 070270.doc; 070270 site questionaire.pdf

Dear Megan our translator is having a hard time reading the label, I zommed in up to 500 and I can 't even make out what it said. Do you think you can let us know what it says or make it larger on your end and then re-send it?

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

From: Robert Roogow
Sent: Wednesday, July 15, 2009 9:25 AM
To: Yesenia Crespo
Subject: FW: Submission Package for 070270

Robert Roogow, MS, CIM
Chief Operating Officer
Independent Investigational Review Board, Inc.
Ph: 954-327-0778
Fax: 954-327-5778

7/30/2009

rroogow@iirb.com

From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Tuesday, July 14, 2009 4:14 PM
To: Robert Roogow
Cc: Sami Selim
Subject: Submission Package for 070270

Dear Robert,

Please find attached the Submission Letter, Study Set-up Form, Site Questionairre, the protocol and Study Scenario Design for IIRB review and approval. I have also attached for submission an advertisement and training certificates. Please let me know if there is anything else you will need.

Best Regards,

Megan

Megan T. Boatwright
Laboratory Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno CA, 93722
mboatwright@gplabs.com

Part 3 Transmittal (Boatwright, 7/17/09, 10:22 AM) Providing a Translation of the Fine Print of the Label (*label verbiage.pdf*)

Megan Boatwright

From: Megan Boatwright
Sent: Friday, July 17, 2009 10:22 AM
To: 'YCrespo@iirb.com'
Cc: Sami Selim
Subject: FW: Submission Package for 070270
Attachments: advertisement.pdf; certificates of training.pdf; AEATF Aerosol Study Protocol 071409.doc; AEATF Aerosol Study Scenario Design 071309.doc; Study Setup Form - 070270.doc; Submission Letter - 070270.doc; 070270 site questionaire.pdf; label verbiage.pdf

Dear Yesenia,

I have attached the "Label verbiage" per your request so the translator can read it. On the label I have drawn boxes around different areas and assigned each a number. The following table has listed the section numbers which is followed by the wording of that section. Please let me know if I can help you with anything else or if you have questions.

Best Regards,

Megan

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Sent: Friday, July 17, 2009 7:04 AM
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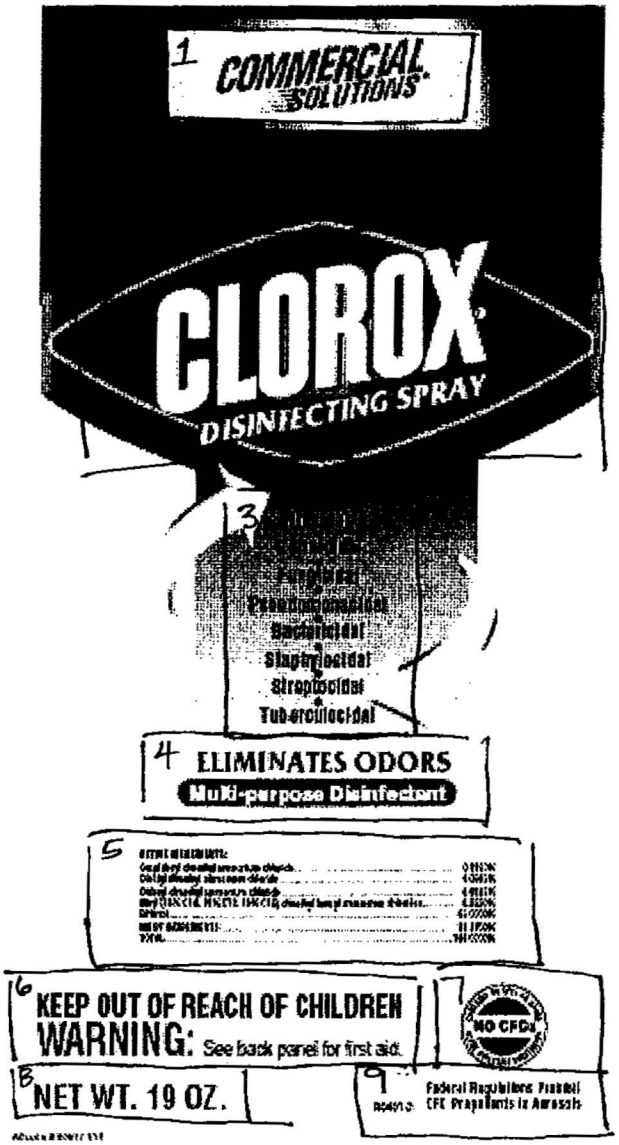
EPA Reg. No. 67619-33 Commercial Solutions/Clorox Disinfecting Spray Page 1 of 2

Artwork shown at approximately 110% of actual size



July 13, 2009

Wording for the front label of the product on page 57 of Protocol 070270

Section	
1	COMMERCIAL SOLUTIONS*
2	CLOROX DISINFECTING SPRAY
3	Virucidal* Germicidal Fungicidal Pseudomonacidal Bactericidal Staphylocidal Streptocidal Tuberculocidal
4	ELIMINATES ODORS Multi-purpose Disinfectant
5	Active Ingredients: Octyl decyl dimethyl ammonium chloride.....0.1890% Dioctyl dimethyl ammonium chloride.....0.0945% Didecyl dimethyl ammonium chloride.....0.0945% Alkyl (50% C14, 40% C12, 10% C16) dimethyl Benzyl ammonium chloride.....0.2520% Ethanol.....65.0000% INERT INGREDIENTS.....34.3700% TOTAL:.....100.0000%
6	KEEP OUT OF REACH OF CHILDREN WARNING: See back panel for first aid
7	CONTAINES NO CFCs OR OTHER OZONE DEPLETING SUBSTANCES NO CFCs
8	Net WT, 19OZ
9	Federal Regulations Prohibit CFC Propellants in Aerosols

Part 4 Transmittal (Crespo, 7/17/09, 10:37 AM) Asking for Clarification on the Reuse of the Protocol Number

Megan Boatwright

From: Yesenia Crespo [YCrespo@iirb.com]
Sent: Friday, July 17, 2009 10:37 AM
To: Megan Boatwright
Cc: Sami Selim
Subject: FW: Submission Package for 070270
Attachments: advertisement.pdf; certificates of training.pdf; AEATF Aerosol Study Protocol 071409.doc; AEATF Aerosol Study Scenario Design 071309.doc; Study Setup Form - 070270.doc; Submission Letter - 070270.doc; 070270 site questionaire.pdf

Megan I have a question this protocol number was already approved early on this year with a different title. Did you guys want to revise this and re-submit this.

Regards,
Yesenia Crespo
Project Leader

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6738 West Sunrise Blvd. Suite 102
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Robert Roogow, MS, CIM
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Independent Investigational Review Board, Inc.

7/30/2009

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Best Regards,

Megan

Megan T. Boatwright
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Fresno CA, 93722
mboatwright@gplabs.com

Part 5 Transmittal (Crespo, 7/17/09, 10:40 AM) Reiterating the Question of Reusing the Protocol Number

Megan Boatwright

From: Yesenia Crespo [YCrespo@iirb.com]
Sent: Friday, July 17, 2009 10:40 AM
To: Megan Boatwright
Cc: Sami Selim
Subject: RE: Submission Package for 070270

Thanks, I sent you an email the protocol and title are the same, so I a little confused. Did you guys just want to submit a revised protocol.

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

From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Friday, July 17, 2009 1:22 PM
To: Yesenia Crespo
Cc: Sami Selim
Subject: FW: Submission Package for 070270

Dear Yesenia,

I have attached the "Label verbiage" per your request so the translator can read it. On the label I have drawn boxes around different areas and assigned each a number. The following table has listed the section numbers which is followed by the wording of that section. Please let me know if I can help you with anything else or if you have questions.

Best Regards,

Megan

From: Yesenia Crespo [mailto:YCrespo@iirb.com]
Sent: Friday, July 17, 2009 7:04 AM

To: Megan Boatwright
Subject: FW: Submission Package for 070270

Dear Megan our translator is having a hard time reading the label, I zommed in up to 500 and I can 't even make out what it said. Do you think you can let us know what it says or make it larger on your end and then re-send it?

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

From: Robert Roogow
Sent: Wednesday, July 15, 2009 9:25 AM
To: Yesenia Crespo
Subject: FW: Submission Package for 070270

Robert Roogow, MS, CIM
Chief Operating Officer
Independent Investigational Review Board, Inc.
Ph: 954-327-0778
Fax: 954-327-5778
rroogow@iirb.com

From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Tuesday, July 14, 2009 4:14 PM
To: Robert Roogow
Cc: Sami Selim
Subject: Submission Package for 070270

Dear Robert,

Please find attached the Submission Letter, Study Set-up Form, Site Questionairre, the protocol and Study Scenario Design for IIRB review and approval. I have also attached for submission an advertisement and training certificates. Please let me know if there is anything else you will need.

Best Regards,

Megan

Megan T. Boatwright
Laboratory Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno CA, 93722
mboatwright@gplabs.com

Part 6 Transmittal (Boatwright, 7/17/09, 11:22 AM) Clarifying the Reuse of the Protocol Number

Megan Boatwright

From: Megan Boatwright
Sent: Friday, July 17, 2009 11:22 AM
To: 'Yesenia Crespo'
Cc: Sami Selim
Subject: RE: Submission Package for 070270

Dear Yesenia,

Sami talked to Robert Roogow and this is a different protocol completely however the study number isn't changing. Everything in the past submitted under this protocol needs to be disregarded. The items being submitted here need to be reviewed using the same study number but from the beginning of the process.

Megan

From: Yesenia Crespo [mailto:YCrespo@iirb.com]
Sent: Friday, July 17, 2009 10:37 AM
To: Megan Boatwright
Cc: Sami Selim
Subject: FW: Submission Package for 070270

Megan I have a question this protocol number was already approved early on this year with a different title. Did you guys want to revise this and re-submit this.

Regards,
Yesenia Crespo
Project Leader

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From: Robert Roogow
Sent: Wednesday, July 15, 2009 9:25 AM

To: Yesenia Crespo
Subject: FW: Submission Package for 070270

Robert Roogow, MS, CIM
Chief Operating Officer
Independent Investigational Review Board, Inc.
Ph: 954-327-0778
Fax: 954-327-5778
rroogow@iirb.com

From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Tuesday, July 14, 2009 4:14 PM
To: Robert Roogow
Cc: Sami Selim
Subject: Submission Package for 070270

Dear Robert,

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Best Regards,

Megan

Megan T. Boatwright
Laboratory Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno CA, 93722
mboatwright@gplabs.com

Part 7 Acknowledgment (Crespo, 7/17/09, 11:43 AM) Thanking GPL for Clarification

Megan Boatwright

From: Yesenia Crespo [YCrespo@iirb.com]
Sent: Friday, July 17, 2009 11:43 AM
To: Megan Boatwright
Subject: RE: Submission Package for 070270

Ok thanks for the clarification, Robert actually left early and I didn't get a chance to ask him.
Thanks much.

From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Friday, July 17, 2009 2:22 PM
To: Yesenia Crespo
Cc: Sami Selim
Subject: RE: Submission Package for 070270

Dear Yesenia,

Sami talked to Robert Roogow and this is a different protocol completely however the study number isn't changing. Everything in the past submitted under this protocol needs to be disregarded. The items being submitted here need to be reviewed using the same study number but from the beginning of the process.

Megan

From: Yesenia Crespo [mailto:YCrespo@iirb.com]
Sent: Friday, July 17, 2009 10:37 AM
To: Megan Boatwright
Cc: Sami Selim
Subject: FW: Submission Package for 070270

Megan I have a question this protocol number was already approved early on this year with a different title. Did you guys want to revise this and re-submit this.

Regards,
Yesenia Crespo
Project Leader

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ycrespo@iirb.com

that any re-use, dissemination, distribution, or copying of this email message is prohibited. If you have received this email message in error, please reply to the sender that you have received the message in error and then delete it. Thank you.

From: Robert Roogow
Sent: Wednesday, July 15, 2009 9:25 AM
To: Yesenia Crespo
Subject: FW: Submission Package for 070270

Robert Roogow, MS, CIM
Chief Operating Officer
Independent Investigational Review Board, Inc.
Ph: 954-327-0778
Fax: 954-327-5778
rroogow@iirb.com

From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Tuesday, July 14, 2009 4:14 PM
To: Robert Roogow
Cc: Sami Selim
Subject: Submission Package for 070270

Dear Robert,

Please find attached the Submission Letter, Study Set-up Form, Site Questionairre, the protocol and Study Scenario Design for IIRB review and approval. I have also attached for submission an advertisement and training certificates. Please let me know if there is anything else you will need.

Best Regards,

Megan

Megan T. Boatwright
Laboratory Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno CA, 93722
mboatwright@gplabs.com

Part 8 Transmittal (Crespo, 7/17/09, 12:17 PM) Forwarding Request from the Translator Asking for a Readable Version of the Back of the Label

Megan Boatwright

From: Yesenia Crespo [YCrespo@iirb.com]
Sent: Friday, July 17, 2009 12:17 PM
To: Megan Boatwright
Subject: FW: Submission Package for 070270.-

Please see the translator comments below.

Yesenia Crespo

From: AGomez5634@aol.com [mailto:AGomez5634@aol.com]
Sent: Friday, July 17, 2009 3:14 PM
To: Yesenia Crespo
Subject: RE: Submission Package for 070270.-

Hi Yesenia:

Thank you very much, but don't forget that I still need the back of the label; it is also illegible. Let me clarify: I do not need the whole back of such label; I have already translated approximately half of it. I ONLY need the right hand side column.

Regards,

Américo 

Part 9 Transmittal (Boatwright, 7/17/09, 4:15 PM) Providing a Readable Version of the Back of the Label (*Clorox label.doc*)

Megan Boatwright

From: Megan Boatwright
Sent: Friday, July 17, 2009 4:15 PM
To: 'Yesenia Crespo'
Cc: 'AGomez5634@aol.com'; Sami Selim
Subject: FW: Clorox Disinfecting Spray Label
Attachments: Clorox label.doc

Dear Yesenia and Americo,

Attached is the back of the label typed out so the translation can be completed. Please let me know if you require anything else.

Megan

From: Mary Huebner
Sent: Friday, July 17, 2009 4:07 PM
To: Megan Boatwright
Subject: Clorox Disinfecting Spray Label

- This product meets AOAC Germicidal Spray Product Test efficacy standards for hospital disinfectants.
- Kills and prevents the growth of mold.
- Deodorizes by killing the germs that cause odors.
- Does not contain bleach.

Use on hard, nonporous surfaces in:

• Restrooms • Hotels • Motels • Offices • Military Installations • Schools • Day Care Centers • Nurseries • Dorms • Shelters • Laboratories • Health Clubs •School Busses • Ambulances • Bowling Alleys • Play Areas • Convenience Stores • Locker Room Facilities • Storage Areas • Kennels

For use on:

• Garbage cans • Waste Baskets • Diaper Pails • Diaper Changing Tables • Toilet Seats • Faucets • Doorknobs • Telephones • Showers • Plastic Shower Curtains • Counter Tops • Desks • Metal Work Benches • Handles

Use on non-critical surfaces in:

Hospitals • Patient Rooms • Nursing Homes • Medical Clinics • Veterinary Offices

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS & DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eye wear (safety glasses). Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handing. Remove contaminated clothing and wash before reuse. If skin contact with product occurs, wash thoroughly with soap and water, especially prior to food handling and preparation.

FIRST AID: IF IN EYES: Hold eyelids 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 the eye. 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. Questions? Call 1-800-797-7225.

PHYSICAL HAZARDS: Flammable: Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° Fahrenheit may cause bursting.

STORAGE/DISPOSAL: Pesticide Storage and Disposal: Do not contaminate water, food, or feed by storage and disposal. Store at temperatures below 130° Fahrenheit. Container Disposal: Do not puncture or incinerate. Do not reuse empty container. Recycle empty container or discard in trash.

• This can is made of an average of 25% recycled steel (10% post-consumer) • Recyclable • Contains no phosphorus • Avoid use on polished wood, painted surfaces or acrylic plastics.

Questions? Comments? Call toll-free 1-888-797-7225

Mfd. For Clorox Professional Products Company, Oakland, CA 94612

The Clorox Company

Made in USA or Argentina

EPA Reg. No. 67619-3

EPA Est. No. 11525-1L-1

5813-ARG-001

See code on bottom of can

Patent Pending

Disinfects against the following bacteria, viruses* and mold:

- Campylobacter jejuni
- Corynebacterium diphtheria
- Enterobacter aerogenes
- Enterococcus faecalis (Vancomycin resistant)
- Escherichia coli O157:H7
- Klebsiella pneumonia
- Listeria monocytogenes
- Mycobacterium bovis (Tuberculosis)
- Mycobacterium smegmatis
- Proteus mirabilis
- Proteus vulgaris
- Pseudomonas aeruginosa
- Pseudomonas cepacia (Burkholderia cepacia)
- Pseudomonas putida
- Salmonella choleraesuis
- Salmonella choleraesuis paratyphi B1 (schottmuelleri)
- Salmonella choleraesuis serotype enteritidis
- Serratia marcescens
- Shigella dysenteriae
- Staphylococcus aureus
- Staphylococcus aureus (Methicillian & Gentamicin resistant)
- Streptococcus pyogenes
- *Adenovirus type 2
- *Cytomegalovirus
- *Echovirus
- *Hepatitis A virus
- *Herpes simplex virus type 1
- *Herpes simplex virus 2
- *Human Immunodeficiency Virus Type 1 (HIV-1)
- *Influenza A2 virus (Hong Kong) (Flu virus)
- *Influenza virus type B
- *Polio virus
- *Respiratory syncytial virus (leading cause of lower respiratory infection in children)
- *Rhinovirus (cold virus)
- *Rhinovirus 39
- *Rotavirus (leading cause of infectious diarrhea in children)
- *Vaccinia virus
- Alternaria alternata
- Candida albicans
- Cladosporium herbarum
- Trichophyton mentagrophytes (Athlete's foot fungus)

Sanitizes in 30 seconds against: Klebsiella pneumonia, Staphylococcus aureus.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For use on non-food contact surfaces only. A potable water rinse is required for surfaces which may be in direct contact with food. **This product must not result in the direct or indirect contamination of food products.**

SPECIFIC INSTRUCTIONS FOR *HIV-1: This product kills *HIV-1 on precleaned surfaces/objects previously soiled with blood/body fluids in health care settings or others settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (*HIV-1) (associated with AIDS).

Special Instructions for Using this Product to Clean and Decontaminate Against *HIV-1 on Surfaces/Objects Soiled with Blood/Body Fluids.

Personal Protection: When handling items soiled with blood or bodily fluids, use disposable latex gloves, gowns, masks, and eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and other objects before applying this product.

Contact Time: Spray 6 to 10 inches from precleaned surface for 3-4 seconds until thoroughly wet. Surface must remain wet for 10 minutes before wiping or air drying.

Disposal of Infectious Materials: Use disposable latex gloves, gowns, masks, and eye coverings. Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

To Disinfect: Spray 6 to 10 inches from precleaned surface for 3-4 seconds until thoroughly wet. Surface must remain wet for 10 minutes before wiping.

To Sanitize Non-food Contact Surfaces: Spray 6-10 inches from precleaned surface for 3-4 seconds or until thoroughly wet. Surface must remain wet for 30 seconds before air drying.

To Control and Prevent the Growth of Mold and Mildew: Spray precleaned surface until thoroughly wet. Surface must remain wet for 10 minutes before wiping or air drying. Respray product as necessary for ongoing control.

To Deodorize: Spray on precleaned surfaces as needed.

R0401-2

Part 10 Transmittal (Crespo, 7/24/09, 8:05 AM) of Approved Informed Consent Form and Experimental Subject's Bill of Rights (*070270b.ICF.doc and 070270b.ESBOR.doc*)

Megan Boatwright

From: Yesenia Crespo [YCrespo@iirb.com]
Sent: Friday, July 24, 2009 8:05 AM
To: Sami Selim
Cc: Megan Boatwright
Subject: 070270b
Attachments: 070270b.ESBOR.doc; 070270b.ICF.doc

Please see attached the approved word ICF documents. Let me know if I can help you with anything else.

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

EXPERIMENTAL SUBJECT'S 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 the purpose of the study;
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 during the study;
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 alternatives to participating 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 status with my employer;
9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether I wish to participate in the study.

You may contact the *Independent Investigational Review Board, toll free at (877) 888-IIRB (4472) from 6 am to 2 pm Pacific Time*, if you have a question about your rights as a research subject.

If you have other questions, you should ask the Principal Investigator or Field Staff

Phone contacts:

Principal Investigator, Sami Selim (English): (559) 275-9091 from 8 am-5pm, Pacific Time

Field Staff: Joel Panara (English) at 800-870-0294, Ext 5500,Victoria Standart (English or Spanish) or Noé Galván (English or Spanish) at 800-870-0294 Ext 5510 from 8 am-5 pm, Pacific Time

APPROVED BY
Independent IRB

_____ 7/21/09
Signature Date

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INFORMED CONSENT FORM

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Title: (Protocol No. 070270b) A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using a Pressurized Aerosol Can for Indoor Surface Disinfecting

Principal Investigator: Sami Selim, Ph.D.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Field Coordinators:

Joel Panara (English)
Field Coordinator
Eurofins | Grayson
211 N. Main Street
Creedmoor, NC 27522
Phone: 919-528-5500

Victoria Standart (English and Spanish)
Field Research Associate
Eurofins | Grayson
211 N. Main Street
Creedmoor, NC 27522
Phone: 919-528-5510

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Noé Galván, Ph.D. (English and Spanish)
Field Research Associate
Product Safety Scientist
PS&RC, Global Stewardship
Clorox Services Co.
7200 Johnson Drive
Pleasanton, CA 94588
Phone: 925-425-6708

Field Locations: (Subject Informed Consent Interview Location)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Suite 105
Fresno, CA 93722
(Study Site Location)
3 Sites in Fresno County, CA

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 559-824-1535 (Sami Selim)

We're asking you to think about being in a research study because you have experience doing janitorial work. Your participation is voluntary. This Informed Consent Form explains the study.

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Independent IRB
7/21/09
Signature Date

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You may take a copy of this form home to think about and discuss with friends or family before you decide whether you want to be in the study. If you have any questions, or if you do not understand anything in this form, please ask one of us to explain. If you would prefer to talk in Spanish, please ask. We can explain the study to you in English or Spanish.

Purpose of this Study

Golden Pacific Laboratories is doing this research to find out how much spray may reach your skin when you use a cleaning product in a pressurized aerosol can. We will measure how much of the spray gets on the clothing you wear during the study, and on your hands, face and neck, while you clean indoor surfaces like bathrooms and kitchens. We will also measure how much of the spray is in the air you breathe during the study. An important purpose of this study is to collect information that will be provided to the U.S. Environmental Protection Agency or EPA. The EPA will use this information to evaluate the levels of exposure to the aerosol spray product in this study and other spray products that are similar to it.

The spray in this study will be Clorox Commercial Solutions® Clorox® Disinfecting Spray. This is a commercial cleaning product used to clean hard surfaces such as bathroom tiles and fixtures and kitchen cabinets and counters. This product is used in offices and buildings such as hospitals, schools, and hotels. It contains chemicals called quaternary ammonium salts, which kill germs.

A group of companies that make germ-killing cleaning products is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products kill germs on indoor surfaces, and are registered by the US Environmental Protection Agency (EPA) as pesticides.

Sami Selim, Ph.D., of Golden Pacific Laboratories is the Principal Investigator in charge of the study. Victoria Standart of Eurofins | Grayson is his main Spanish-speaking assistant.

Test Product

The material being tested in this study is Clorox Disinfecting Spray. This is a commercial cleaning product used to disinfect and deodorize hard, non-porous surfaces such as bathrooms (walls, showers, toilets, etc.), kitchens (cabinets, faucets, etc.). This product is recommended for use in offices and commercial and institutional buildings, such as hospitals, schools, and hotels. Clorox Disinfecting Spray contains chemicals known as quaternary ammonium salts which kill germs. You will be given a copy of the product label, and if you request it, you will be provided the Material Safety Data Sheet or "MSDS" for this product.

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Subject Selection

To be in this study you must be healthy male or female, ages of 18 and older, and you must be able to read and speak English or Spanish. You will need to prove your age with a government-issued photo ID—a driver's license or state issued ID. You must have experience doing janitorial work, and must want to be in this study. You must be willing to sign a consent form, and to provide some additional personal information, and to follow the directions of the investigators.

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You will not be able to participate in this research if you are related by blood or marriage to employees of Golden Pacific Laboratories, Eurofins | Grayson or a cleaning product manufacturer; if you are pregnant or breast-feeding; if you've had allergic reactions to soap, rubbing alcohol, or other cleaning products; if you have sores on your skin; if you are taking medicines that might react with the test product; or if you have heart or breathing problems.

Eighteen to 24 people will be in this study. We will sign up a few more people than we need, in case anyone can't participate on the day of the test.

Deleted: like you

We'll do the study in a vacant building (or in unoccupied rooms of non-vacant buildings) here in Fresno County. You can be in the study only once, but if you are the alternate on one day and are not selected, you may be able to be in the study on another day.

Study Enrollment

Before the day of the study you will be required to come to the offices of Golden Pacific Laboratories at 4720 W. Jennifer Ave., Suite 105, in Fresno. This visit will take about an hour. You'll meet with the Principal Investigator, Dr. Selim, or if you prefer, with a researcher who speaks Spanish. They will tell you more about what to expect during the study and what will be expected of you. They will also answer any questions you have about the study.

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We'll ask you about your work and about your general health. We'll ask for your name and age, and about your experience using spray products for cleaning or pest control. If we decide you are eligible, and if you decide you want to be in the study, we will ask you to sign this Informed Consent Form. We will then measure your height and weight, and we will ask you for your clothing sizes.

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If we enroll you in the study we will ask you to come to the study site on a certain day and time. We will call you the day before to remind you and to make sure you still want to be in the study. We'll also ask you to be sure to take a shower or a bath before coming to the study site.

Study Procedures

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We will do the testing at a vacant building (or unoccupied rooms in non-vacant buildings) in Fresno County, and it will take 3 or 4 hours on one day. After you arrive you will change into special clothing for the test and get fitted with two small pumps to sample the air you breathe. Then we'll ask you to spray walls, counters, and fixtures until the surfaces are visibly wet in bathrooms or kitchens. You will use the aerosol for hard surfaces as you normally would with horizontal spraying moving upward and downward from the starting point to hard surfaces such as laminate, tile, porcelain, glass, and metal. You will be asked to use one to four cans for spraying in multiple rooms, taking breaks if you need to in between the rooms. This may involve up to 30 minutes of actual spraying time. After that you'll give the special clothing back to us, change back into your own clothes, get paid, and go your way.

Here's exactly what will happen.

1. On the day of the study you will go to the study location at the time you've been told, and meet the research team.

2. Because it's important that you NOT be in this study if you are pregnant, on the day of the test each female volunteer will go to a private area and will be given a pregnancy test kit like the ones you can buy at the drug store. A female researcher will be able to explain how to use it and answer questions. After you give yourself the test we'll ask you if you want to stay in the study. If you decide not to, you won't be asked why, and the results of the test will not be recorded. You'll be paid $100 for coming to the test site, and then you'll be free to go. If you want to stay in the study, a trained female researcher will double-check the results with you. No-one but you and she will see the results, but we will make a note that the test was performed.

3. Dr. Selim and the research team will review with you and the other participants what will happen, and you'll have another chance to ask questions. We will remind you that you may change your mind about being in the study at any time before or after the study begins. All you need to do is tell us you've changed your mind. There will be no penalty of any kind to you if you decide to withdraw from the study.

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Independent IRB
7/21/09
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4. Someone of your own sex will show you to a clean, private changing area and help you get ready for the study. We will ask you to take off your street clothes down to your underwear. Then you will put on cotton long underwear (long johns), a long sleeved cotton shirt, and long cotton pants. We will provide all these clothes to you. We may need to trim the arms or legs of the long underwear so it doesn't stick out. You'll put your street clothes and valuables in a locked storage area, and keep the key with you.

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5. We'll give you safety glasses to wear while you are using the spray.

6. Before the test begins you will wash your hands and face with Ivory soap and water, and dry them with paper towels. We will check your hands to make sure you don't have cuts, scrapes, or any conditions that might increase the risk of skin problems during testing.

7. We will attach two small air sampling pumps to a belt around your waist. If you don't have a belt, we will provide one for you to use. We will attach a small tube to your shirt collar and connect it to one of the pumps. We will attach a small air sampler to the other pump and position it in front of you with a small strap around your neck. Both of these pumps will sample the air you breathe while you are using the aerosol. Each pump is about the size of a portable radio. The tube is about the size of a pen, and the air sampler is about the size of a tennis ball.

8. We will give you a can of Clorox Disinfecting Spray. The label on the can says it can be sprayed on hard surfaces in bathrooms and kitchens. The label on the can says to spray the surface until thoroughly wet. We will tell you that if the bathroom or kitchen you are cleaning has a fan, you may turn it on during cleaning if that is what you would normally do. We will ask if you have any questions.

9. We will take you to a bathroom or kitchen area where you will begin your work, and show you the other areas to work in after you finish that room. We will turn on your air pumps and ask you to put on your safety glasses. We will ask you to enter the bathroom or kitchen, shake the spray can for about 10 seconds, and begin spraying surfaces as you normally do on your job. One of us will watch you as you work, keeping track of how long you work and how much surface you spray. We may also take pictures or video to show what happened in the study, but those pictures will not show faces or tattoos in the final report. **If you still do not want to have your picture taken, you should not participate in this study.**

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10. We will ask you to apply at least one can of spray, and maybe as many as 4 cans. You will work in as many rooms as it takes to use up the assigned number of cans. We will sometimes ask you to stop between rooms and place your spray can on a scale so we can weigh it to see how much has been used. When you empty one can you'll be given a fresh one. You can also ask for a fresh can at any time. You may take a short break at any time you want, just like you would do at work. You won't be able to smoke or eat during the test, but you can have a cold drink during the break. If you need to use the toilet, one of the researchers will rinse your hands before you go to collect any spray that may be on them.

11. When you finish spraying, a researcher of your own sex will take you back to the changing area and collect samples:

    a. The researcher will remove the air sampling pumps and equipment;.

    b. The researcher will rinse your hands with rubbing alcohol and water and save the rinse water;

    c. The researcher will wipe your face and neck with a damp pad to collect any of the spray that might be on your skin;

    d. The researcher will help you remove your shoes and socks;

    e. The research will help you take off your outer shirt and pants and will save them for analysis;

    f. The researcher will help you take off the long underwear, and will save it for analysis.

When we've collected all these samples, you will dress again in your street clothes. We'll check your hands before you leave for redness or other signs of irritation. We will pay you $100 in cash and you will be free to go.

Risks

If you are in this study you would be exposed to several kinds of risks:

1. Risk of a reaction to the aerosol spray. Direct contact with the product can cause temporary eye redness, pain and swelling or skin irritation, and breathing it can cause coughing and irritate your throat. You will wear safety glasses to keep the spray out of your eyes, and long sleeves and pants to keep it off your skin. You might also have an allergic reaction to

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the spray, or it might interact with medicines you are taking. If you have had a reaction to a cleaning product before, or if you are taking medicine, be sure to tell us. If you notice any redness or itching, or if you think you may have gotten some of the spray in your eye, stop spraying right away and tell a researcher.

2. Risk of discomfort. The air pumps on your belt and the air hoses used to sample the air you breathe may be uncomfortable. Wearing two layers of clothing may also be uncomfortable.

3. Risk of stinging from alcohol wash and wipes. The diluted rubbing alcohol used to rinse your hands and wipe your face and neck may sting, if you have any cuts or abrasions on your hands or face.
4. Risk from heat. Because you'll be wearing an extra layer of clothing you might get too hot. We will monitor the temperature and humidity during the test, and will stop the study if it gets too hot to be safe. If you feel faint or too hot, or are sweating a lot, stop spraying right away and tell a member of the research team.

5. Risk of embarrassment. You may find it embarrassing to have a researcher with you while you change clothes. This is necessary to make sure the special underwear fits properly, and that it and the outer clothing don't get dirty when the test is over. The researcher who helps you will be of your own sex, and will be the only other person with you. You will wear your own underwear all the time.

6. If you are female, you might be surprised to learn on the day of the research that you are pregnant. No-one but you will know if the test shows that you're pregnant, and the results will not be recorded.

Unknown/Unforeseeable Risks

Participating in this study may pose other risks to you that we don't know about or can't predict. If we learn anything new that might influence your decision to participate, we'll share it with you right away.

Research-Related Injuries

If you are hurt while you are in this study, a nearby medical facility that knows about this study will provide care. If necessary, we will take you there. We will pay for needed medical treatment that is not paid for by your own insurance or by someone else. To find out more, or if you think you may have been hurt during the study, call Dr. Selim at Golden Pacific Laboratories (559 275-9091) from 9 am to 5 pm Monday through Friday.

You do not waive any of your legal rights by signing this form.

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Alternatives to Participation
If you decide to be in this study it will be because you want to. There will be no direct benefit to you if you do decide to participate, and no harm to you if you decide not to. The choice is up to you.

Benefits
You will not benefit directly from being in this study. What we learn from this study will help make sure that cleaning products like Clorox Disinfecting Spray can be used safely. This may indirectly benefit you and others who do janitorial work. You may also benefit if you ask for your own results from this study, so you can learn how much spray got on you compared to other workers doing the same job. The people who are paying for the study will also benefit from it, since they need to do this study to keep their cleaning products on the market.

Questions about this Study
If you have questions, you can ask them at any time—before, during, or after the study. Just ask Dr. Selim or any other member of the research team.

If you have any questions regarding your rights as a research participant, please contact Kim Lerner, Chair of the Independent Investigational Review Board, Inc. at toll free 1- (877) 888-iirb (4472). You can reach her from 6am-2pm Pacific Time, Monday-Friday. 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 for the purpose of protecting the rights of participants in a research study. 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.

Deleted: If you have any questions about your rights as a volunteer, or to report a problem in the study, please call Kim Lerner, Chair of the Independent Investigational Review Board, Inc., toll-free at 1-877-888-4472. You can reach her from 6am to 2pm Pacific time, Monday through Friday. The Independent Investigational Review Board has reviewed this study, and is charged with protecting the rights of you and the other volunteers. You can also find out more about your rights and role in research at the IIRB, Inc. website—www.iirb.com. ¶

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Costs and Payment
It will cost you nothing to participate in this study. At the end of the informed consent interview you will be paid $20 in cash for your time and trouble coming to our office. If you are selected for the study and come to the assigned study site, you will be paid $100 in cash when you are finished for the day, whether or not you are actually tested.

Confidentiality
We will give you a special ID number for this study, and we will record and report all data under that number. We will keep only one record linking your name to this ID number, and we will store it apart from other data, in a locked cabinet. We will not identify you by name or in any other way in study reports. Any pictures of you in a report of this study will not show your face.

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We will restrict access to records of this study to only a few people. But the people who are paying for it, the government agencies who will review the reports, and the IIRB, Inc., that looks out for your safety may all review study records. Because of this we can't completely guarantee confidentiality.

Right to Withdraw
You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team. If you decide not to participate in this study or to withdraw from it, you will not be penalized in any way or lose any benefits.

Removal from Study
Dr. Selim, the Principal Investigator in charge of this study, can remove you from this study even if you'd like to stay in it. He might remove you if, for example:

- He thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped because it gets too hot to continue safely, or for other reasons.

If you are removed from the study, or if the entire study is stopped, you will still be paid for your time and trouble.

Consent and Signature
I have read this Informed Consent Form and all my questions have been answered in a language I understand well. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this form. I'll get my own copy of this form with all signatures.

Date/Time: _____ _____
Subject's Signature

_____
Subject's Name (Print)

[*For Spanish language version of the IC document only, but in English*]
This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

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Date/Time: _____ _____

Spanish Speaking Researcher's Signature

_____

Spanish Speaker's Name (Print)

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I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____

Sami Selim, Ph.D.
Principal Investigator, Golden Pacific Laboratories, LLC

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Copy of consent form given to subject: (DATE) _____ BY (INITIALS) _____

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Independent Investigational Review Board, Inc.
Approved: 7/21/09

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Version: 7/21/09
Protocol: 070270b

APPROVED BY
Independent IRB
7/21/09
Signature Date

Initials:
Date:

Part 11 Transmittal (Crespo, 7/27/09, 8:06 AM) of IIRB Response Letter, Dated July 27, 2009 Approving the Protocol, along with Informed Consent Form, Experimental Subject's Bill of Rights and advertisements in English and Spanish. The transmittal also provided the Spanish translations of Label for Product to be Used in the Study, Subject Self-reporting Demographic Form, Employer Contract Script and Subject Invitation to Participate Script, MSDS for Clorox Disinfecting Spray and Community Notification Flyer

Megan Boatwright

From: Yesenia Crespo [YCrespo@iirb.com]
Sent: Monday, July 27, 2009 8:06 AM
To: Sami Selim
Cc: Megan Boatwright
Subject: 070270b
Attachments: Sami Selim 07270b.pdf

Please see attached

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

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

Kim Lerner
Chairman

Anita McSharry, R.N.
President

DATE: July 27, 2009

TO: Sami Selim, Ph.D.
Principal Investigator

FROM: Authorized Signatory
Independent Investigational Review Board, Inc.

SUBJECT: Approval Clinical Research;
- English/Certified Spanish Translation Informed Consent Form version 7/21/2009
- English/Certified Spanish Translation California Experimental Subject's Bill of Rights
- Research Protocol dated 7/14/2009
- Site Questionnaire
- English/Certified Spanish Translation Advertisements
- Aerosol Application Scenario: Rationale for Study Design dated 7/13/2009
- Certified Spanish Translation Appendix A: Label for Product to be used in the study
- Certified Spanish Translation Subject Self-Reporting Demographic Form
- Certified Spanish Translation Employer Contact Script and Subject Invitation to Participate Script
- Certified Spanish Translation MSDS for Clorox Disinfecting Spray
- Certified Spanish Translation Community Notification Flyer

PROTOCOL: (070270b) A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using a Pressurized Aerosol Can for Indoor Surface Disinfecting

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 (2l 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 July 21, 2009, the Committee reviewed and unanimously approved the Investigators, Informed Consent Form, California Experimental Subject's Bill of Rights, Research Protocol and Print Advertisements for the above noted research study. The Site Questionnaire, Aerosol Application Scenario: Rationale for Study Design, Certified Spanish Translation Appendix A: Label for Product to be used in the study, Certified Spanish Translation Subject Self-Reporting Demographic Form, Certified Spanish Translation Employer Contact Script and Subject Invitation to Participate Script, Certified Spanish Translation MSDS for Clorox Disinfecting Spray and Certified Spanish Translation Community Notification Flyer were reviewed and unanimously accepted.

The Informed Consent Form is unanimously approved. The approved English/Certified Spanish Translation Informed Consent Forms are identified as Version 7/21/2009 and stamped, "Approved 7/21/2009". The Informed Consent Form contains all regulatory required consent elements. The English/Certified Spanish Translation California Experimental Subject's Bill of Rights are unanimously approved. The approved English/Certified Spanish Translation California Experimental Subject's Bill of Rights are stamped, "Approved 7/21/2009".

The following advertisements were approved and stamped "Approved" 7/21/2009:
- Print Ad version "Research Study Volunteers" - as revised; (English/Certified Spanish Translation) (Necessary revisions have been incorporated and are included in the submitted advertisement information. See attached)
- Print Ad version "Professional Janitors Wanted" - as revised; (English/Certified Spanish Translation) (Necessary revisions have been incorporated and are included in the submitted advertisement information. See attached)

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.

The study has been approved for a 12 month period. Prior to the end of approval on 7/20/2010, 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.

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:kk

EXPERIMENTAL SUBJECT'S 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 the purpose of the study;
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 during the study;
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 alternatives to participating 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 status with my employer;
9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether I wish to participate in the study.

You may contact the *Independent Investigational Review Board, toll free at (877) 888-IIRB (4472) from 6 am to 2 pm Pacific Time*, if you have a question about your rights as a research subject.

If you have other questions, you should ask the Principal Investigator or Field Staff

Phone contacts:

Principal Investigator, Sami Selim (English): (559) 275-9091 from 8 am-5pm, Pacific Time

Field Staff: Joel Panara (English) at 800-870-0294, Ext 5500,Victoria Standart (English or Spanish) or Noé Galván (English or Spanish) at 800-870-0294 Ext 5510 from 8 am-5 pm, Pacific Time

APPROVED BY
Independent IRB

Signature 7/21/09
Date

CARTA DE LOS DERECHOS DEL SUJETO EXPERIMENTAL

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 el propósito del estudio;
2. Que se me informe qué me sucederá y si cualquiera de los procedimientos, pesticidas ó dispositivos, es diferente a los que se usan en la práctica estándar;
3. Que se me informe acerca de los riesgos, efectos secundarios, ó molestias, frecuentes y/ó importantes, de las cosas que me sucederán durante el estudio;
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 las alternativas a la participación en el estudio;
6. Que se me permita hacer cualquier pregunta(s) relacionada con el estudio, tanto antes de ponerme de acuerdo para 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 de que el estudio haya comenzado. Esta decisión no afectará a mi situación con mi empleador;
9. Recibir una copia del formulario de consentimiento firmado y fechado; y
10. Estar libre de presión cuando esté tomando en consideración si deseo participar en el estudio.

Usted puede contactarse con el *Independent Investigational Review Board, llamando al teléfono gratuito (877) 888-IIRB (4472) de las 6 a.m. a las 2 p.m. Hora del Pacífico*, si usted tiene una pregunta acerca de sus derechos en calidad de sujeto de una investigación científica.

Si tiene otras preguntas, usted debería preguntarle al Investigador Principal o a un miembro del Personal de Campo.

Teléfonos para contactarse:

Investigador Principal, Sami Selim (inglés): (559) 275-9091 de 8 a.m. a 5 p.m., Hora del Pacífico.

Personal de Campo: Joel Panara (inglés) al 800-870-0294, Ext. 5500, Victoria Standart (inglés o español) o Noé Galván (inglés o español) llamando al 800-870-0294, Ext. 5510 de 8 a.m. a 5 p.m., Hora del Pacífico.

APROBADO POR
Independent IRB

Firma

21/julio/09
Fecha

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

July 23, 2009

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:

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS
(Protocol: 070270 Part 2) (Approved: 7/21/09) (Principal Investigator: Sami Selim, PhD)
(Antimicrobial Exposure Assessment Task Force II [AEATF II])

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 SUJETO EXPERIMENTAL
(Protocolo: 070270 Part 2) (Aprobado: 21/julio/09) (Investigador Principal: Sami Selim, PhD)
(Antimicrobial Exposure Assessment Task Force II [AEATF II])

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.

PROFESSIONAL JANITORS WANTED

Seeking volunteers for a research study evaluating exposure to cleaning products while using a commonly used aerosol product. Volunteers will be compensated a total of up to $120 for their inconvenience.

Please contact Sami Selim at 559-824-1535 (English) or

Noé Galván at 559-917-9119 (English/Spanish)

for more information.

Study sponsored by the Antimicrobial Exposure Assessment Task Force administered by the American Chemistry Council, and directed by Golden Pacific Laboratories of Fresno, CA. 559-275-9091

APPROVED 7/24/09
Independent Investigational Review Board

SE NECESITA PERSONAL PROFESIONAL DE LIMPIEZA

Estamos buscando voluntarios para un estudio de investigación que evalúa la exposición a productos de limpieza, mientras que se usa un producto en aerosol que se usa comúnmente.
Se compensará a los voluntarios con un total máximo de $120 por el inconveniente.

Por favor contáctese con Sami Selim llamando al 559-824-1535 (inglés) o

con Noé Galván llamando al 559-917-9119 (inglés/español)

para más información.

El estudio está patrocinado por la Antimicrobial Exposure Assessment Task Force, administrado por el American Chemistry Council y dirigido por Golden Pacific Laboratories de Fresno, CA.
559-275-9091

APPROVED
Independent Investigational Review Board
7/21/09

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

July 23, 2009

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:

Janitorial Advertisement
(Approval Date: 7/21/09)
(Protocol: 070270 Part 2) (Sami Selim, PhD) (AEATF II)

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:

Anuncio para Empleados de Limpieza
(Fecha de Aprobación: 21/julio/09)
(Protocolo: 070270 Part 2) (Sami Selim, PhD) (AEATF II)

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.

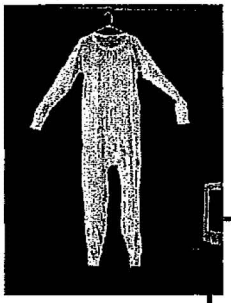
Research Study Volunteers

The Antimicrobial Exposure Assessment Task Force II (AEATF II), a group of companies that make antimicrobial cleaning products, is doing research to measure how much chemical gets on workers' skin and into the air they breathe when they use antimicrobial products. We are looking for experienced janitorial workers to spray surfaces in rooms and let us collect exposure data. Study participants will receive ~~$100~~ up to $120 for their inconvenience.

To volunteer you must be:	You are not qualified if you:
• At least 18 years old	• Are less than 18 years of age
• Able to read and speak English or Spanish	• Do not have a government-issued photo identification card
• In good health	• Read neither English nor Spanish
• Male or non pregnant, non-nursing female	• Are not in good health
• Experienced and trained in using antimicrobial cleaning products	• Work for a cleaning product manufacturer
• Live in Fresno County	• Are a pregnant or nursing female
	• Do not live in Fresno County

You will be asked to do the following:

- Let us monitor you as you do your work for a day using an aerosol can containing antimicrobial chemicals
- Sign a consent form before participating (in English or Spanish)
- Wear long underwear under cotton pants and shirt, which will be supplied to you (see pictures)
- Let us have the supplied clothes at the end of the day
- Let us wash your hands and wipe your face with rubbing alcohol (see picture)
- Wear two small air samplers on your belt (see picture)



You should also know that:

- Participation is completely voluntary
- You can withdraw from the study whenever you want
- Information from the study will be used by EPA to better understand worker exposure.

If you are interested, for additional information please contact:

Joel Panara (English)
800-870-0294, Ext 5500; or
Victoria Standart (English / Spanish)
800-870-0294, Ext 5510

APPROVED
7/21/09
Independent Investigational Review Board

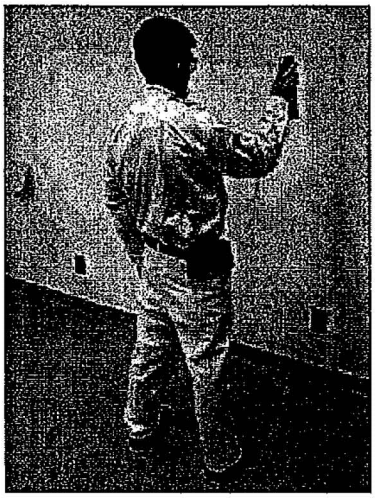
Voluntarios para un Estudio de Investigación Científica

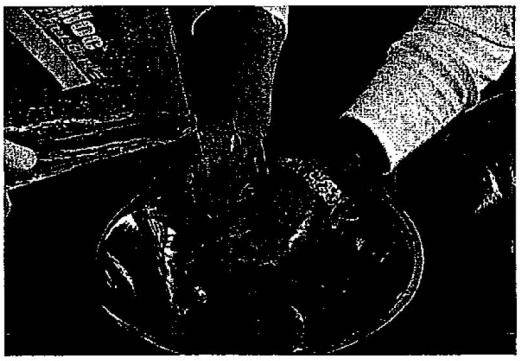
La Antimicrobial Exposure Assessment Task Force II (AEATF II) es un grupo de compañías de que fabrican productos de limpieza anti-microbianos, que están llevando a cabo investigación científica para medir cuánta substancia química se agarran los trabajadores en la piel y en el aire que respiran cuando ellos usan productos anti-microbianos. Están buscando trabajadores de la limpieza experimentados para que desempeñen su trabajo usual y dejarnos recoger datos de la exposición. Los participantes del estudio recibirán un máximo de $120 por su inconveniente.

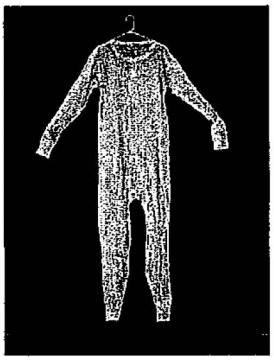
Para ofrecerse como voluntario usted debe:	**Usted no cumple con los requisitos si:**
• Tener por lo menos 18 años, pero menos de 65 • Que pueda leer y hablar inglés o español • Gozar de buena salud • Ser hombre, ó mujer que no esté embarazada ni lactando • Ser experimentado y estar entrenado en el uso de productos de limpieza anti-microbianos • Ser residente del Condado de Fresno	• Es menor de 18 años de edad • Si no tiene una identificación con foto que sea emitida por el gobierno • Si no lee ni inglés ni español • Si no goza de un buen estado de salud • Si trabaja para un fabricante de productos de limpieza • Si es una mujer que está embarazada ó lactando • No vive en el Condado de Fresno

Le pedirán que haga lo siguiente:

- Que nos permita monitorearlo mientras que usted hace su trabajo, durante un día, usando una lata de aerosol que contenga substancias químicas anti-microbianas
- Que firme un formulario de consentimiento antes de participar (en inglés ó en español)
- Que use ropa interior larga debajo de los pantalones y camisas de algodón, los cuales se los proporcionarán (ver las fotos)
- Que nos deje tener la ropa que le hayamos dado, al final del día
- Que nos deje lavarle las manos y frotarle la cara, con alcohol de frotar (ver la foto)
- Que use dos dispositivos pequeños, en su cinturón, para el muestreo de aire (ver la foto)







Usted debería saber que:

- La participación es completamente voluntaria
- Usted puede retirarse del estudio cuando quiera
- La información proveniente del estudio será usada por la EPA para entender mejor la exposición de los trabajadores.

Si está interesado en información adicional, por favor póngase en contacto con:

Joel Panara (inglés)
800-870-0294 ext. 5500 ó
Victoria Standart
(inglés / español)
800-870-0294 ext. 5510

APPROVED
Independent Investigational Review Board
7/21/09

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

July 23, 2009

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:

Flyer "Research Study Volunteers"
(Approval Date: 7/21/09)
(Protocol: 070270 Part 2) (Sami Selim, PhD) (AEATF II)

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 «Voluntarios para un Estudio de Investigación Científica»
(Fecha de Aprobación: 21/julio/09)
(Protocolo: 070270 Part 2) (Sami Selim, PhD) (AEATF II)

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.

Front Label [Frente de la etiqueta]

Soluciones Comerciales*

CLOROX®

Aerosol Desinfectante

Viricida*
•
Germicida
•
Funguicida
•
Pseudomonacida
•
Bactericida
•
Estafilocida
•
Estreptocida
•
Tuberculocida

ELIMINA LOS OLORES

Desinfectante Multiuso

Ingredientes Activos:

Octil decil dimetil cloruro de amonio	0,1890%
Dioctil dimetil cloruro de amonio	0,0945%
Didecil dimetil cloruro de amonio	0,0945%
Alquil (50% C14, 40% C12, 10% C16) dimetil bencil cloruro de amonio	0,2520%
Etanol	65,0000%
INGREDIENTES INERTES	34,3700%
TOTAL:	100,0000%

MANTENER FUERA DEL ALCANCE DE LOS NIÑOS

ADVERTENCIA: Ver la etiqueta de atrás para los primeros auxilios

PESO NETO 19 OZ. (539 gramos)

NO CONTIENE CFCs U OTRAS SUBSTANCIAS QUE DISMINUYEN LA CAPA DE OZONO

NO CONTIENE CFCs

Los Reglamentos Federales prohíben los CFCs en los propelentes de los Aerosoles

R0401-2

Back label [la parte de atrás de la etiqueta]

- Este producto cumple con las normativas estándar de eficacia, la Prueba ADAC de Productos Germicidas en Aerosol, para los desinfectantes de hospitales.
- Mata y evita el crecimiento de moho.
- Desodoriza al matar los gérmenes que causan los malos olores.
- No contiene lejía

Usar en superficies duras, no-porosas en:
• Cuartos de baño • Hoteles • Moteles • Oficinas • Instalaciones Militares • Escuelas • Centros Diurnos de Cuidado Infantil • Guarderías Infantiles • Dormitorios • Refugios • Laboratorios • Clubes de Gimnasia • Autobuses Escolares • Ambulancias • Salas de Bowling • Zonas de Juegos • Tiendas de Alimentos • Instalaciones con Vestuarios • Zonas de Almacenaje • Perreras

Para usar en:
• Recipientes [cubos] de basura • Papeleras [cestos para papeles] • Mesas para cambiar Pañales • Asientos de Inodoros • Grifos de agua corriente • Picaportes • Teléfonos • Duchas • Cortinas de plástico para la Ducha • Mostradores • Escritorios • Bancos metálicos de trabajo • Pasamanos, asas

Usar en superficies no-críticas, en:
Hospitales • Salas de Pacientes • Residencias para Ancianos • Clínicas Médicas • Consultorios Veterinarios.

PRECAUCIONES:

PELIGROS PARA LOS SERES HUMANOS Y ANIMALES DOMÉSTICOS

después de haber manipulado el producto. Quítese las ropas contaminadas y lávelas antes de volver a usarlas. Si el producto entrase en contacto con la piel, lávese minuciosamente con agua y jabón, especialmente antes de manipular y preparar alimentos.

PRIMEROS AUXILIOS: EN LOS OJOS:

Mantenga los párpados abiertos y enjuáguese lentamente y con suavidad, usando agua durante 15-20 minutos. Quítese los lentes de contacto. Si todavía tuviese el producto después de haber transcurrido los primeros 5 minutos, entonces continúe enjuagándose los ojos. Llame a un centro de control de intoxicaciones [*poison control center* en inglés] o a un doctor para que lo asesore en lo referente a más tratamiento. Cuando llame a un centro de control de intoxicaciones, a un doctor o cuando vaya para tratamiento, lleve el envase o la etiqueta del producto. ¿Tiene preguntas? Llame al 1-800-797-7225.

ADVERTENCIA: Causa lesión considerable, pero temporal, en los ojos. Que no se le meta en los ojos ni en la ropa. Use anteojos protectores (anteojos de seguridad). El contacto prolongado o repetido con la piel puede causar reacciones alérgicas en algunos

Desinfecta, atacando las siguientes bacterias, virus* y mohos:

- Campylobacter jejuni
- Corynebacterium diphtheria
- Enterobacter aerogenes
- Enterococcus faecalis (resistente a la Vancomicina)
- Escherichia coli O157:H7
- Klebsiella pneumonia
- Listeria monocytogenes
- Mycobacterium bovis (Tuberculosis)
- Mycobacterium smegmatis
- Proteus mirabilis
- Proteus vulgaris
- Pseudomonas aeruginosa
- Pseudomonas cepacia (Burkholderia cepacia)
- Pseudomonas putida
- Salmonella choleraesuis
- Salmonella choleraesuis paratyphi B1 (schottmuelleri)
- Salmonella choleraesuis serotype enteritidis
- Serratia marcescens
- Shigella dysenteriae
- Staphylococcus aureus
- Staphylococcus aureus (resistente a Methicillian y Gentamicin)
- Streptococcus pyogenes
- *Adenovirus tipo 2
- *Cytomegalovirus
- *Echovirus
- virus *Hepatitis A
- virus *Herpes simplex tipo 1
- virus *Herpes simplex 2
- * Virus de Inmunodeficiencia Humana tipo 1 (VIH-1)
- virus *Influenza A2 (Hong Kong) (virus de la gripe)
- virus *Influenza tipo B
- virus *Polio
- virus *Respiratory syncytial (causa principal de infecciones en las vías respiratorias inferiores en los niños)
- *Rhinovirus (virus del resfrío)
- *Rhinovirus 39
- *Rotavirus (causa principal de la diarrea infecciosa en los niños)
- virus *Vaccinia
- Alternaria alternata
- Candida albicans
- Cladosporium herbarum
- Trichophyton mentagrophytes (hongo Pie de Atleta)

Sanea en 30 segundos contra: Klebsiella pneumonia, Staphylococcus aureus.

MODO DE EMPLEO: El usar este producto de manera incongruente con su etiqueta, constituye una infracción a la ley federal. Solamente para el uso sobre superficies de contacto que no contengan alimentos. Se requiere un enjuague con agua potable para las superficies que puedan estar en contacto directo con alimentos. Este producto no puede resultar en la contaminación, directa o indirecta, de productos alimenticios.

INSTRUCCIONES ESPECÍFICAS PARA EL *VIH-1: Este producto mata al VIH-1 en superficies/objetos limpiados previamente que hayan sido manchados anteriormente con sangre/fluidos corporales en ambientes médicos o en otros ambientes de los cuales se espera que exista un manchado similar en las superficies inanimadas/objetos con sangre o fluidos corporales y en las que las superficies/objetos, posiblemente manchados con sangre o fluidos corporales pueden ser asociados con la trasmisión potencial del Virus de Inmunodeficiencia Humana Tipo 1 (VIH-1) (asociado con el SIDA)

Instrucciones Especiales para el Uso de este Producto para Limpiar y Descontaminar de *VIH-1 Superficies/Objetos manchados con Sangre/Fluidos corporales.

individuos. Lávese minuciosamente con agua y jabón

PELIGROS FÍSICOS: Inflamable: El contenido bajo presión. Aléjelo del calor, las chispas y las llamas. No perfore ni incinere el envase. La exposición a temperaturas superiores a los 130° Fahrenheit [54° C] puede hacer que explote.

ALMACENAMIENTO/ELIMINACIÓN:

Almacenamiento y Eliminación del Pesticida: No contamine el agua ni los alimentos ni el forraje, por almacenarlo y eliminarlo. Almacenar a temperatura por debajo de los 130° Fahrenheit [54° C]. Para Deshacerse del Envase: No pinchar ni incinerar. No volver a usar el envase vacío. Recicle el envase vacío o deshágase de él tirándolo a la basura.

• Esta lata está hecha de un 25% de acero reciclado (10% pos-consumidor) • Reciclable • No contiene fósforo • Evite el uso en la madera lustrada, en superficies pintadas o en plásticos acrílicos.

(código de barras)

¿Tiene Preguntas? ¿Comentarios?
Llame gratis
1-800-797-7225
Fabricado para Clorox Professional Products Company, Oakland, CA 94512
® 1997
The Clorox Company
fabricado en los EE.UU. o en la Argentina
EPA Reg. No. 67619-3 [№ de registro de la Agencia de Protección Medioambiental]
EPA Est. No. 11525-IL-1 [№ de Establecimiento de la EPA]
6B13-ARG-001
Ver el código en el fondo de la lata.
Patente Pendiente

Protección Personal: Cuando manipule objetos manchados con sangre o fluidos personales, use guantes de látex descartables, guardapolvo, mascarilla, y anteojos protectores.

Procedimiento para la limpieza: Antes de aplicar este producto, limpie a fondo las superficies y los objetos, que debe quedar libres de sangre y otros fluidos corporales.

Tiempo de Contacto: Pulverice a una distancia de 6 a 10 pulgadas (de 15 a 26 centímetros) de la superficie previamente limpia durante 3 ó 4 segundos hasta que ésta quede totalmente húmeda. La superficie debe permanecer húmeda por 10 minutos antes de pasar un trapo o secar con aire.

Desecho de los Materiales Infectados: Use guantes de látex descartables, guardapolvo, mascarilla y anteojos protectores. Los objetos contaminados con sangre y otros fluidos corporales se deberán esterilizar por medio de una autoclave y se deberán desechar de acuerdo a los reglamentos locales sobre el modo de eliminar desechos infecciosos.

Para Desinfectar: Pulverice a una distancia de 6 a 10 pulgadas (de 15 a 26 centímetros) de la superficie previamente limpia durante 3 ó 4 segundos hasta que quede totalmente húmeda. La superficie debe quedar húmeda durante 10 minutos antes de pasar un trapo.

Para Sanear Superficies que no Tengan Contacto con Alimentos: Pulverice a una distancia de 6 a 10 pulgadas (de 15 a 26 centímetros) de la superficie previamente limpia durante 3 ó 4 segundos hasta que quede totalmente húmeda. La superficie debe quedar húmeda durante 10 minutos antes de secar con aire.

Para Controlar y Prevenir la aparición de Moho y Hongos: Pulverice a una distancia de 6 a 10 pulgadas (de 15 a 26 centímetros) de la superficie previamente limpia durante 3 ó 4 segundos hasta que quede totalmente húmeda. La superficie debe quedar húmeda durante 10 minutos antes de pasar un trapo o secar con aire.

Para Desodorizar: Pulverice la superficie previamente limpia, según se necesite.

R0401-2

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

July 20, 2009

To Whom It May Concern:
A Quién Corresponda:

This is to certify that the attached document translated from English into Spanish is an accurate representation of the document received by this office. This document is designated as:

APPENDIX A: Label for Product To Be Used in Study
(Approval Date: 7/20/09)
(Protocol No.: 070270 – AEATF II)
(Sami Selim, PhD)

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del documento recibido por esta oficina. Dicho documento es:

ANEXO A: Etiqueta del Producto a Usarse en el Estudio
(Fecha de Aprobación: 20/julio/09)
(Protocolo №: 070270 – AEATF II)
(Sami Selim, 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.

FORMULARIO DEMOGRÁFICO LLENADO POR EL SUJETO

Nombre del Voluntario _____

Dirección (calle) _____

Ciudad, Estado, Código Postal [*Zip*] _____

Número(s) de Teléfono _____

Edad actual _____ años Género ☐ Masculino ☐ Femenino

Peso _____ libras Estatura _____ pies _____ pulgadas

Tamaño de Camisa: ☐ Small ☐ Medium ☐ Large ☐ X Large ☐ XX Large ☐ XXX Large

Tamaño de Cintura: ☐ 24-28 pulg. ☐ 28-32 pulg. ☐ 32-36 pulg. ☐ 36 - 40 pulg. ☐ 40 - 44 pulg. ☐ 44 – 50 pulg.

Años de experiencia usando atomizador [pulverizador] de aerosoles _____

¿Cada cuánto tiempo usa atomizadores de aerosoles? _____ por ☐ semana ☐ mes

¿Los olores provenientes de perfumes, de la gasolina en la gasolinera o de los vehículos de Diesel, le molestan más a usted que a sus amigos?

☐ Sí ☐ No

¿Cómo describiría su salud general? ☐ Excelente ☐ Buena ☐ Regular ☐ Mala
Comentarios _____

Marque aquí si le gustaría obtener sus resultados de este estudio, comparados con la parte más baja, más alta y mediana del grupo ☐ Sí ☐ No

Mi firma al pie indica que la información que he proporcionado es correcta:

_____ _____
Firma del Voluntario Fecha

LIBRETO DE CONTACTO PARA EL EMPLEADOR y LIBRETO DE INVITACIÓN AL SUJETO PARA PARTICIPAR

Para los empleadores que hablan inglés -

Introducción

Me llamo [ ] y trabajo con.....

Han contratado a mi compañía para llevar a cabo un estudio que mide cuánto, del producto de limpieza, se deposita sobre las ropas y la piel de los empleados de limpieza, cuando éstos limpian superficies mediante el uso de un limpiador en aerosol.

¿Su compañía proporciona servicios de limpieza a negocios en el Condado de Fresno?

[Si dice que sí, continúe. Si dice que no, agradézcale y termine la llamada]

Este estudio se llevaría a cabo fuera de las horas normales de trabajo y no implica a su compañía ni clientes, de ningún modo. Nos gustaría poner un volante en su empresa, el cual menciona al estudio y le solicita a cualquiera que le interese que se ponga en contacto directo con nosotros, durante horas que no sean de trabajo. ¿Estaría dispuesto a poner un volante para el estudio?

[Si respondió que sí, continúe. Si no, agradézcale y termine la llamada]

Estamos convocando dos reuniones para explicarles el estudio a los administradores de empresas de limpieza y para responder a cualquier pregunta que ellos puedan tener. Los volantes se distribuirán en estas reuniones. Uno es [fecha y lugar] y el otro es [fecha y lugar]. ¿Usted podría asistir a ambas reuniones?

[Si respondió que sí, registre el nombre de ellos y la reunión a la que van a asistir, agradézcales por el tiempo dedicado, indíqueles que usted espera verlos en la reunión pertinente y termine la llamada]

[Si respondió que no, o no está seguro, pregúnteles si le gustaría recibir una copia del volante de reclutamiento y haga que alguien se ponga en contacto con ellos para seguir debatiendo el estudio].

[Si respondió que sí, registre el nombre de ellos, la dirección, el método preferido para entregar el volante y, la mejor hora para ponerse en contacto para seguimiento].

[Si respondió que no, agradézcales el tiempo de ellos y termine la llamada].

Libreto para Invitar a Sujetos a Participar

[Identifíquese usted mismo y a qué compañía está afiliado, pregúnteles si están llamando acerca del estudio de aerosol. Si responden que sí, pregúnteles cómo se enteraron acerca del estudio y documente la respuesta. Pregúntele al sujeto potencial si él/ella querría más información acerca del estudio. Si respondió que sí, continúe].

Estamos llevando a cabo una investigación científica para averiguar cuánta substancia química de limpieza pueda llegar a la piel cuando se usa una lata de aerosol para limpiar baños y áreas de cocinas. Nosotros mediremos cuánta cantidad de la substancia química de limpieza le llega a las ropas que usted usa durante el estudio, en sus manos, cara y cuello y cuánto hay en el aire que usted respira mientras que limpia cuartos de baño.

El material que se está probando en este estudio es un producto llamado CLOROX DISINFECTING SPRAY, un producto que se usa para limpiar superficies duras tal como duchas, inodoros [*toilets*], mostradores, paredes y acero inoxidable.

El proyecto en sí llevará alrededor de 3 a 4 horas en un día. Durante ese tiempo, usted se cambiará de ropa y usará una ropa especial para la prueba y le colocarán un dispositivo para hacer un muestreo del aire que respira usted, luego le pedirán que aplique líquido anti-microbiano usando una lata de aerosol presurizado a las superficies, que incluye duchas, inodoros [*toilets*], a mostradores y paredes, hasta que se humedezcan con el spray. Le requerirán que aplique una o más latas llenas hasta un total de 4 latas llenas, a superficies en varias salas, de la manera en la que usted lo haría cuando usa este tipo de producto. Al vaciar usted una lata, la lata vacía será recogida y le proporcionarán una lata nueva y llena. Luego usted le dará la ropa especial al equipo de la investigación científica y volverá a ponerse sus propias ropas.

Si lo seleccionaran para participar en el estudio, usted recibirá $100 [cien dólares] en efectivo, al final del día del estudio. Para cumplir con los requisitos para la participación, usted debe mostrar su identificación que tenga foto, para probar su edad. Usted debe ser mayor de 18 años de edad y debe poder leer, ya sea inglés ó español. Usted debe gozar de buena salud. Si usted es mujer, usted no debe estar embarazada ni amamantando [dándole el pecho] a un niño. Además, usted debe tener experiencia y haber sido entrenado en el uso de productos de limpieza que matan gérmenes.

¿Le gustaría obtener más información acerca del proyecto?

(Si dijo que no, agradézcales por el tiempo).

(Si dijo que sí, instrúyalos de la siguiente manera)

Si quisiera participar en el proyecto, primero usted vendrá a las oficinas de Golden Pacific Laboratories en 4720 W. Jennifer Ave., Suite 105, en Fresno, para reunirse con el Investigador Principal, el Dr. Sami Selim, entre las horas de la 1 p.m. y las 5 p.m. de lunes a viernes. Habrá allí un investigador que hable español, si usted prefiere hablar del estudio en español. Nosotros podemos arreglar para reunirnos con usted también en los fines de semana. La oficina se encuentra cerca de la Shaw Avenue detrás de Costco. Nosotros repasaremos junto a usted el estudio, en gran detalle y le responderemos a todas sus preguntas en lo concerniente al estudio y

le contaremos más acerca de lo qué esperar mientras que esté participando y qué es lo que se espera de usted. La primera visita le llevará alrededor de una hora. Si le interesa, nosotros podemos arreglar una hora para la reunión, ahora mismo. ¿Preferiría una visita en un día de semana ó en un fin de semana? ¿Cuál sería la mejor hora para usted?

(Se documentará la hora y la fecha de la cita)

(Nota: si los sujetos potenciales le hicieran preguntas que no estén tratadas en este libreto telefónico, infórmeles que las preguntas adicionales puede contestárselas el Dr. Sami Selim o el investigador que hable español.)

AVISO

Durante los próximos días, usted pudiera notar cierta actividad inusual en el edificio de al lado. El Consejo Americano de Química estará llevando a cabo un estudio de monitoreo de la exposición de trabajadores. Este estudio se está llevando a cabo con empleados de limpieza que son de la zona. Mientras que estos limpiadores estén trabajando, van a estar usando ropas de trabajo que consisten en camisas blancas de manga larga y pantalones largos, y ellos pudieran estar usando, en sus cinturones, algo que se parece a los reproductores de MP3. Usted también pudiera ver al personal del estudio usando batas blancas guardapolvo, como las que se usan en laboratorios. Las personas que participan en este estudio están midiendo la cantidad de exposición química que reciben los limpiadores cuando usan un producto de limpieza en aerosol, similar a lo que usted pudiera usar en su casa o empresa. Este proyecto durará alrededor de una semana. Si usted desea más información, ó si le preocupa este proyecto, de algún modo, por favor póngase en contacto con los siguientes individuos:

Dr. Sami Selim de Golden Pacific Laboratories (559-275-9091)
ó
Dr. Has Shah del Consejo Americano de Química (703-741-5637)

Si prefiere hablar en español, por favor contáctese con:

Victoria Standart (inglés y español)
Field Research Associate
Eurofins | Grayson
211 N. Main Street
Creedmoor, NC 27522
Teléfono: 919-528-5510

ó

Noé Galván, PhD (inglés y español)
Field Research Associate
Product Safety Scientist
PS&RC, Global Stewardship
Clorox Services Co.
7200 Johnson Drive
Pleasanton, CA 94588
Teléfono: 925-425-6708

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

July 23, 2009

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:

Forms
(Approval Date: 7/22/09)
(Protocol: 070270 Part 2) (Sami Selim, PhD) (AEATF II)

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:

Formularios
(Fecha de Aprobación: 22/julio/09)
(Protocolo: 070270 Part 2) (Sami Selim, PhD) (AEATF II)

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.

Clorox Professional Products Company
1221 Broadway
Oakland, CA 94612
Tel (510) 271-7000

Hoja de Datos de Seguridad de Materiales

I Producto: SPRAY DESINFECTANTE CLOROX® COMMERCIAL SOLUTIONS™

Descripción: AEROSOL PERFUMADO

Otras denominaciones
Reg EPA No. 67619-3
Spray Desinfectante Clorox

Distribuidor
Clorox Sales Company
1221 Broadway
Oakland, CA 94612

Teléfonos de emergencia
En caso de emergencia médica, llame al:
(800) 446-1014
En caso de emergencia de transporte, llame a Chemtrec al:
(800) 424-9300

II Datos de peligro para la salud

CONTACTO CON LOS OJOS: Causa irritación moderada y reversible en los ojos.
CONTACTO CON LA PIEL: Causa irritación menor después del contacto prolongado. El contacto prolongado o repetido con frecuencia, sobre la piel, puede causar reacciones alérgicas en algunos individuos.
INGESTIÓN: Posee baja toxicidad si lo ingiere. Puede causar una irritación menor en la oca. La ingestión de grandes cantidades puede resultar en embriaguez por el etanol.
INHALACIÓN: El mal uso intencional por concentrar e inhalar vapores, puede ser perjudicial o mortal. La inhalación de altas concentraciones puede causar irritación de las vías respiratorias. Los síntomas incluyen dolores de cabeza, mareos, náuseas, vómitos y malestar general.
AFECCIONES MÉDICAS GENERALMENTE AGRAVADAS POR LA EXPOSICIÓN: No se conoce ninguna.
PROCEDIMIENTOS DE PRIMEROS AUXILIOS EN EMERGENCIAS: OJOS: Enjuáguese los ojos inmediatamente con abundante agua durante por lo menos 15 minutos. Si persistiese la irritación, llame a un médico.
PIEL: Lávese con abundante agua y jabón. SI SE INGIERE: Beba un vaso de agua. Llame a un médico.

III Ingredientes peligrosos

Ingredientes	Concentración	Límite de exposición para el trabajador
Etanol CAS №64-17-5	60-80%	1000ppm TLV – TWA
Propano CAS №7409806 (propelente)	1-5%	1000ppm PEL – TWA
Isobutano CAS №75-28-3	5-10%	No establecido

Ninguno de los ingredientes de este producto está en la lista de carcinógenos de la IARC, el NTP o la OSHA.

TLV\TWA: Valor Límite del Umbral \ Promedio del Peso Ponderado.

PEL: Límite Permisible de Exposición. Fuente: OSHA

IV Protección y precauciones especiales

No se han identificado ni protección ni precauciones especiales para el uso de este producto de acuerdo con las condiciones de uso dadas al consumidor.

Se dan las siguientes recomendaciones para las instalaciones de producción y para otras condiciones y situaciones en las que existe un potencial elevado para la exposición accidental, en gran escala o prolongada.

Practicas higiénicas: Usar gafas [anteojos] de seguridad y guantes protectores cuando manipule el producto.
Controles de ingeniería: Usar ventilación a prueba de explosión para minimizar la exposición a los vapores o al vaho.
Prácticas de trabajo: Minimizar el contacto con los ojos y la piel y la inhalación del vapor o el vaho.

V Datos de Reglamentación y Transporte

Clase de riesgo del DOT de EE.UU.: ORM – D

Nombre Apropiado para el Flete: Bien del Consumidor

EPA - SARA Título III / CERCLA: Este producto está regulado por las Secciones 311/312. El producto envasado no hay que declararlo.

Estado TSCA : Todos los componentes de este producto aparecen en el inventario de la TSCA.

VI Procedimientos en caso de Derrame/Eliminación de Desechos

Procedimientos en caso de derrame: Eliminar todas las fuentes de ignición. Ventilar el área. Quitar el exceso con un estropajo [*mop*]. Quite todo material que haya quedado, con agua jabonosa. Vuelva a echar agua. Protección Respiratoria: Si tiene que encargarse de derrames grandes industriales o en un almacén, las personas deberían usar protección respiratoria aprobada por NIOSH. Eliminación de desechos: No pinchar ni incinerar (quemar) latas vacías ni llenas. Eliminar los desechos de acuerdo con los reglamentos estatales y locales para los productos al consumidor. Las latas vacías pueden ser enterradas en terraplenes. Precauciones a tomar en el Manipuleo y Almacenaje: No almacenar por encima de los 120 °F. No perforar ni quemar. Aleje a los aerosoles del fuego o de las chispas. Almacenar de acuerdo con NFPA 30B para el Nivel 2 Aerosoles. Otras Precauciones: N/A

VII Datos de reactividad

Estabilidad: Estable

Condiciones a Evitar: Temperaturas mayores de los 120 °F

Incompatibilidad/Materiales a Evitar: Álcalis y ácidos

Polimerización peligrosa o Descomposición: No se conoce ninguna

VIII Datos sobre incendio y explosión

Punto de inflamación o punto crítico: El punto de inflamación del líquido es de 66 °F al usar un dispositivo Herzog de taza cerrada. La extensión de la llama es entre 16-18 pulgadas sin punto de inflamación.
Agentes Extintores de Fuego: Todos los tipos.
Procedimientos Especiales para Combatir Incendios: N/A
Peligros Inusuales de Incendio y Explosión: Las llamas de alcohol pueden no ser visibles enseguida. La exposición a temperaturas por mayores de los 120 °F (49 °C) puede causar que reviente o que se escape. Mantenga los envases frescos. Use equipos o escudos para proteger al personal de los envases que revienten.

IX Datos físicos

pH (no propelente)..... 9.2
Viscosidad (no propelente)..... .. 3,2 cps a 20 °C
Densidad (no propelente).....0,86 g/ml a 25 °C
Aspecto y Olor.....Floral / olor frutado

DATOS PROPORCIONADOS SOLAMENTE PARA USO EN RELACIÓN CON LA SALUD Y LA SEGURIDAD OCUPACIONAL FECHA DE PREPARACIÓN 05/Febrero
CleanSource #240340

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

July 24, 2009

To Whom It May Concern:
A Quién Corresponda:

This is to certify that the attached document translated from English into Spanish is an accurate representation of the document received by this office. This document is designated as:

Material Safety Data Sheet
(Protocol No.: 070270b – AEATF II)
(Sami Selim, PhD)

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del documento recibido por esta oficina. Dicho documento es:

Hoja de Datos sobre la Seguridad del Material
(Protocolo №: 070270b – AEATF II)
(Sami Selim, 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.

INFORMED CONSENT FORM

Title: (Protocol No. 070270b) A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using a Pressurized Aerosol Can for Indoor Surface Disinfecting

Principal Investigator:
Sami Selim, Ph.D.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Field Coordinators:

Joel Panara (English)
Field Coordinator
Eurofins | Grayson
211 N. Main Street
Creedmoor, NC 27522
Phone: 919-528-5500

Victoria Standart (English and Spanish)
Field Research Associate
Eurofins | Grayson
211 N. Main Street
Creedmoor, NC 27522
Phone: 919-528-5510

Noé Galván, Ph.D. (English and Spanish)
Field Research Associate
Product Safety Scientist
PS&RC, Global Stewardship
Clorox Services Co.
7200 Johnson Drive
Pleasanton, CA 94588
Phone: 925-425-6708

Field Locations: (Subject Informed Consent Interview Location)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Suite 105
Fresno, CA 93722
(Study Site Location)
3 Sites in Fresno County, CA

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 559-824-1535 (Sami Selim)

We're asking you to think about being in a research study because you have experience doing janitorial work. Your participation is voluntary. This Informed Consent Form explains the study.

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Independent IRB
Signature 7/21/09 Date

Initials: _____
Date: _____

We're asking you to think about being in a research study because you have experience doing janitorial work. Your participation is voluntary. This Informed Consent Form explains the study.

You may take a copy of this form home to think about and discuss with friends or family before you decide whether you want to be in the study. If you have any questions, or if you do not understand anything in this form, please ask one of us to explain. If you would prefer to talk in Spanish, please ask. We can explain the study to you in English or Spanish.

Purpose of this Study

Golden Pacific Laboratories is doing this research to find out how much spray may reach your skin when you use a cleaning product in a pressurized aerosol can. We will measure how much of the spray gets on the clothing you wear during the study, and on your hands, face and neck, while you clean indoor surfaces like bathrooms and kitchens. We will also measure how much of the spray is in the air you breathe during the study. An important purpose of this study is to collect information that will be provided to the U.S. Environmental Protection Agency or EPA. The EPA will use this information to evaluate the levels of exposure to the aerosol spray product in this study and other spray products that are similar to it.

The spray in this study will be Clorox Commercial Solutions® Clorox® Disinfecting Spray. This is a commercial cleaning product used to clean hard surfaces such as bathroom tiles and fixtures and kitchen cabinets and counters. This product is used in offices and buildings such as hospitals, schools, and hotels. It contains chemicals called quaternary ammonium salts, which kill germs.

A group of companies that make germ-killing cleaning products is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products kill germs on indoor surfaces, and are registered by the US Environmental Protection Agency (EPA) as pesticides.

Sami Selim, Ph.D., of Golden Pacific Laboratories is the Principal Investigator in charge of the study. Victoria Standart of Eurofins | Grayson is his main Spanish-speaking assistant.

Test Product

The material being tested in this study is Clorox Disinfecting Spray. This is a commercial cleaning product used to disinfect and deodorize hard, non-porous surfaces such as bathrooms (walls, showers, toilets, etc.), kitchens (cabinets, faucets, etc.). This product is recommended for use in offices and commercial and institutional buildings, such as hospitals, schools, and hotels. Clorox

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Disinfecting Spray contains chemicals known as quaternary ammonium salts which kill germs. You will be given a copy of the product label, and if you request it, you will be provided the Material Safety Data Sheet or "MSDS" for this product.

Subject Selection
To be in this study you must be healthy male or female, ages of 18 and older, and you must be able to read and speak English or Spanish. You will need to prove your age with a government-issued photo ID—a driver's license or state issued ID. You must have experience doing janitorial work, and must want to be in this study. You must be willing to sign a consent form, and to provide some additional personal information, and to follow the directions of the investigators.

You will not be able to participate in this research if you are related by blood or marriage to employees of Golden Pacific Laboratories, Eurofins | Grayson or a cleaning product manufacturer; if you are pregnant or breast-feeding; if you've had allergic reactions to soap, rubbing alcohol, or other cleaning products; if you have sores on your skin; if you are taking medicines that might react with the test product; or if you have heart or breathing problems.

Eighteen to 24 people will be in this study. We will sign up a few more people than we need, in case anyone can't participate on the day of the test.

We'll do the study in a vacant building (or in unoccupied rooms of non-vacant buildings) here in Fresno County. You can be in the study only once, but if you are the alternate on one day and are not selected, you may be able to be in the study on another day.

Study Enrollment
Before the day of the study you will be required to come to the offices of Golden Pacific Laboratories at 4720 W. Jennifer Ave., Suite 105, in Fresno. This visit will take about an hour. You'll meet with the Principal Investigator, Dr. Selim, or if you prefer, with a researcher who speaks Spanish. They will tell you more about what to expect during the study and what will be expected of you. They will also answer any questions you have about the study.

We'll ask you about your work and about your general health. We'll ask for your name and age, and about your experience using spray products for cleaning or pest control. If we decide you are eligible, and if you decide you want to be in the study, we will ask you to sign this Informed Consent Form. We will then measure your height and weight, and we will ask you for your clothing sizes.

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Initials: _____
Date: _____

If we enroll you in the study we will ask you to come to the study site on a certain day and time. We will call you the day before to remind you and to make sure you still want to be in the study. We'll also ask you to be sure to take a shower or a bath before coming to the study site.

Study Procedures

We will do the testing at a vacant building (or unoccupied rooms in non-vacant buildings) in Fresno County, and it will take 3 or 4 hours on one day. After you arrive you will change into special clothing for the test and get fitted with two small pumps to sample the air you breathe. Then we'll ask you to spray walls, counters, and fixtures until the surfaces are visibly wet in bathrooms or kitchens. You will use the aerosol for hard surfaces as you normally would with horizontal spraying moving upward and downward from the starting point to hard surfaces such as laminate, tile, porcelain, glass, and metal. You will be asked to use one to four cans for spraying in multiple rooms, taking breaks if you need to in between the rooms. This may involve up to 30 minutes of actual spraying time. After that you'll give the special clothing back to us, change back into your own clothes, get paid, and go your way.

Here's exactly what will happen.

1. On the day of the study you will go to the study location at the time you've been told, and meet the research team.

2. Because it's important that you NOT be in this study if you are pregnant, on the day of the test each female volunteer will go to a private area and will be given a pregnancy test kit like the ones you can buy at the drug store. A female researcher will be able to explain how to use it and answer questions. After you give yourself the test we'll ask you if you want to stay in the study. If you decide not to, you won't be asked why, and the results of the test will not be recorded. You'll be paid $100 for coming to the test site, and then you'll be free to go. If you want to stay in the study, a trained female researcher will double-check the results with you. No-one but you and she will see the results, but we will make a note that the test was performed.

3. Dr. Selim and the research team will review with you and the other participants what will happen, and you'll have another chance to ask questions. We will remind you that you may change your mind about being in the study at any time before or after the study begins. All you need to do is tell us you've changed your mind. There will be no penalty of any kind to you if you decide to withdraw from the study.

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Date: _____

4. Someone of your own sex will show you to a clean, private changing area and help you get ready for the study. We will ask you to take off your street clothes down to your underwear. Then you will put on cotton long underwear (long johns), a long sleeved cotton shirt, and long cotton pants. We will provide all these clothes to you. We may need to trim the arms or legs of the long underwear so it doesn't stick out. You'll put your street clothes and valuables in a locked storage area, and keep the key with you.

5. We'll give you safety glasses to wear while you are using the spray.

6. Before the test begins you will wash your hands and face with Ivory soap and water, and dry them with paper towels. We will check your hands to make sure you don't have cuts, scrapes, or any conditions that might increase the risk of skin problems during testing.

7. We will attach two small air sampling pumps to a belt around your waist. If you don't have a belt, we will provide one for you to use. We will attach a small tube to your shirt collar and connect it to one of the pumps. We will attach a small air sampler to the other pump and position it in front of you with a small strap around your neck. Both of these pumps will sample the air you breathe while you are using the aerosol. Each pump is about the size of a portable radio. The tube is about the size of a pen, and the air sampler is about the size of a tennis ball.

8. We will give you a can of Clorox Disinfecting Spray. The label on the can says it can be sprayed on hard surfaces in bathrooms and kitchens. The label on the can says to spray the surface until thoroughly wet. We will tell you that if the bathroom or kitchen you are cleaning has a fan, you may turn it on during cleaning if that is what you would normally do. We will ask if you have any questions.

9. We will take you to a bathroom or kitchen area where you will begin your work, and show you the other areas to work in after you finish that room. We will turn on your air pumps and ask you to put on your safety glasses. We will ask you to enter the bathroom or kitchen, shake the spray can for about 10 seconds, and begin spraying surfaces as you normally do on your job. One of us will watch you as you work, keeping track of how long you work and how much surface you spray. We may also take pictures or video to show what happened in the study, but those pictures will not show faces or tattoos in the final report. **If you still do not want to have your picture taken, you should not participate in this study.**

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Date: _____

10. We will ask you to apply at least one can of spray, and maybe as many as 4 cans. You will work in as many rooms as it takes to use up the assigned number of cans. We will sometimes ask you to stop between rooms and place your spray can on a scale so we can weigh it to see how much has been used. When you empty one can you'll be given a fresh one. You can also ask for a fresh can at any time. You may take a short break at any time you want, just like you would do at work. You won't be able to smoke or eat during the test, but you can have a cold drink during the break. If you need to use the toilet, one of the researchers will rinse your hands before you go to collect any spray that may be on them.

11. When you finish spraying, a researcher of your own sex will take you back to the changing area and collect samples:

    a. The researcher will remove the air sampling pumps and equipment;.

    b. The researcher will rinse your hands with rubbing alcohol and water and save the rinse water;

    c. The researcher will wipe your face and neck with a damp pad to collect any of the spray that might be on your skin;

    d. The researcher will help you remove your shoes and socks;

    e. The research will help you take off your outer shirt and pants and will save them for analysis;

    f. The researcher will help you take off the long underwear, and will save it for analysis.

    When we've collected all these samples, you will dress again in your street clothes. We'll check your hands before you leave for redness or other signs of irritation. We will pay you $100 in cash and you will be free to go.

Risks

If you are in this study you would be exposed to several kinds of risks:

1. Risk of a reaction to the aerosol spray. Direct contact with the product can cause temporary eye redness, pain and swelling or skin irritation, and breathing it can cause coughing and irritate your throat. You will wear safety glasses to keep the spray out of your eyes, and long sleeves and pants to keep it off your skin. You might also have an allergic reaction to

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the spray, or it might interact with medicines you are taking. If you have had a reaction to a cleaning product before, or if you are taking medicine, be sure to tell us. If you notice any redness or itching, or if you think you may have gotten some of the spray in your eye, stop spraying right away and tell a researcher.

2. Risk of discomfort. The air pumps on your belt and the air hoses used to sample the air you breathe may be uncomfortable. Wearing two layers of clothing may also be uncomfortable.

3. Risk of stinging from alcohol wash and wipes. The diluted rubbing alcohol used to rinse your hands and wipe your face and neck may sting, if you have any cuts or abrasions on your hands or face.
4. Risk from heat. Because you'll be wearing an extra layer of clothing you might get too hot. We will monitor the temperature and humidity during the test, and will stop the study if it gets too hot to be safe. If you feel faint or too hot, or are sweating a lot, stop spraying right away and tell a member of the research team.

5. Risk of embarrassment. You may find it embarrassing to have a researcher with you while you change clothes. This is necessary to make sure the special underwear fits properly, and that it and the outer clothing don't get dirty when the test is over. The researcher who helps you will be of your own sex, and will be the only other person with you. You will wear your own underwear all the time.

6. If you are female, you might be surprised to learn on the day of the research that you are pregnant. No-one but you will know if the test shows that you're pregnant, and the results will not be recorded.

Unknown/Unforeseeable Risks
Participating in this study may pose other risks to you that we don't know about or can't predict. If we learn anything new that might influence your decision to participate, we'll share it with you right away.

Research-Related Injuries
If you are hurt while you are in this study, a nearby medical facility that knows about this study will provide care. If necessary, we will take you there. We will pay for needed medical treatment that is not paid for by your own insurance or by someone else. To find out more, or if you think you may have been hurt during the study, call Dr. Selim at Golden Pacific Laboratories (559 275-9091) from 9 am to 5 pm Monday through Friday.

You do not waive any of your legal rights by signing this form.

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Independent IRB
Signature 7/21/09 Date

Initials: _____
Date: _____

Alternatives to Participation
If you decide to be in this study it will be because you want to. There will be no direct benefit to you if you do decide to participate, and no harm to you if you decide not to. The choice is up to you.

Benefits
You will not benefit directly from being in this study. What we learn from this study will help make sure that cleaning products like Clorox Disinfecting Spray can be used safely. This may indirectly benefit you and others who do janitorial work. You may also benefit if you ask for your own results from this study, so you can learn how much spray got on you compared to other workers doing the same job. The people who are paying for the study will also benefit from it, since they need to do this study to keep their cleaning products on the market.

Questions about this Study
If you have questions, you can ask them at any time—before, during, or after the study. Just ask Dr. Selim or any other member of the research team.

If you have any questions regarding your rights as a research participant, please contact Kim Lerner, Chair of the Independent Investigational Review Board, Inc. at toll free 1- (877) 888-iirb (4472). You can reach her from 6am-2pm Pacific Time, Monday-Friday. 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 for the purpose of protecting the rights of participants in a research study. 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.

Costs and Payment
It will cost you nothing to participate in this study. At the end of the informed consent interview you will be paid $20 in cash for your time and trouble coming to our office. If you are selected for the study and come to the assigned study site, you will be paid $100 in cash when you are finished for the day, whether or not you are actually tested.

Confidentiality
We will give you a special ID number for this study, and we will record and report all data under that number. We will keep only one record linking your name to this ID number, and we will store it apart from other data, in a locked cabinet. We will not identify you by name or in any other way in study reports. Any pictures of you in a report of this study will not show your face.

APPROVED BY
Independent IRB
Signature 7/21/09 Date

Initials: _____
Date: _____

We will restrict access to records of this study to only a few people. But the people who are paying for it, the government agencies who will review the reports, and the IIRB, Inc., that looks out for your safety may all review study records. Because of this we can't completely guarantee confidentiality.

Right to Withdraw
You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team. If you decide not to participate in this study or to withdraw from it, you will not be penalized in any way or lose any benefits.

Removal from Study
Dr. Selim, the Principal Investigator in charge of this study, can remove you from this study even if you'd like to stay in it. He might remove you if, for example:

- He thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped because it gets too hot to continue safely, or for other reasons.

If you are removed from the study, or if the entire study is stopped, you will still be paid for your time and trouble.

Consent and Signature
I have read this Informed Consent Form and all my questions have been answered in a language I understand well. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this form. I'll get my own copy of this form with all signatures.

Date/Time: _____ _____
Subject's Signature

_____
Subject's Name (Print)

[*For Spanish language version of the IC document only, but in English*]
This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

APPROVED BY
Independent IRB
Signature 7/21/09 Date

Initials: _____
Date: _____

Date/Time: _____ _____
Spanish Speaking Researcher's Signature

_____
Spanish Speaker's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____
Sami Selim, Ph.D.
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

Independent Investigational Review Board, Inc.
Approved: 7/21/09

Version: 7/21/09
Protocol: 070270b

APPROVED BY
Independent IRB
Signature 7/21/09 Date

Initials: _____
Date: _____

FORMULARIO DE CONSENTIMIENTO INFORMADO

Título: (Protocolo № 070270b) Un Estudio para la Medición de Exposición Potencial Dérmica e Inhalación, durante la Aplicación de un Producto Líquido Pesticida Anti-microbiano mediante el Uso de una Lata Atomizadora de Aerosol Presurizado, para la Desinfección de las Superficies de Interiores

Investigador Principal:

Sami Selim, PhD
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Coordinadores de Campo:

Joel Panara (inglés)
Coordinador de Campo
Eurofins | Grayson
211 N. Main Street
Creedmoore, NC 27522
Teléfono: 919-528-5500

Victoria Standart (inglés y español)
Directora Adjunta de Investigaciones de Campo
Eurofins | Grayson
211 N. Main Street
Creedmoore, NC 27522
Teléfono: 919-528-5510

Noé Galván, PhD (inglés y español)
Director Adjunto de Investigaciones de Campo
Científico en Seguridad de Productos
PS&RC, Global Stewardship
Clorox Services Co.
7200 Johnson Drive
Pleasanton, CA 94588
Teléfono: 925-425-6708

Lugares de Campo:

(Lugar de la Entrevista al Sujeto para el Consentimiento Informado)
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722
(Ubicación del Sitio del Estudio)
Tres (3) sitios en el Condado de Fresno, CA

Patrocinador:

Antimicrobial Exposure Assessment Task Force II (AEATF II).

Número Telefónico las 24 Horas:

559-824-1535 (Sami Selim)

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Le estamos pidiendo que piense acerca de estar en un estudio de investigación científica porque usted tiene experiencia en el trabajo de limpiezas. Su participación es voluntaria. Este Formulario de Consentimiento Informado explica el estudio.

Usted puede llevarse a su casa una copia de este formulario, para pensarlo y debatirlo con amigos o familiares, antes de decidir si desea estar en el estudio. Si tiene cualquier pregunta(s), o si no entiende algo que contenga este formulario, por favor pídanos a uno de nosotros que se lo explique. Si usted prefiere hablar español, por favor pídalo. Nosotros podemos explicarle el estudio a usted en inglés o en español. También tenemos a disposición un investigador que habla español, quien lo puede ayudar a usted a entender la investigación científica.

El Propósito de este Estudio

Golden Pacific Laboratories está llevando a cabo esta investigación científica para averiguar cuánto spray pueda llegar a su piel cuando usted usa un producto de limpieza en una lata presurizada de aerosol. Nosotros mediremos qué cantidad del spray se mete sobre las ropas que usted usa durante el estudio y sobre sus manos, cara y cuello mientras que usted limpia superficies de interiores, tal como cuartos de baño y cocinas. También mediremos cuánta cantidad del spray hay en el aire que usted respira durante el estudio. Un propósito importante de este estudio es recopilar información que se le proporcionará a la Agencia Estadounidense de Protección Medioambiental o EPA. La EPA usará esta información para evaluar los niveles de exposición al producto de aerosol en spray, en este estudio y otros productos en spray que son similares a él.

El spray en este estudio será Clorox Commercial Solutions® Clorox® Disinfecting Spray. Este es un producto comercial de limpieza que se usa para limpiar superficies duras tal como azulejos de cuartos de baño y artefactos sanitarios y gabinetes de cocina y mostradores. Este producto se usa en oficinas y en edificios tal como hospitales, escuelas y hoteles. Contiene substancias químicas llamadas sales de amoníaco cuaternario, las cuales matan gérmenes.

Un grupo de compañías que fabrican productos de limpieza que matan gérmenes, está pagando por este estudio. A ellos se les llama Antimicrobial Exposure Assessment Task Force II. Estos productos matan a los gérmenes que están sobre las superficies interiores, y se encuentran registrados por la Agencia Estadounidense de Protección Medioambiental (la EPA), a manera de pesticidas.

Sami Selim, PhD, de Golden Pacific Laboratories es el Investigador Principal a cargo del estudio. Victoria Standart de Eurofins | Grayson es la asistente principal de habla hispana.

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Firma
21/julio/09
Fecha

El Producto a Prueba
El material que se está probando en este estudio es Clorox Disinfecting Spray. Este es un producto de limpieza comercial que se usa para desinfectar y desodorizar las superficies duras que no sean porosas, tal como los cuartos de baño (paredes, duchas, inodoros, etc.), cocinas (gabinetes, grifos, etc.). Se recomienda este producto para el uso en oficinas y en edificios comerciales e institucionales, tal como hospitales, escuelas y hoteles. Clorox Disinfecting Spray contiene substancias químicas que se conocen como sales cuaternarias de amoníaco, las cuales matan a los gérmenes. Le darán una copia de la etiqueta del producto y si usted lo solicita, le proporcionarán la Hoja de Datos de Seguridad de Materiales o «MSDS» para este producto.

La Selección de los Sujetos
Para estar en este estudio, usted debe ser una persona sana, hombre o mujer, mayor de 18 años de edad y usted debe poder leer y hablar inglés ó español. Usted va a tener que comprobar su edad con una identificación con foto emitida por el gobierno – una licencia de conducir ó una identificación emitida por el estado. Usted debe tener experiencia en el trabajo de limpieza y debe desear estar en este estudio. Usted debe estar dispuesto a firmar un formulario de consentimiento y a proporcionar alguna información personal adicional y seguir las instrucciones de los investigadores.

Usted no podrá participar en esta investigación científica si usted está relacionado, por sangre o por casamiento, con empleados de Golden Pacific Laboratories, Eurofins | Grayson o un fabricante de productos de limpieza; si usted está embarazada o amamantando [dando el pecho]; si usted ha tenido reacciones alérgicas al jabón, al alcohol de frotar, o a otros productos de limpieza; si usted tiene llagas en la piel; si usted está tomando medicamentos que puedan reaccionar con el producto a prueba; o si usted tiene problemas del corazón o respiratorios.

De dieciocho (18) a veinticuatro (24) personas estarán en este estudio. Inscribiremos a unas pocas personas más de las que necesitemos, en el caso de que alguien no pueda participar en el día de la prueba.

Nosotros llevaremos a cabo el estudio en un edificio vacío (o en salas desocupadas de edificios que no estén vacíos) aquí en el Condado de Fresno. Usted puede estar en el estudio solamente una vez, pero si usted es el alterno en un día y no es seleccionado, usted pudiera estar en el estudio otro día.

La Inscripción en el Estudio
Antes del día del estudio, le requerirán que venga a las oficinas de Golden Pacific Laboratories en 4720 W. Jennifer Ave., Suite 105, en Fresno. Esta visita llevará alrededor de una hora. Usted se reunirá con el Investigador Principal, el Dr. Selim, o si usted lo prefiere, con un investigador que hable español. Ellos le contarán más, a usted, acerca de qué esperar durante el estudio y qué se esperará de usted. Ellos también responderán a cualquier pregunta(s) que usted tenga acerca del estudio.

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Independent IRB
Firma
21/julio/09
Fecha

Nosotros le preguntaremos a usted acerca de su trabajo y acerca de su salud general. Le preguntaremos su nombre y edad y acerca de su experiencia en el uso de productos en spray para limpiar o para el control de plagas. Si decidiésemos que usted es elegible y si usted decide que quiere estar en el estudio, nosotros le pediremos que firme el Formulario de Consentimiento Informado. Nosotros luego le mediremos su estatura y peso y le preguntaremos sus tamaños [tallas] de ropas.

Si nosotros lo inscribimos a usted en el estudio, le pediremos que venga al lugar del estudio, en cierto día y a cierta hora.

Lo llamaremos el día anterior para recordarle y para cerciorarnos de que usted aún quiera estar en el estudio. También le pediremos que no se olvide de darse una ducha o un baño antes de venir al sitio del estudio.

Los Procedimientos del Estudio

Nosotros haremos las pruebas en un edificio vacío (o en salas desocupadas de edificios que no estén vacíos) en el Condado de Fresno y llevará 3 ó 4 horas en un día. Después de que usted llegue, usted se cambiará de ropa, se pondrá una ropa especial para la prueba y le pondrán dos bombas pequeñas para hacer el muestreo del aire que respira usted. Luego, le pediremos que pase el spray en paredes, mostradores y artefactos, hasta que las superficies estén visiblemente húmedas en baños y cocinas. Usted usará el aerosol para las superficies duras, como usted lo haría normalmente, pulverizando con el spray moviéndose hacia arriba y hacia abajo, desde el punto en el que empiece, a superficies duras tal como laminados, azulejos, porcelana, vidrio y metal. Le pedirán que use de 1 a 2 latas para pulverizar en varias salas, tomándose descansos si los necesita, entre las salas. Esto pudiera llevarle hasta unos 30 minutos de tiempo de pulverización real. Después de eso, usted nos devolverá las ropas especiales a nosotros, se volverá a poner sus propias ropas, le pagarán y podrá irse.

A continuación se muestra lo que sucederá exactamente:

1. En el día del estudio, usted irá al lugar del estudio a la hora que le hayan dicho y se reunirá con el equipo de investigaciones.

2. Debido a que es importante que usted NO esté en este estudio si está embarazada, en el día de la prueba cada voluntaria irá a un área privada y le darán un equipo para hacerse la prueba de embarazo, como los que usted puede comprar en la farmacia. Una investigadora podrá explicarle a usted cómo usarlo y responderá a sus preguntas. Después de que usted se haga la prueba, nosotros le preguntaremos si quiere quedarse en el estudio. Si usted decidió no quedarse, no le preguntarán el porqué y los resultados de la prueba de embarazo no serán registrados. Le pagarán $100 [cien dólares] por venir al sitio de la prueba y luego tendrá la libertad de poderse ir. Si desea quedarse en el estudio, una investigadora

APROBADO POR
Independent IRB
Firma
21/julio/09
Fecha

capacitada volverá a verificar los resultados junto a usted. Nadie, excepto usted y ella, verá los resultados, pero nosotros haremos una nota de que la prueba se hizo.

3. El Dr. Selim y el equipo de investigaciones científicas revisarán junto a usted y a los otros participantes, qué es lo que sucederá, y usted tendrá otra oportunidad de hacer preguntas. Nosotros le haremos recordar que usted puede cambiar de parecer acerca de estar en el estudio, en cualquier momento, antes o después de que empiece el estudio. Todo lo que usted tiene que hacer es decirnos que usted ha cambiado de parecer. No habrá multa de ninguna clase, para usted, si es que usted decide retirarse del estudio.

4. Alguien del mismo sexo que usted, lo llevará a usted a un área limpia, privada, para cambiarse y lo ayudará a prepararse para el estudio. Nosotros le pediremos a usted que se quite las ropas de calle, hasta quedarse en ropa interior. Luego usted se pondrá ropa interior larga (calzoncillos largos) de algodón, una camisa de algodón de manga larga y pantalones largos de algodón. Todas estas ropas se las proporcionaremos a usted. Nosotros pudiéramos necesitar recortar las mangas o el largo de los pantalones de la ropa interior larga, de modo que no sobresalga nada hacia afuera. Usted pondrá sus ropas de calle y sus objetos de valor en un área de almacenamiento bajo llave y guardará la llave con usted.

5. Le daremos gafas [anteojos] de seguridad para que los use mientras que esté usando el spray.

6. Antes de que empiece la prueba, usted se lavará las manos y la cara con jabón Ivory y agua, y se las secará con toallas de papel. Nosotros le examinaremos las manos para cerciorarnos de que usted no tenga tajos, raspaduras, ni cualquier afección que pueda incrementar el riesgo de problemas en la piel durante las pruebas.

7. Nosotros le adjuntaremos dos bombas pequeñas de muestreo de aire, en un cinturón alrededor de su cintura. Si usted no tiene un cinturón, nosotros le proporcionaremos uno para que lo use. Le adjuntaremos un tubo pequeño en el cuello de su camisa y se conectará a una de las bombas. Le adjuntaremos un pequeño dispositivo para el muestreo de aire, a la otra bomba y lo colocaremos frente a usted con una pequeña correa alrededor de su cuello. Ambas bombas harán un muestreo del aire que usted respira mientras que esté usando el aerosol. Cada bomba es más o menos del tamaño de un receptor portátil de radio. El tubo es más o menos del tamaño de una pluma de escribir y el dispositivo que muestrea el aire, es más o menos del tamaño de una pelota de tenis [*tennis*].

8. Le daremos una lata de Clorox Disinfecting Spray. La etiqueta de la lata dice que puede pulverizarse sobre superficies duras en cuartos de baño y en cocinas. La etiqueta de la lata dice que pulverice las superficies hasta que estén bien húmedas.

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Independent IRB
Firma
21/julio/09
Fecha

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Nosotros le diremos que si el baño o la cocina que usted esté limpiando tienen un ventilador, usted puede prenderlo durante que esté limpiando si eso es lo que usted haría normalmente. Nosotros le preguntaremos si tiene cualquier pregunta.

9. Nosotros lo llevaremos a usted a un baño o cocina, donde usted empezará su trabajo y le mostraremos otras áreas para que trabaje, después de que usted termine esa sala. Nosotros encenderemos sus bombas de aire y le pediremos que se ponga sus gafas [anteojos] de seguridad. Nosotros le pediremos que entre al baño o cocina, que sacuda la lata de spray durante unos 10 segundos y que empiece a pulverizar superficies de la manera en la cual usted lo hace normalmente en su trabajo. Uno de nosotros lo observará a usted mientras que usted esté trabajando, registrando cuánto tiempo trabaja usted y cuántas superficies pulveriza usted. Nosotros también pudiéramos sacar fotos o grabar un vídeo, para mostrar lo que sucedió en el estudio, pero esas fotos no mostrarán caras ni tatuajes en el informe final. **Si usted aún no quiere que le saquen fotos, usted no debería participar en este estudio.**

10. Le pediremos que aplique por lo menos una lata de spray y quizá tantas como 4 latas. Usted trabajará en tantas salas, según se necesite, para gastar el número de latas que le hayan asignado. A veces, nosotros le pediremos que pare entre salas y que ponga su lata de spray en una balanza, de modo que nosotros podamos pesarla para ver cuánto se ha usado. Cuando usted vacíe una lata, le darán una nueva. Usted también puede pedir que le den una lata nueva en cualquier momento. Usted puede tomarse un descanso [*break*] breve en cualquier momento que lo desee, de la misma manera en que usted lo haría en su trabajo. No podrá fumar ni comer durante la prueba pero usted puede tomar una bebida fría durante el descanso. Si usted necesitase usar el cuarto de baño, uno de los investigadores le enjuagará las manos a usted, antes de que usted vaya al cuarto de baño, para recoger cualquier spray que pueda haber en ellas.

11. Cuando usted termine de pasar el spray, un investigador de su mismo sexo lo llevará a usted de vuelta al área para cambiarse y para recoger muestras:

    a. El investigador quitará las bombas del muestreo de aire y equipo;

    b. El investigador le enjuagará las manos a usted con alcohol de frotar y agua y guardará el agua del enjuague;

    c. El investigador le limpiará la cara y el cuello a usted, con una almohadilla humedecida, para recoger cualquier líquido pulverizado [*spray*] que pueda haber en su piel;

    d. El investigador lo ayudará a usted a quitarse su camisa y calcetines;

APROBADO POR
Independent IRB
Firma
21/julio/09
Fecha

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e. El investigador lo ayudará a usted a quitarse su camisa de uso exterior y los pantalones, y los guardará para analizarlos;

f. El investigador lo ayudará a usted a quitarse la ropa interior larga y la guardará para ser analizada;

Cuando hayamos juntado todas estas muestras, usted volverá a vestirse en sus ropas de calle. Nosotros le revisaremos sus manos antes de que usted se vaya, para ver si hay enrojecimiento u otras señales de irritación. Le pagaremos $100 [cien dólares] en efectivo y se podrá ir libremente.

Riesgos

Si usted está en este estudio, usted estará expuesto a varias clases de riesgos:

1. Riesgo de una reacción al spray en aerosol. El contacto directo con el producto puede causar enrojecimiento temporal en sus ojos, puede causar dolor e hinchazón o irritación en la piel y el respirarlo puede causarle tos e irritarle la garganta. Usted usará gafas [anteojos] de seguridad para evitar que el spray entre en contacto con sus ojos, y mangas y pantalones largos para mantenerlo alejado de su piel. Usted también podría tener una reacción alérgica al spray, o éste podría interactuar con medicamentos que usted esté tomando. Si usted ha tenido una reacción a un producto de limpieza anteriormente, o si usted está tomando algún medicamento, asegúrese de decirnos eso a nosotros. Si usted notase cualquier enrojecimiento o picazón, o si usted piensa que pudo habérsele metido algo del spray en sus ojos, deje de pasar el spray enseguida y dígaselo a un investigador.

2. Riesgo de molestia. Las bombas de aire en su cinturón y las mangueras de aire que se usan para hacer el muestreo del aire que respira usted, pueden ser incómodas. El hecho de usar dos capas de ropas también pudiera ser incómodo.

3. El riesgo de escozor proveniente del lavado con alcohol y de los trapos. El alcohol de frotar diluido que se usa para enjuagar sus manos y para frotarse la cara y cuello, pudiera causar escozor, si usted tiene algún tajo(s) o abrasiones en sus manos o cara.

4. Riesgo del calor. Debido a que usted estará usando una capa extra de ropa, usted pudiera sentir demasiado calor. Nosotros monitorearemos la temperatura y humedad durante la prueba y detendremos el estudio si se pone muy caliente como para que sea seguro. Si usted sintiese como que se va a desmayar o con mucho calor, o si está sudando mucho, deje de pulverizar enseguida y dígaselo un miembro del equipo de investigaciones científicas.

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Independent IRB
Firma
21/julio/09
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5. Riesgo de vergüenza [turbación]. Usted pudiera sentirse avergonzado de que un investigador esté con usted mientras que usted se cambia de ropas. Esto es necesario para cerciorarse de que la ropa interior especial le quede bien y que tanto esa ropa como las ropas exteriores no se ensucien cuando la prueba haya terminado. El investigador que lo ayude a usted será de su propio sexo y será la única persona que va a estar con usted. Usted usará su propia ropa interior todo el tiempo.

6. Si usted es mujer, usted podría sorprenderse al enterarse, en el día de la investigación científica, que usted está embarazada. Nadie, sino usted, sabrá si la prueba muestra que usted está embarazada y los resultados no se registrarán.

Riesgos Desconocidos/Imprevisibles
El participar en este estudio pudiera causar otros riesgos para usted, que nosotros no conozcamos o que no podamos predecir. Si aprendiésemos cualquier cosa nueva que pueda influir a su decisión para participar, nosotros la compartiremos con usted enseguida.

Lesiones Relacionadas con la Investigación Científica
Si usted se lastimase mientras que está en este estudio, una instalación médica cercana que sabe acerca de este estudio, proporcionará atención médica. Si fuese necesario, nosotros lo llevaremos hasta allí. Nosotros pagaremos por el tratamiento médico que se necesite, que no lo pague su propio seguro u otro. Para averiguar más, o si usted piensa que puede haberse lastimado durante el estudio, llame al Dr. Selim en Golden Pacific Laboratories (559 275-9091) desde las 9 a.m. a las 5 p.m., de lunes a viernes.

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

Alternativas a la Participación
Si usted decide estar en este estudio, será porque usted lo desea. No habrá beneficio directo para usted si usted decide participar, y ningún daño para usted si usted decide no participar. La opción queda librada a usted.

Beneficios
Usted no se beneficiará directamente por estar en este estudio. Lo que nosotros aprendamos de este estudio ayudará a cerciorarse de que productos de limpieza como el Clorox Disinfecting Spray puedan usarse de manera segura. Esto pudiera beneficiarlo a usted indirectamente y a otros quienes hagan trabajos de limpieza. Usted también pudiera beneficiarse si usted pide sus propios resultados, provenientes de este estudio, de modo que usted pueda aprender cuánto spray recibió usted, comparado con el de otros trabajadores que estén haciendo el mismo trabajo que usted. Las personas quienes están pagando por el estudio también se beneficiarán de

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Independent IRB
Firma
21/julio/09
Fecha

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Fecha: _____

él, dado que ellos necesitan hacer este estudio para mantener sus productos de limpieza en el mercado.

Preguntas acerca de este Estudio
Si usted tiene preguntas, puede hacerlas en cualquier momento – antes, durante o después del estudio. Simplemente pregúntele al Dr. Selim o a cualquier otro miembro del equipo de investigaciones científicas.

Si usted tiene cualquier pregunta(s) concerniente a sus derechos en calidad de participante de una investigación científica, por favor póngase en contacto con la señora Kim Lerner, Presidenta del Independent Investigational Review Board, Inc., llamando al teléfono gratuito 1-(877) 888-IIRB (4472). Usted puede ponerse en contacto con ella desde las 6 a.m. – 2 p.m. Hora del Pacífico, de lunes a viernes. 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 un estudio 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.

Costos y Pago
No le costará nada a usted por participar en este estudio. Al final de la entrevista del consentimiento informado, le pagarán $20,00 [veinte dólares] en efectivo, por su tiempo y molestia por venir a nuestra oficina. Si usted fuese seleccionado para el estudio y viene al sitio del estudio asignado, a usted le pagarán $100 [cien dólares] en efectivo cuando usted haya terminado el día, ya sea que usted haya hecho la prueba o no.

Confidencialidad
Le daremos un número de identificación especial para este estudio y registraremos y reportaremos todos los datos bajo ese número. Nosotros guardaremos solamente un registro que vincula a su nombre con este número de identificación y lo almacenaremos aparte de otros datos, en un gabinete cerrado bajo llave. No lo identificaremos a usted por nombre ni de ninguna otra manera, en informes del estudio. Cualquier foto que le hayan sacado a usted y que esté en un informe de este estudio, no mostrará su cara.

Nosotros restringiremos al acceso a los expedientes de estudio, a solamente unas pocas personas. Pero las personas quienes están pagando por él, las agencias del gobierno que revisarán los informes y el IIRB, Inc. que cuida su seguridad, todos pueden revisar expedientes del estudio. Debido a esto, nosotros no podemos garantizar completamente confidencialidad.

APROBADO POR
Independent IRB
Firma
21/julio/09
Fecha

El Derecho a Retirarse
Usted tiene la libertad de retirarse de este estudio en cualquier momento, por cualquier razón. Simplemente dígaselo a cualquier miembro del equipo de la investigación científica. Si usted desea no participar en el estudio o retirarse de él, usted no será penalizado de ningún modo ni perderá ningún beneficio(s).

La Remoción del Estudio
El Dr. Selim, el Investigador Principal a cargo de este estudio, puede removerlo a usted de este estudio aún si usted quisiera quedarse en él. Él podría quitarlo a usted si, por ejemplo:

- Él piensa que el quedarse en el estudio podría ponerlo a usted en peligro,
- Usted fracasa en seguir las instrucciones de los investigadores,
- El estudio fuese detenido porque hace mucho calor para continuar con seguridad, o por otras razones.

Si a usted lo quitasen del estudio, o si el estudio entero fuese detenido, a usted aún le pagarán por su tiempo y molestia.

APROBADO POR
Independent IRB
Firma
21/julio/09
Fecha

Consentimiento y Firma

Yo he leído este Formulario de Consentimiento Informado y todas mis preguntas han sido contestadas en un idioma que entiendo bien. Yo consiento voluntariamente a formar parte de este estudio en calidad de sujeto de una investigación científica. Yo no renuncio a ningún derecho(s) legal por firmar este formulario. Yo recibiré mi propia copia de este formulario con todas las firmas.

Fecha/Hora: _____ _____

Firma del Sujeto

_____

Nombre del Sujeto (en Letra de Molde o de Imprenta)

[*Para la versión en español del documento de Consentimiento Informado solamente, pero en inglés*]

This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____

Spanish Speaking Researcher's Signature

_____

Spanish Speaking Researcher's Name (Print)

Yo he revisado este Formulario de Consentimiento Informado con el voluntario mencionado anteriormente y he contestado todas sus preguntas. He hecho todo el esfuerzo para cerciorarme de que el voluntario entienda el propósito, los riesgos y beneficios de la investigación científica, qué sucederá en el día de la prueba y la libertad de él/ella de retirarse en cualquier momento y por cualquier razón. He hecho esto en circunstancias que minimizan la posibilidad de coerción o de influencia indebida y, yo creo que el voluntario(a) ha tomado una opción informada y libre para participar.

Fecha/Hora: _____ _____

Sami Selim, PhD
Investigador Principal/Golden Pacific Laboratories, LLC

Copia del formulario de consentimiento dado al sujeto: (FECHA)_____POR (INICIALES)___

Independent Investigational Review Board, Inc.
Aprobado: 21/julio/09

APROBADO POR
Independent IRB
Firma
21/julio/09
Fecha

Iniciales: _____
Fecha: _____

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

July 27, 2009

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 No. 070270b) A Study For Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using a Pressurized Aerosol Can for Indoor Surface Disinfecting
(Protocol: 070270b) (7/21/09) (Sami Selim, PhD) (AEATF II)

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 № 070270b) Un Estudio para la Medición de Exposición Potencial Dérmica e Inhalación, durante la Aplicación de un Producto Líquido Pesticida Anti-microbiano mediante el Uso de una Lata Atomizadora de Aerosol Presurizado, para la Desinfección de las Superficies de Interiores
(Protocolo: 070270b) (21/julio/09) (Sami Selim, PhD) (AEATF II)

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.

Part 12 Transmittal (Boatwright, 8/4/09, 5:50 PM) of Request for Minutes and Roster, Dated August 04, 2009 ***(roster.09-0601.epa.doc and 070270b.minutes7.21.09.docx)***

Shah PhD., Hasmukh C.

From: Megan Boatwright [mboatwright@gplabs.com]
Sent: Tuesday, August 04, 2009 5:50 PM
To: Shah PhD., Hasmukh C.
Subject: FW: Request for Minutes and Rooster
Attachments: roster.09-0601.epa.doc; 070270b.minutes7.21.09.docx

Has,

Please find attached the roster and the minutes.

Megan

From: Robert Roogow [mailto:RRoogow@iirb.com]
Sent: Tuesday, August 04, 2009 2:02 PM
To: Megan Boatwright
Subject: FW: Request for Minutes and Rooster

Minutes and Roster

Robert Roogow, MS, CIM
Chief Operating Officer
Independent Investigational Review Board, Inc.
Ph: 954-327-0778
Fax: 954-327-5778
rroogow@iirb.com

sender that you have received the message in error and then delete it. Thank you.

From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Tuesday, August 04, 2009 10:54 AM
To: Robert Roogow
Subject: RE: Request for Minutes and Rooster

Thank you Robert for your timely response. Can you please resend me the IRB polices and Roster, I think you sent them originally to Sami and I don't have access to them?

Thank you again,

Megan

From: Robert Roogow [mailto:RRoogow@iirb.com]
Sent: Tuesday, August 04, 2009 7:07 AM

To: Megan Boatwright
Subject: RE: Request for Minutes and Rooster

I will get them to you by the end of the day. There have been no changes to the IRB policies or Roster since I sent you earlier this month. I will prepare the redacted minutes for you today. Let me know if there is anything else you are going to need.

Regards,
Robert

Robert Roogow, MS, CIM
Chief Operating Officer
Independent Investigational Review Board, Inc.
Ph: 954-327-0778
Fax: 954-327-5778
rroogow@iirb.com

From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Monday, August 03, 2009 6:35 PM
To: Robert Roogow
Subject: Request for Minutes and Rooster

Dear Robert,

Can you please send me a copy of the meeting minutes and rooster for the meeting on July 21, 2009 were the aerosol study 070270b was approved for our records?

Thank you,
Megan

Megan T. Boatwright
Golden Pacific Laboratories, LLC
559-275-9091

Tuesday, July 21, 2009
MINUTES

ATTENDANCE:

PRESENT
Shari Somerstein, RPh
Edward Wiederhorn
Julie Blasingim alternate for George Garbarino
Marcos Rejtman, DO
Rabbi Akiva Mann
Kim Lerner
Frances Conway, RN

GUEST
Katy Kysela, Director of Research, IRB Liaison

ALSO PRESENT
David Wells, MD
Glenn Moran, MD

NOT PRESENT
George Garbarino

I. CALL TO ORDER

The meeting was called to order at 10:15 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 7/14/2009 MINUTES (The order of the Minutes does not reflect the order in which they were reviewed.)

The minutes of the meeting held 7/14/2009 were reviewed and unanimously approved as reviewed.

III. REVIEW PROTOCOLS

III a. STUDY INITIAL APPROVALS

J (Protocol 070270b) A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using a Pressurized Aerosol Can for Indoor Surface Disinfecting
Principal Investigator: Sami Selim, Ph.D.
Approval Clinical Research;

- Informed Consent Form version 7/21/2009
- California Experimental Subject's Bill of Rights
- Research Protocol dated 7/14/2009
- Site Questionnaire
- Advertisements
- Aerosol Application Scenario: Rationale for Study Design dated 7/13/2009

Motion was made, seconded and the Committee approved the Investigator(s), Informed Consent Form, California Experimental Subject's Bill of Rights, Research Protocol, and Print Ads for the above noted research study. The Site Questionnaire and Aerosol Application Scenario: Rationale for Study Design were reviewed and accepted.

Risk
The following comments were made by the board:

- The IRB determined that risks to subjects are minimized through appropriate inclusion/exclusion criteria, the test substance being used in the study is approved by the EPA, subjects will be required to wear protective safety goggles, use of a double layer of long sleeve shirt and pants (includes dosimetry clothing), subject experience in use of janitorial products together with use of test substance at concentrations approved by the EPA, limitation of actual

product spraying time, use of regular work breaks and available water and sports drinks to reduce overheating and fatigue and use of a temperature controlled environment for study conduct, use of experienced same-sex researchers when subjects must change in and out of study clothes (subjects will not change out of their underwear), use of rubbing alcohol which has low toxicity and subjects will have their hands checked for abrasions, cuts and scrapes prior to application of the rubbing alcohol and female subjects undergoing the pregnancy test do not have to show the test results to the experienced female researcher if they do not want to and can leave the study, unless it is negative and they want to participate in the study, use of the air handlers is considered equivalent to carrying around 2 MP3 players.

- The IRB determined that there is no clinical benefit to subject, however society may benefit in the future by increasing product safety use.

The IRB reviewed the description of risks and benefits in the submitted documentation and determined that the information in the submitted documentation justified the determination that the risks are minimized and that the risks are justified in relations to the anticipated benefits.

Subject Selection
The following comments were made by the board:

- The IRB noted that subjects will be enrolled who are experienced in janitorial/cleaning work and the study will be measuring worker exposure to Clorox Disinfecting Spray while cleaning.

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 in the protocol and the submitted Informed Consent Form and determined that documentation of consent is appropriate.

Data Safety Monitoring
The IRB reviewed the description of the data safety monitoring plan in the protocol and determined that the information in the protocol and submitted documentation justified the determination that the plan is appropriate.

Privacy & Confidentiality
The IRB reviewed the description of provisions for privacy and confidentiality in the submitted documentation and determined that the information in the protocol justified the determination that the provisions are appropriate.

Vulnerable Populations
The IRB determined that no vulnerable populations are anticipated in this research.

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 7/21/2009 and stamped, “Approved 7/21/2009”. The Informed Consent Form contains all regulatory required consent elements. The California Experimental Subject’s Bill of Rights is approved. The approved California Experimental Subject’s Bill of Rights is stamped “Approved 7/21/2009”.

The following advertisements were approved and stamped “Approved” 7/21/2009:
- Print Ad version “Professional Janitors Wanted” - as revised; (Necessary revisions have been incorporated and are included in the submitted advertisement information.)
- Print Ad version “Research Study Volunteers” - as revised; (Necessary revisions have been incorporated and are included in the submitted advertisement information.)

Based on the nature 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

INDEPENDENT INVESTIGATIONAL REVIEW BOARD INC.
The IRB of Choice When the Choice is Yours

IRB MEMBERSHIP ROSTER

- The following lists the 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.

- No member of the Independent Investigational Review Board, Inc has employment or other relationship (for example, full-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant) of any study sponsor, or otherwise involved with the research.

PRIMARY MEMBERS

Kim Lerner, BS, CHAIR (Non-Scientific) *Affiliated* *Member since 1989*	Ms. Lerner is co-founder of the Independent Investigational Review Board, Inc.. Ms. Lerner provides extensive knowledge of regulatory compliance and the research industry. She has incorporated her extensive knowledge of continuous quality improvement into all aspects of the IIRB, Inc.
Frances Conway, RN, VICE CHAIR (Scientific) *Affiliated* *Member since 2008*	Ms. Conway is a registered nurse with knowledge of regulatory requirements as related to IRB compliance with FDA, DHHS, and EPA regulations.
Marcos Rejtman, DO (Scientific) *Unaffiliated* *Member since 2005*	Dr. Rejtman is Board Certified in Family Practice, Geriatric Medicine and Hospice & Palliative Care. Through his experience, Dr. Rejtman is able to evaluate protocols from a scientific perspective with a focus on risks/benefit analysis.
Rabbi Akiva D. Mann, MA (Non-Scientific) *Unaffiliated* *Member since 1997*	Rabbi Mann is the Director of The Institute of Jewish Knowledge and Learning and provides moral and ethical perspectives to the review process.
Edward Wiederhorn (Non-Scientific) *Unaffiliated* *Member since 1995*	Mr. Wiederhorn is a community representative to the IIRB, Inc. He is a member of the American Association of Retired Persons (AARP) and has been involved with Fraternal and Charitable Organizations.
Shari Somerstein, RPh (Scientific) *Unaffiliated* *Member since 1999*	Ms. Somerstein has extensive experience in clinical pharmacology and the drug development process through analysis of clinical and non-clinical data, with a focus on human research protection.
George J. Garbarino (Non-Scientific) *Unaffiliated* *Member since 2004*	Mr. Garbarino has been an advocate for Labor Union members and brings a wide range of experience in the area of workers' rights.

ALTERNATE MEMBERS

Alternate Members serve as a voting member, when filling the role of an absent voting member. Alternate Non-Scientific Members can serve as an alternate voting member for Kim Lerner, but cannot serve as a Chair of the IRB. Alternate Scientific Members can serve as a voting alternate member for Frances Conway, but cannot serve as a Vice Chair of the IRB.

Julie A. Blasingim, BA, MBA (Non-Scientific) *Affiliated* *Member since 2009*	Ms. Blasingim comes to the IRB with extensive knowledge of human research protection issues and regulatory compliance. She presents ongoing educational programs and regulatory updates to the IRB members and IIRB staff.
Ernest Bertha, MD, MBA *(Scientific) *Unaffiliated* *Member since 2009*	Dr. Bertha is a Board Certified Pediatrician specializing in emergency medicine, bringing with him a background of pediatric acute care medicine.
David D. Wells, MD (Scientific) *Unaffiliated* *Member since 1996*	Dr. Wells has served as an Emergency Medicine Department Chairman. He has worked with different ethnic populations, especially migrant workers and brings his sensitivity of the social mores of the underprivileged to the IRB.
Glenn K. Moran, MD, FACOFP (Scientific) *Unaffiliated* *Member since 2004*	Dr. Moran is Board Certified in Family Practice. Through his present practice, he is able to contribute up to date information related to the current medical world. In addition, Dr, Moran is a Professor of Osteopathic Medicine at a local university.

Robert Lettman, Esq (Non-Scientific) *Affiliated Member since 2004*	Mr. Lettman is a practicing Attorney providing legal understanding with regard to the rights of research participants.
Levi G. Williams, Esq (Non-Scientific) *Unaffiliated Member since 2007*	Levi Williams is a practicing Attorney with a focus on cultural diversity, including multi-racial and juvenile rights.

CHANGES FROM PREVIOUS ROSTER (Version: 1/6/09)

Removal of Anita McSharry, RN as Vice Chair, addition of Frances Conway, RN as Vice Chair, addition of Julie Blasingim, BA, MBA as alternate IRB Member, addition of Ernest Bertha, MD, MBA as alternate IRB Member as well as other minor clarifications.