Antimicrobial Exposure Assessment Task Force II (AEATF II)

VOLUME 1

Primary Documentation:

Mopping Application Scenario and Study Protocol

February 25, 2008

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Part 1 Transmittal Letter

February 25, 2008

John Carley
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Dear Mr. Carley:

The American Chemistry Council Biocides Panel Antimicrobial Exposure Assessment Task Force II (AEATF) is pleased to provide the documents for EPA's review and submission to the Human Studies Review Board for discussion at the April 9-10, 2008 meeting as the following numbered volumes:

1) *Antimicrobial Exposure Assessment Task Force II (AEATF II) VOLUME 1: Primary Documentation – Mopping Application Scenario and Study Protocol, February 25, 2008;*
2) *Antimicrobial Exposure Assessment Task Force II (AEATF II) VOLUME 2: Secondary Documentation – Mopping Application Scenario and Study Protocol, February 25, 2008;*
3) *Antimicrobial Exposure Assessment Task Force II (AEATF II) VOLUME 3: Primary Documentation – Wiping Application Scenarios and Study Protocol, February 25, 2008;*
4) *Antimicrobial Exposure Assessment Task Force II (AEATF II) VOLUME 4: Secondary Documentation – Wiping Application Scenarios and Study Protocol, February 25, 2008;*
5) *Antimicrobial Exposure Assessment Task Force II (AEATF II) VOLUME 5: Governing Document for a Multi-Year Antimicrobial Chemical Exposure Monitoring Program – Interim Draft Document, February 8, 2008; and*
6) *Antimicrobial Exposure Assessment Task Force II (AEATF II) VOLUME 6: Standard Operating Procedures for a Multi-Year Antimicrobial Chemical Exposure Monitoring Program, February 25, 2008.*

Please note that all of the Standard Operating Procedures (SOPs) in Volume 6 are final, signed versions. Further, a list of the complete "library" of AEATF II SOPs is provided in this volume. Please let me know if any of the SOPs in this list, which have not been provided in support of these submitted protocols, are of particular interest to EPA or the HSRB, and I will provide them to you expeditiously.

AEATF greatly appreciates the review that EPA and the HSRB had given to its previously submitted draft protocols and related documents. In these revised versions of the AEATF mopping and wiping application protocols, AEATF has attempted to address all general and specific comments resulting from meetings of the HSRB, the EPA's Scientific Advisory Panel (SAP), the EPA Office of Pesticide Programs (OPP), California EPA's Department of Pesticide Regulation (DPR) and Health Canada's Pest Management Regulatory Agency. Finally, as the AEATF will be conducting the mopping and wiping studies in Fresno County, CA, it has submitted the Independent Investigational Review Board (IIRB)-approved protocols to the California EPA (Department of Pesticide Regulation and Office of Environmental Health Hazard Assessment) for its review and approval. I will send you the California EPA comments soon after I have received them.

Please free to call me at 703-741-5637, if you need any clarification or additional information.

Sincerely,

Hasmukh Shah

Hasmukh Shah
Manager, AEATF

cc: William Jordan, EPA, OPP
Timothy Leighton, EPA, OPP

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Part 2 40 CFR 26.1125 Checklist

40 CFR 26.1125 Prior submission of proposed human research for EPA review

AEATF-II Mop Scenario/Protocol AEA02/070265: Feb 25, 2008

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

	Requirement	Y/N	Comments/Page Refs
All information relevant to the proposed research specified by § 26.1115(a)	(1) Copies of • all research proposals reviewed by the IRB, • scientific evaluations, if any, that accompanied the proposals reviewed by the IRB, • approved sample consent documents, • progress reports submitted by investigators, and reports of injuries to subjects.	Y n/a Y n/a	V1:8-166; V2:7-166; 191-325 V1:172-192
	(2) Minutes of IRB meetings . . . in sufficient detail to show • attendance at the meetings; • actions taken by the IRB; • the vote on these actions including the number of members voting for, against, and abstaining; • the basis for requiring changes in or disapproving research; • a written summary of the discussion of controverted issues and their resolution.	Y	V2:331-332
	(3) Records of continuing review activities.	n/a	
	(4) Copies of all correspondence between the IRB and the investigators.	Y	V2:5-332
	(5) • A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; • any employment or other relationship between each member and the institution, for example, full-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.	Y Y	V2:333-335 V2:333-335
	(6) Written procedures for the IRB in the same detail as described in §26.1108(a) and §26.1108(b).	Y	Separately submitted to EPA under confidentiality claim
	(7) Statements of significant new findings provided to subjects, as required by §26.1116(b)(5).	n/a	
The following Information, to the extent not already included:	§1125(a) a discussion of: (1) The potential risks to human subjects	Y	V1:43-45
	§1125(a) a discussion of: (2) The measures proposed to minimize risks to the human subjects;	Y	V1:43-45
	§1125(a) a discussion of: (3) The nature and magnitude of all expected benefits of such research, and to whom they would accrue	Y	Nature V1:45-46. No discussion of magnitude of benefits
	§1125(a) a discussion of: (4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and	Y	V1:42
	§1125(a) a discussion of: (5) The balance of risks and benefits of the proposed research.	Y	V1:46
	§1125(b): All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.	Y	Original V2:64-74; 248-258 Approved V1:172-192
	§1125(c): Information about how subjects will be recruited, including any advertisements proposed to be used.	Y	V1:55-59; 106; 109-110
	§1125(d): A description of the circumstances and methods proposed for presenting information to potential human subjects for the purpose of obtaining their informed consent.	Y	V1:56-57
	§1125(e): All correspondence between the IRB and the investigators or sponsors.	Y	V2:5-332
	§1125(f): Official notification to the sponsor or investigator . . . that research involving human subjects has been reviewed and approved by an IRB.	Y	V1:168-169

Part 3 Mopping Application Scenario: Rationale for Study Design

Antimicrobial Exposure Assessment Task Force II (AEATF II)

MOPPING APPLICATION SCENARIO: RATIONALE FOR STUDY DESIGN

January 14, 2008

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MOPPING APPLICATION SCENARIO: RATIONALE FOR STUDY DESIGN

1. Introduction

This document summarizes the rationale for critical elements of the design of the AEATF II mopping application monitoring study. Mopping application represents an exposure scenario being addressed as part of the overall AEATF II monitoring program.

2. Scenario Definition

A scenario is defined as a set of related tasks, pesticide formulations, equipment, engineering controls, and worker and/or consumer practices. For the purposes of the AEATF II Monitoring Program, the **mopping application scenario** is defined as the mop-based application of a label-specified end-use formulation containing an antimicrobial chemical. This includes the tasks of mopping and dirty mop bucket solution emptying. It is common in institutional settings today that automated dispensing systems provide the applicator with ready-to-use mop solutions, and the applicator does not mix and load the end-use mop solution in a bucket. Therefore, the applicator's exposure during a single workday in these conditions would arise only from the task of application and intermittent disposing or emptying the dirty mop bucket solution. The distribution of daily exposures under the "mopping" scenario would then adequately describe the handler's daily exposure to the antimicrobial.

In some circumstances, however, a mop applicator could also be manually mixing and loading the mop solution, i.e., preparing the end-use dilution by adding a concentrate to water in a bucket. In these cases, the daily exposure for an antimicrobial handler would arise from two discrete tasks, i.e., mopping (including dirty mop solution disposal) and mixing/loading of mop solution. These mixing and loading tasks are not included as part of the AEATF II mopping application scenario. (To provide data for regulatory agencies to address the possible addition of this task the AEATF II will conduct separate studies of mixing and loading via open pouring of liquids.)

The AEATF II study restricts the mopping application scenario to professional applicators only. This focus on professional applicators is a practical necessity, given that consumer handlers are involved in much shorter task durations where very low exposures are anticipated (see section 5.2 below). 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 mop applicator exposure is expected to be greater, on the

average, than that of consumers. Further, the mop technology typically used by professionals, i.e., string mop and bucket systems (source: Johnson Diversey), are expected to have higher exposure potential than those often used by consumers, e.g., sponge mops, ready-to-use mops. This higher exposure assumption has been discussed with regulatory agencies (e.g., U.S. EPA, California EPA) and is considered likely given the nature of applicator handling with string and bucket mop systems, i.e., string mops have greater surface area than ready-to-use mop heads, increasing the opportunity for dermal contact. In addition, application using string mops involves a "figure 8" motion that creates greater potential for inadvertent dermal contact compared to the "back and forth" motion used with ready to use mop systems. Further, dermal exposure levels from other ready-to-use products (e.g., hand-held pressurized aerosols) have typically been observed to be lower than those associated 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 mopping 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, <u>when normalized for the amount of active ingredient handled</u>, are not greater than those for professional applicators.

3. Existing Mopping Application Exposure Data

Since 1992 the EPA has conducted professional and consumer mixer/loader and applicator exposure and risk assessments relying primarily on the exposure data in 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 (Pesticides Handlers Exposure Database, User's Guide Version 1.1, Health Canada, U.S. Environmental Protection Agency, American Crop Protection Association, February 1995). However, PHED does not include any data directly relevant to mopping application methods.

In addition to PHED, another source of existing data being used by regulatory agencies in the case of antimicrobials is that represented by an exposure monitoring program (Popendorf et al. 1992) conducted by the Chemical Manufacturers Association (CMA). On 4 March 1987, a Data Call-In Notice was issued for submission of data for antimicrobial pesticide active ingredients. In response, the CMA developed a generic biocide exposure assessment protocol and conducted a study, *Chemical Manufacturers Association Antimicrobial Exposure Assessment Study* (conducted by Dr. William Popendorf at the University of Iowa; Popendorf et al. 1992) based on the protocol. The CMA effort

originally considered a list of 10 pesticide active ingredients. This list was reduced to nine, considering several criteria. Exposures to seven of these nine chemicals were assessed, as well as exposure to zinc chloride, which was used as a surrogate tracer for a process and chemical which could not otherwise be assessed. In total, 88 separate monitoring events (MEs) were obtained for nine different application methods (pour liquid, pump, pour solid, place solid, aerosol spray, high pressure spray, low pressure spray, mop and wipe) to assess both dermal and inhalation exposures.

The CMA study measured aerosol (pressurized canisters), mopping, and wiping application exposure for the active ingredients for the active ingredients ortho phenyl phenol (OPP) and ortho benzyl p-chlorophenol (OBPCP). The CMA study represents the only existing data in the case of the mopping scenario.

Mopping application in the CMA study was observed in a hospital setting, in a university building used for classes, and in an office building. All applicators were professional janitorial staff, but the method did not vary from setting to setting. The product was mixed with water in a portable mop bucket that the applicator moved while mopping. Exposure potential was observed to be low with this type of application, but mopping technique appeared to be a significant variable across applicators. Some subjects in the CMA study splashed product onto their legs or touched their lower legs with the mop while putting it into or taking it out of the bucket, some allowed their bucket to touch dermal dosimeters as they lifted and moved it, some contacted the handle or rim of the bucket with the string-mop head and then grasped that area with their hands when moving the bucket. Mopping application duration ranged from 21 to 66 minutes.

Based on EPA's review (Mostaghimi 1995), CMA's study data met some regulatory agency requirements, but was lacking in other areas. Specific areas in which the study complied with the procedures specified by the EPA's dermal and inhalation exposure guidelines included the following:

1) Most of the dermal samples had detection limits low enough to allow accurate reporting of the sample, according to EPA guidelines.
2) Some of the field recovery data were acceptable; five chemicals had acceptable recoveries from gloves, and two chemicals had acceptable recoveries from air, and the results were corrected for losses in the field using correction factors determined from the recovery data.
3) The materials used in the analyses were acceptable in most cases and were adequate for further analysis. To assess dermal exposure, gauze pads were used for dry residues, cotton gloves were used for assessing exposure to hands, and placement of dermal pads was found to be acceptable. For inhalation exposure, standard flow rates were used for air impingers and personal sampling pumps, standard NIOSH factors were

applied to respirators to estimate reduction of exposure inside the respirators; and

4) Documentation of data collected during laboratory and field operations was adequate based on both CMA's description of their data gathering efforts and presentation of data provided in Appendix C of CMA's Amended Report. In addition, replicate-specific notes were provided for any unusual problems that may have contributed to error.

However, the following areas of the CMA study were found to be lacking:

1) Good laboratory practices, especially in the area of providing quality assurance, should be followed more closely;

2) A majority of extraction efficiencies were below the minimum level suggested in the guidelines. Perhaps more importantly, the percent field recoveries (which represent the amount recovered after actual conditions encountered in the study) of many of the chemicals were lower than the minimum needed to assess exposure. Therefore, either new active ingredients would need to be used in future studies, or methods to increase recoveries should be employed.

3) Calibration of the air equipment resulted in most of the 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. The limited number of replicates combined with poor recovery data severely limits the conclusions that can be made from CMA's study. Therefore, the EPA and other regulatory agency reviews indicated that additional data for all application method/use setting combinations should be obtained to make more solid conclusions about exposures in a variety of settings.

Limitations identified by EPA in the CMA's study data were also corroborated by other reviewers. First, the California Environmental Protection Agency (CA EPA) notes 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 (Powell et al., 1995). Canada also reviewed the study and made similar conclusions (Worgan and Rozario, 1993). In summary, in order to assess potential risks from exposure to antimicrobials, EPA has extremely limited data on which to rely. In fact, EPA has repeatedly identified those data as inadequate.

In each of the following 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."

- PHMB. September 2005. EPA739-R-05-003
- Benzisothiazoline-3-one. September 2005. EPA739-R-05-007
- Para-Tertiary-Amylphenol, Potassium Sodium Salt. January 2005. EPA738-R-05-001
- Azadioxabicyclooctane. September 2005. EPA739-R-05-010
- Chlorine Dioxide and Sodium Chlorite. August 2006. EPA738-R-06-007
- Pine Oil. October 2, 2006. (publication number unavailable)
- Aliphatic Alkyl Quaternaries (DDAC). August 2006. EPA739-R-06-008
- Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC). August 2006. EPA7389-R-06-009

The above list is not exhaustive but is intended to point out that the Agency has clearly and repeatedly required additional exposure data for assessing risks from occupational and residential uses of antimicrobial pesticides.

4. Goal of the AEATF II Mopping Application Monitoring Study

The AEATF II program, as described in the Governing Document (2007), 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 mopping application scenario is an important component of the AEATF II program and the focus of this protocol. As noted in the previous section, existing monitoring data for this scenario are inadequate.

The primary purpose of the mopping 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 constructed to broadly represent those expected for the future application of arbitrary antimicrobial pesticides. AEATF II anticipates the resulting database will contain sufficient data to support exposure assessments for mopping application.

For the mopping application scenario (as is true for all AEATF II scenarios) only a small number of expensive experimentally-obtained monitoring events (MEs) are possible. Each ME represents the exposure possible for a single future handler-day. Although it is only a single task, mopping application still encompasses

more handling conditions than any small number of MEs can practically include in a single study. For example, there are many possible active ingredients (ai), multiple amounts of active ingredient used, multiple concentrations of active ingredient used, different volumes of product used, different workers and their associated behaviors, and multiple environmental and other handling conditions. All of these are expected to affect exposure to varying degrees.

In view of this limitation, a practical goal for this study is that the small sample of mopping application MEs be biased towards increased diversity of handling conditions. As a result, the diverse sample of MEs is expected to at least cover the middle portion of the future exposure distribution, cover the upper portion of the future exposure distribution, and capture the range of exposure variation that is expected to exist. The successful use of a small sample of MEs to represent the diversity in the target population of future 'mopping-days' is aided by the following:

1. Dermal and inhalation exposure to the chemicals are considered generic (i.e., independent of the particular active ingredient used). This *generic principle* permits use of a small set of surrogate active ingredients to predict exposure from other active ingredients;
2. The *principle of proportionality* of exposure to the true amount of active ingredient contact. If a diverse amount of active ingredient handled (AaiH) is used across MEs, then exposures measured for one level of AaiH can be used to predict different levels of AaiH; and
3. *Expert knowledge* of possible handler conditions expected throughout the scenario permits re-construction (and/or selection) of synthetic MEs that represent a diverse set of future mopping application conditions.

5. Purposive Diversity Selection of Monitoring Events

A diversity selection approach is being used by the AEATF II to implement the mopping application study. In the AEATF II approach, instances of possible handler-day conditions under the scenario are synthetically constructed and handler-day exposures measured using surrogate workers. These conditions (including workers) are either purposively or randomly chosen in such a manner that the synthetic handler-days (i.e., monitoring events, or "MEs") span the diversity of conditions in the scenario. The ME construction 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; and
3. Using different workers for each ME rather than repeated use of the same worker.

Diversifying these three 'meta-characteristics' indirectly varies many known and unknown handling-conditions. Purposively varying other minor handling-conditions, such as mopping surface, can further reduce homogeneity of MEs within the same site.

The AEATF II has determined, in consultation with the U.S. EPA, Health Canada, and California EPA, that a purposive diversity selection (PDS) approach is appropriate considering the regulatory purpose of the data and feasibility. A PDS approach is one that is primarily purposive but can be coupled with random choice elements when feasible to reduce intentional selection bias. The AEATF II Governing Document (2007) describes diversity and purposive diversity selection more generally in the context of the AEATF II Monitoring Program.

5.1. Varying 'Sites' and 'Clusters'

The mopping application monitoring study will be conducted inside 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 1,000,000 persons. Consequently, there is a substantial janitorial population and a large number of vacant commercial buildings that are potentially acceptable for monitoring activities.

The use of a single geographic area is based on the premise that indoor janitorial mopping 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 mopping inside of buildings throughout Fresno County, CA would not be expected to differ substantially if we used another metropolitan area or spanned multiple cities over the country. 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 most 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 mopping 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 mop 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., Johnson Diversey; www.johnsondiversey.com; Johnson Diversey 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 geographical locations 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 outlines above, there would appear to be little benefit from such an increase in cost.

Monitoring will always be conducted within vacant commercial buildings. The purpose in conducting these studies in vacant buildings is to be free from personal interferences with non-subjects and the potential contamination from other sources of a commonly-used active ingredient (DDAC). It also allows the focus to be on mopping only as opposed to the broad range of janitorial activities a subject might engage in that could also involve the active ingredient. Using vacant buildings also offers more potential variability in study timing, architectural, and surface composition differences.

Each combination of facility (building or building complex) and monitoring period (i.e. dates) is termed a 'site'. Diversity is induced by requiring that monitoring events occur at multiple sites over the Fresno metropolitan area. 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 reduces 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. However, there are practical efficiencies to be gained by conducting multiple MEs at the same site. Consequently the mopping 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, hallways, dining areas, stairs.

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. As discussed in section 6 below, a total of three sites are required for the mopping scenario. Each site will be used for a single cluster of mopping application MEs. The set of different sites should posses the following general characteristics:

1. Each site must be a different building (or a group of adjacent buildings). The buildings in different sites should be of different types. For example, an office building would be a different type than a church.
2. Monitoring activities for different sites should be schedule at least one week apart.
3. For purposes of the mopping application study, the buildings or facilities must be large enough and have indoor rooms/areas that provide relevant and adequate surface areas for mopping.

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

- The property is listed and vacant
- The property is within Fresno County, California
- The building falls into one of three categories:
    a. Office buildings
    b. Retail space
    c. Meeting facilities (e.g. school, church, dance hall)

These three building categories provide diversity in architecture and floor plan. The properties within each of these three categories will be investigated independently and in random order until a single acceptable facility is found for each category. Facility acceptance criteria will include:

- Available for rental for only a short duration (e.g. one month) rather than only on a long-term (e.g. year) basis.
- Functional HVAC sytem

- Operating electrical service
- Minimal surface area requirement with acceptable diversity in available surfaces (e.g., unobstructed hallways, bathrooms, stairs, empty rooms)
- Property does not require cleaning or maintenance prior to use

This procedure results in a random sample of one facility from the population of all acceptable facilities (of each type) in Fresno County, California. Monitoring activities are then scheduled purposively for each facility, but no closer than a week apart.

5.2. Varying Task Duration

The second key diversity meta-parameter controlled by PDS for the mop study is task duration. Because all MEs in the study use a single AI at the same concentration, task duration is a surrogate for the amount of a.i. handled. This, in turn, is a surrogate for the potential amount of a.i. contacted.

Task duration was selected given its likely relationship to the magnitude of exposure (dermal and inhalation routes) and availability of existing data that inform typical ranges of time duration for mopping tasks. Two key data sources were identified in this regard:

1. *Time and motion data (cleaning task durations) collected by the International Sanitary Supply Association (ISSA; www.issa.com).*

   Table 1 presents estimated cleaning times for health care industry cleaning professionals performing mopping operations (83 minutes/day). This estimated mopping time is supported by the upper-bound time observed in previous monitoring conducted by the Chemical Manufacturer's Association (CMA) (Popendorf et al. 1992) at 21-66 minutes.

2. *AEJV national consumer product use survey (Jacobs et al. 2006)*

   Mopping duration information is provided, in the case of consumer applicators, by a proprietary national product use survey conducted by the Antimicrobial Exposure Joint Venture. The AEJV survey represents results from a national-scale prospective diary instrument. Eligible and willing participants (from a "phase 1" screener who provided an EPA registration number for at least one antimicrobial product used at least once a month) were mailed a dairy and asked to record their antimicrobial home care product application over a 4-week recording period. Information collected included the date of usage occasions, product used, product type, application site, surface area/item cleaned, whether product was diluted, whether surface was rinsed off/wiped down, who applied the product, and who was present during application. The completed survey

return rate was 27%, a value typical for a 4-week diary fielded via the TNS Consumer Mail Access Panel (http://www.tns-us.com/panels/).

The AEJV survey results indicate that mopping tasks, using either ready-to-use or other products (i.e., involving bucket dilutables and equipment such as string and bucket mopping systems), ranged from 5 minutes or less to an upper-bound of 60 minutes. The average cleaning event duration involving all purpose cleaner bucket dilutables (which may involve the use of mop equipment) and ready-to-use mop systems was 10.0 and 12.6 minutes, respectively.

For the AEATF II mop study, practical lower and upper limits to monitoring durations are dictated by two opposing factors. On one end is the analytical method LOQ, and the desire to obtain actual measurements (rather than non-detects) beneath normal work clothing. Based on information gained from methods development and knowledge of exposure measured by Popendorf (1992), the lower limit of exposure monitoring duration consistent with detectability is estimated to be 30 minutes.

At the other extreme is the maximum duration dictated by human endurance and the estimated maximum time a person typically spends mopping. Both of these factors point toward a maximum duration of approximately 90 minutes of near-continuous activity. This appears to be a reasonable value with respect to ergonomic considerations, i.e., human endurance, based upon personal observation.

Consequently, the diversity of duration of study participant mopping activities will range from approximately 30 to 90 minutes. This represents the range of estimated time spent mopping floors per day by cleaning professionals in the health care or hotel industries and consumers. This duration is estimated to achieve detectable levels of active ingredients on dosimetry matrices.

Task duration will be varied among the N_M MEs in each cluster. This is accomplished by partitioning the 30-90 minute range into N_M intervals of equal size. Each of the N_M task-duration intervals will be $D = 60/N_M$ minutes in length. Each ME will be randomly assigned to a different task duration interval. The task duration will only be controlled to within D minutes. (However, the exact task duration will be recorded.) This task duration stratification process will be repeated independently for each cluster of MEs.

Table 1: Justification for Duration of Task and Area Treated Estimated Cleaning Times for Healthcare- Mop/Wipe Operations[1]

ISSA Operation Number	***ISSA Operation***	***Cleaning Time***
117	Trash/Clean Disinfect Surfaces and Bath/Replace Supplies/Wet Mop Floor	16.2
	Wiping Operations	
69	Bathroom Shower Fixtures Damp Wipe	0.67
70	Bathroom Shower Stall, Damp Wipe	1.5
71	Bathroom Soap Dispenser, Damp Wipe	0.17
72	Bathroom Call Switch, Damp Wipe	0.05
75	Bed Frame, Damp Wipe	2.8
76	Bed Footboard, Damp Wipe Sprayer	0.25
80	Bedside Commode, Clean	0.5
81	Bedside Stand, Damp Wipe	0.92
93	Grab Rail, Damp Wipe	0.1
109	Sinks, Scrub, Damp Wipe	0.67
111	Table, Over Bed: Damp Woe [sic] (Wipe?)	0.75
102	Light, Over Bed: Damp Wipe	0.13
	Total Wiping	8.51 min
	Mopping Operations	
259	12 min/1000 ft^2 (24 oz head) *Room Size* *(12 ft X 20 ft= 240ft^2) - Main Room, 2 bed*[2] *(6 ft x 6 ft= 36 ft^2)- bathroom* *Total- 276 ft^2* *Mopping Time Calculation* *(12 min/1000 ft^2)(276 ft^2)= 3.31 minutes*	3.31 minutes
Total Time in Room Mopping/Wiping		11.82

Calculations	
Total minutes per workday	8 hours (60 minutes)= 480 minutes
Rooms Cleaned per day	(480 minutes)/(16.2 minutes/room)= 29.6 or 30 rooms/day. 20-25 rooms per day is the likely maximum based on typical work patterns (breaks, trips to the cleaning closet for fresh chemicals, etc.)
Total minutes spent wiping	25(8.51 minutes)= 212.75 minutes/day
Total minutes spent mopping	25(3.31)= 82.75 minutes/day

Note that the estimated time to clean a room does not include changing linens, making or disposing of mop solutions/wipes, transit time between rooms, etc. so resulting estimates are quite conservative.

[1] Times obtained from ISSA; the International Sanitary Supply Association (ISSA; www.issa.com) is a trade association of more than 4,700 member companies from over 83 countries that manufacture, market and distribute cleaning and maintenance products, equipment and related services to hospitals and other healthcare facilities, schools, factories, foodservice establishments, corporate complexes, commercial businesses, and a vast array of other industrial and institutional facilities worldwide.

5.3. Varying Surrogate Workers

The final meta-characteristic that is formally varied is the surrogate worker. These are professional workers with experience in performing mop applications, who are available and consent to perform these tasks at/in appropriate facilities on the specified dates. These are referred to as surrogate workers because they are not viewed as any sample from an existing population of workers. Rather they are viewed simply as another component of the synthetic ME that is being constructed to predict a single instance of a future day's exposure to an arbitrary antimicrobial pesticide. Each surrogate worker provides his/her unique set of behaviors to the mopping task. Use of the same worker for all monitoring events would over-represent a single type of behavior. As a result, diversification of worker behavior among MEs is accomplished by simply requiring that each ME be based on a different surrogate worker.

Surrogate workers will all be professional workers in the Fresno CA metropolitan area. Flyers soliciting subjects are posted at all cooperating janitorial service providers in the area. Individuals who express a desire to participate in the study within a fixed period of time will be contacted and screened in random order. Individuals who meet the study requirements will be recruited until the required number of surrogate workers is obtained. Surrogate workers are randomly assigned to MEs. As a precaution, more participants are recruited than expect to be needed.

This process results in a simple random sample of qualifying subjects from the volunteer pool. Note, however, that is not the same as a random sample from the existing population of professional janitorial workers. By definition, volunteers are self-selected and could have different characteristics than non-volunteers. Such distinctions have no relevance in this case, however. There is no particular need to obtain a random sample from the Fresno janitorial population. This existing population is not the target population for the study. The MEs are synthetic constructs that attempt to predict aspects of a future handler-day population. It is purposive by definition. Thus, a random sample of just one ME component (e.g. subject) from a subpopulation (e.g. Fresno County) provides no statistical advantage. In fact, a random sample of subjects from the volunteer pool is not the only possibility. For example, a more diverse sample of surrogate workers from this pool could also be acceptable if a clear diversifying characteristic were available for all workers. Lacking this, the mop application study uses the reasonable default option of a random sample from the volunteer pool.

6. Sample Size Determination

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.

Only in these two situations can statistical theory predict how increasing sample size decreases estimation error. In other experimental situations, sample size must be determined using one of the two 'random' situations above as a reference model. The random reference model is constructed so that it reflects the actual (non-random) situation as closely as possible. 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 random sampling or randomization occurs.

The mop application study constructs synthetic MEs that predict elements of the target population of future daily exposures. The goal is to use these data to characterize some 'population' aspect of the future exposure to arbitrary antimicrobial pesticides. Hence, this study is more closely aligned with the random sampling situation (1) above.

6.1. Reference Sampling Model

For the mop application study, random nested (or cluster) sampling is used as the reference model for the combination of purposive and random diversity selection actually used. This reference model assumes that:

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

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

3. The within cluster (i.e., within-site) correlation of log normalized exposure is equal to ICC.

6.2. Benchmark Objective

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

For the mop application study, the benchmark objective is that sample estimates of the arithmetic mean and 95th percentile of normalized exposure are accurate to within 3-fold 95% of the time. Both the AEATF II and EPA feel 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 handler-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 mopping application task. This study, however, provides just six mop applicator monitoring events spread over three different facilities. These data do provide a crude estimate of total relative variation (GSD), but no reliable estimate of ICC.

An improved estimate of total relative variation can be obtained by incorporating information from other sources. The CMA study also provided data for exposure due to wiping applications (6 MEs) and for hand-held aerosol applications (5 MEs). In addition, PHED provides high quality normalized exposure data for 15 hand-held aerosol monitoring events collected from 15 different residential houses. As is the case for mopping, both wiping and hand-held aerosol application are repetitive tasks. The relative variation in normalized exposure for repetitive activities might be expected to be driven primarily by variation in subject behavior. If so, then these four sets of data might be expected to have similar geometric standard deviations.

The feasibility of using the normalized dermal exposure results from these four data sets (Table 2) together to estimate relative total variation for the mop study was 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 (Glazer 1983)

among groups was applied to the $\log_e$-transformed, normalized dermal exposure values. These results are summarized in Table 3. 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 1.05. The resulting estimate of geometric standard deviation (GSD = exp{SD}) is 2.86 and used in the determination of sample size.

Table 2: Source (Study)-Specific Normalized Dermal Exposure Values for Each Monitoring Event (Unit).

Source (Study)	Monitoring Event ID	Normalized Dermal Exposure (µg / lbs ai handled)
CMA (Mop)[1]	1	20,855
	5	22,186
	7	503,250
	9	16,656
	10	34,394
	11	37,088
CMA (Wipe)[2]	2	4,313,916
	6	1,747,115
	8	1,058,688
	61	49,252
	62	471,758
	73	2,570,922
CMA (Aerosol, Hands)[3]	47	126,263
	79	48,913
	80	666,667
	87	413,043
	90	340,909
PHED (Aerosol, Study 521)[4]	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

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

There are no reliable data on the magnitude of the within-cluster correlation (ICC) in normalized exposure resulting from mopping. 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., hospitals, hotels, residences) 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 high within-site correlation is expected, is 0.3 (AHETF, 2007, Appendix C). This represents a likely upper-bound for most indoor antimicrobial exposure scenarios.

Table 3: Estimates of the Variation in Total Normalized Dermal Exposure from Existing Studies.

Study	N	Standard Deviation of Log_e Normalized Exposure
CMA (Wipe)	6	1.61
CMA (Mop)	6	1.26
CMA (Aerosol-Hands)	5	1.05
PHED (Aerosol, Study 521)	15	0.62
Common Variation Model:[1]		
Common SD of Log_e Exposure		1.05
Common GSD of Exposure[2]		2.86
Common CV of Exposure[3]		1.42

[1]Assuming a separate mean for each study, but a common standard deviation on the log scale.
[2]Geometric standard deviation = exp(SD)
[3]Coefficient of variation derived from the log-scale SD assuming a lognormal distribution

6.4. Determination of Sample Size

A Monte Carlo simulation approach was used to determine 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 each simulation 10,000 random data sets are 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 are

calculated. If θ is the parameter of interest and T is the calculated estimate, then the fold relative accuracy (*fRA*) is defined as:

(1) $$fRA = \text{Max}\ (\ T / \theta,\ \ \theta / T)$$

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 simplicity, the EPA sometimes refers to fRA_{95} as the 'K-factor'.) The simulation methods are the same as those used for the AHETF monitoring program (AHETF, 2007, Appendix C). This simulation method and its theoretical basis is described in greater detail in the AHETF documentation.

For a configuration of N_C=3 clusters (or sites) and N_M=6 MEs per cluster, Table 4 lists the 95% bounds on relative accuracy ('K-factors') obtained with GSD=2.86 and possible intra-cluster correlations (ICC) ranging between 0 and 0.3. We note that the desired relative accuracy bound of 3 is achieved even with an ICC as large as 0.3. Smaller, and more likely, ICCs yield better accuracy. Additional simulations indicate that these conclusions are insensitive to moderate changes in the assumed GSD.

Thus, a design of 3 sites and 6 MEs per site appears acceptable for the mop application study.

Table 4: 95% Bound on Relative Accuracy ("K-Factor") at Specified ICC Values for 3 Clusters (Locations) and 6 Monitoring Events per Cluster.

ICC	95th Percentile of Fold Relative Accuracy for Normalized Dermal Exposure (CV = 1.42, GSD = 2.86)	
	Arithmetic Mean	95th Percentile
0	1.9	2.1
0.1	2.1	2.4
0.2	2.3	2.6
0.3	2.5	3.0

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Part 4 Protocol: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using Bucket and Mop Equipment for Cleaning Indoor Surfaces

PROTOCOL

(Revision Date: 1/16/07)

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 Bucket and Mop Equipment for Cleaning Indoor Surfaces

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 Field Sites in Fresno County, CA

Sponsor Study Identification

AEA03

GPL Study Number

070265

Total Number of Pages: 134

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1.0 GENERAL INFORMATION

Study Title

A Study For Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using Bucket and Mop Equipment for Cleaning Indoor Surfaces

Sponsor Study No: AEA03
GPL Study No: 070265

Objective

This study is being conducted to determine potential dermal and inhalation exposures associated with mopping indoor surfaces with an antimicrobial pesticide product.

Proposed Experimental Start Date: TBA

Proposed Experimental Termination Date: TBA

Proposed Final Report Issue Date: TBA

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) and cooperating contractors.

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 recommendations 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

40CFR 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).

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Field Coordinator:	Tami I. Belcher Grayson Research, LLC 211 N Main Street Creedmoor, NC 27522 Phone: (919) 528-5508 E-mail: tbelcher@graysonresearch.com
Field Location:	3 Field Sites in Fresno County, CA
Reviewing IRB:	Independent Investigational Review Board, Inc. 6738 West Sunrise Blvd. – Suite 102 Plantation, FL 33313 Phone: (877) 888-4472 Website: www.iirb.com

2.0 INTRODUCTION AND STUDY OBJECTIVE

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 customarily 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 monitor exposure to subjects who mop floors with a liquid antimicrobial pesticide product. Each monitored applicator will apply product using a single type of application equipment (e.g., bucket and mop) and will generally involve work periods of 30 to 90 minutes.

All study participants will be adult subjects capable of and experienced in performing the functions described in the protocol. All study 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 number of subjects monitored will be at least 18. Potential dermal and inhalation exposure of each individual study participant will be measured during mopping activities for a time-duration that is representative of the use of professional antimicrobial products as well as while emptying the mopping bucket. The test material, Sani-Care Lemon Quat, an EPA approved product, containing didecyl dimethyl ammonium chloride (DDAC), CAS No. 7173-51-5, and n-alkyl dimethyl benzyl ammonium chloride (ADBAC), CAS No. 68424-85-1 will be applied at a target rate not to exceed the maximum label-recommended rate. All participants will be independently monitored while mopping floors utilizing representative mopping equipment represented by buckets and string mops. The EPA-approved label for the commercially available product to be used in this study is provided in Appendix A. The test material will be used in this study in accordance with the product label.

The study will be conducted in three vacant commercial buildings. Each building will be of a different type and will be used to monitor exposure on different dates. The duration of study participant mopping activities is approximately 30 to 90 minutes. This represents the range of estimated

time spent mopping floors per day by cleaning professionals in the health care or hotel industries and consumers. This duration is estimated to achieve detectable levels of the most abundant active ingredient on dosimetry matrices.

Potential dermal exposure to the test substance while mopping or while emptying the buckets will be measured externally using whole body inner (cotton long underwear) and outer (work clothing) dosimeters, socks, hand washes, and face/neck wipes. All monitored subjects will wear one layer of clothing (normal outer work garments as well as shoes and socks) which will be provided, over inner whole body cotton dosimeters. The outer work garments will be representative of normal work clothing and consist of cotton long pants, cotton long-sleeved shirts, and non-porous shoes. The potential inhalation exposure for each subject will be measured by means of a personal air sampling pump set at a typical sampling rate (2 L/minute) and an OSHA Versatile Sampler (SKC, OVS, XAD2) tube with a glass fiber filter. Hand exposure will be measured by washing the hands with a solution of 50% water/50% isopropyl alcohol. Face exposure will be measured by wiping the face with gauze moistened with 50% water/50% isopropyl alcohol. Following exposure from mopping or from emptying the buckets, the inner and outer dosimeters, the OVS tubes, the hand washes, and face and neck wipes will be analyzed for residues of DDAC. The dosimetry garments as well as shoes and socks will be provided by the AEATF II. Subjects will be given and required to wear any Personal Protection Equipment (PPE) specified by the product label. Sani-Care Lemon Quat is a professional use product, and the product label specifies the PPE requirements as protective eyewear.

3.0 RATIONALE AND OBJECTIVE OF THE STUDY

The need for the data to be generated via the proposed study has been previously considered (AEATF, 2008a). Currently, US EPA relies upon the results of the CMA study conducted more than 15 years ago to characterize exposure from mopping using an antimicrobial (Popendorf et al. 1992). That study has a total of 6 measurements of whole body exposure at levels above the Limit of Quantification (LOQ). 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 2 years. There appears to be no publicly available data with which to make a credible estimate of exposure for persons using a bucket and string mop. Thus, the rationale for conducting this study is to measure dermal and inhalation exposure in a large enough group of typical users to adequately estimate central tendency and variability for this use 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.

Detailed justification for the various components of the study and study design is described in (AEATF, 2008b). The AEATF will be using passive dosimetry methods for measuring dermal and inhalation exposures. A recent summary of available passive dosimetry and biomonitoring studies conducted in the same individuals indicates that the passive dosimetry methods proposed by AEATF II will neither over- nor under-estimate actual dosage (Ross et al., 2007). However, under certain circumstances (see Section 10.2.3), it is possible that there will be some over-estimation bias in the study design proposed in this protocol. Generally, from a regulatory perspective a slight overestimation bias in estimating human exposure is preferable to underestimation.

4.0 RATIONALE FOR USE OF HUMAN SUBJECTS

Human subjects are required in this study because they will normally be exposed to the test material 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. A minimum of 18 MEs are required in order to capture the expected variation in mopping application conditions using the product and application devices. Sufficient data is not available from other studies. The low toxicity of the diluted test material and very low expected exposure of subjects wearing extra dosimetry clothing and clean shoes and socks should mean that there is little incremental risk associated with performing this task, compared to their daily duties.

5.0 OVERSIGHT OF ETHICAL CONDUCT

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

The submission package to the IIRB includes a supplemental document regarding the study design justification for duration of task and area treated (AEATF, 2008), the Informed Consent Form (Appendix B), the Experimental Subject's Bill of Right (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), a copy of the product label

(Appendix A) and 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 J). The documents utilized with subjects (Appendices A, C, D, E, F, G and 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 approval. Recruitment of subjects into the study will not be initiated until all approvals (EPA, HSRB, and California DPR) have been granted.

All protocol changes (amendments and deviations) shall be reported to the IIRB 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 approval. All other amendments must be reviewed and approved by the IIRB prior to implementation, or as specifically instructed by IIRB policy in this regard. Approval will be granted in accordance with IIRB policy and procedures, and may be granted by telephone provided it is documented in writing in the study raw data. The IIRB 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 prior to implementation. Deviations will be reported in writing by letter, fax or email as soon as possible following the change.

The Principal Investigator shall follow written instructions provided by the IIRB for prompt reporting to the IIRB, 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.

6.0 BALANCE OF RISKS AND BENEFITS

6.1 Risks to the Subjects

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

The antimicrobial active ingredients DDAC and ADBAC in Sani-Care Lemon Quat 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 its safety profile, DDAC and ADBAC have been approved for use in many formulations, and are extensively used in many janitorial products. The test material, Sani-Care Lemon Quat 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). Additionally, the safety of the test material has been established through long term professional use of the product. The product will be used according to its label. The Sani-Care Lemon Quat concentrated formulation will be handled only by researchers and the diluted material (1:64) in a ready-to-use form will be provided to the subjects. 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' time of exposure will be limited to 30-90 minutes, and the time involved in performing the described activity will not exceed the maximum normal daily activity. Subjects will be provided regular breaks at 30 minute intervals (or less if they request) 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. The 90 minute work duration will be broken up into 10 minute intervals starting at 30 minutes. Any subject working more than 30 minutes will be given breaks at a minimum of 30 minute intervals; however, this represents a significant cardiovascular workout and there is a small possibility for a cardiovascular accident. There is a small risk from discomfort or inconvenience of wearing the air sampling device. There could also be some risk of embarrassment from disrobing to the subject's underwear in the presence of a same-sex researcher.

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 DDAC and ADBAC quats in this study is very high. The test material 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 same-sex, and experienced. 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 pump is equivalent to that from wearing a portable radio, 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 heat or cardiovascular stress. 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.

6.2 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. 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. 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. Depending on how EPA uses the data, calculated risks could be increased or decreased compared to currently estimated chemical risk. 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. Society may benefit from continued ability to use antimicrobials that improve the quality of life. 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.

6.3 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.

6.4 Community Involvement

Community involvement in the context of scientific research has been recently discussed by the U.S. Environmental Program Agency (http://www.epa.gov/nerl/sots/SEAOES-review-draft.pdf). While the mop 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 mop exposure study. The community of individuals that use a mop to clean/disinfect surfaces is enormous and includes millions of workers and at least 100 million residents in the U.S. alone. Government agencies such as the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP), Health Canada's Pesticide Management Regulatory Agency (PMRA), and the California Department of Pesticide Regulation (DPR), are involved in the review and approval of this study and effectively serve to represent, indirectly, involvement of the broad community of persons that use mopping equipment. The regulatory agency role includes hosting meetings that are open to the public regarding the proposed studies and the study results (e.g., EPA-sponsored meetings involving the Humans Studies Review Board (HSRB); http://www.epa.gov/OSA/hsrb/). Review of the study protocol by an independent investigational review board also represents an opportunity for community involvement in the context that members of the board are likely to also be consumers who are familiar with cleaning procedures and equipment used for mopping.

In contrast, there is a specific group of individuals who could be more directly impacted by the conduct of this study. These are the individuals in the local community that conduct business in the building or office adjacent to the study locations. In the event the proprietor or their customers observe people dressed in laboratory research garments, or just an unusual amount of activity in a nearby location that has been vacant, it may cause concern. Thus, a flyer will be generated and distributed to the proprietors or their employees in businesses 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.

7.0 TEST SUBSTANCE

The test substance for these studies is the formulated product, LEMON QUAT, containing didecyl dimethyl ammonium chloride (DDAC) and n-Alkyl dimethyl benzyl ammonium chlorides (ADBAC). The quaternary ammonium antimicrobials are commonly known as “quats”. DDAC is the active ingredient selected for measurement, based on its stability, abundance in the formulation, and sensitivity of its analytical method.

7.1 Test Substance Identification

Product Name:	SANI-CARE LEMON QUAT	
Manufacturer:	Buckeye International, Inc.	
EPA Registration No.:	47371-131-559	
Lot Number:	to be recorded in the raw data.	
Active Ingredients and CAS Numbers:		
Didecyl dimethyl ammonium chloride		7173-51-5
n-Alkyl dimethyl benzyl ammonium chloride		68424-85-1
Composition:	2.54% DDAC, 1.69% ADBAC	
Appearance:	to be recorded in the raw data	
Formulation Description:	Yellow, lemon scented liquid	

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.

Retained samples from the lot of test substance used in the study will be archived with GPL.

7.2 Justification for Use of Test Substance

LEMON QUAT is an end use product registered with the EPA for use on smooth surfaces in indoor environments. LEMON QUAT contains didecyl dimethyl ammonium chloride (DDAC) and n-Alkyl dimethyl benzyl ammonium chlorides (ADBAC). DDAC was selected as the analyte based primarily upon its abundance (3x the largest ADBAC homologue), and on its stability, and the sensitivity of its analytical method. The quats ADBAC 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 DDAC was not apparent.

The analytical method for DDAC on the proposed monitoring matrices at very low concentrations has been validated (GPL, 2004). Additionally, DDAC is a single quat (as opposed to ADBAC, the other active ingredient in LEMON QUAT which is an homologous series of quats) and has the requisite degree of stability under field, storage and transit conditions. The freezer storage stability of DDAC on the different matrices to be used in this study has been completed showing that DDAC is stable on the different matrices when stored in a freezer for 6 months (GPL, 2005).

The very sensitive and selective analytical method developed for the analysis of DDAC 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, Sani-Care Lemon Quat has been deemed suitable by the Sponsor and EPA as a surrogate compound for generating exposure data for other antimicrobial pesticides.

7.3 Safety Precautions

A copy of the Material Safety Data Sheet and the product label will be provided to the study team (professional observers and researchers) and each of the subjects and included in the study file. Label safety requirements will be explained to the subjects involved in the study. All label-specified PPE will be provided and use

directions will be followed by the subjects and ensured by the study research personnel.

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 at the field site at the dressing and mopping areas.

Subjects will be provided and will wear protective eyewear throughout the monitoring period. At 30 minute intervals through termination of the study, the subjects will have their hands washed by study personnel using 50% isopropyl alcohol/water. At the end of the study, subjects will proceed to wash their hands thoroughly with soap and water. The Principal Investigator will examine their hands and note any irritation to the skin at termination of each participant's monitoring.

7.4 Dilution of Concentrate and Calibration of Application Equipment

The preparation of diluted solution to be loaded in the bucket will be performed by research personnel using graduated cylinders and/or calibrated containers appropriate for the materials handled. The concentrate will be diluted to the final concentration per label direction, i.e., 1:64 with tap water. Exposures resulting from mixing and loading activities will be measured in separate studies where more test material can be handled since it is not likely that the analytical method will detect residues from pouring a few ounces of the concentrate. A separate study will measure exposure for open pouring, and results from the two studies combined to estimate total exposure to a person doing all functions. This method is discussed in the Governing Document. The basic rationale for this "discretizing" of tasks is that EPA has asked for exposure estimates of hundreds of tasks that combine exposure functions. It is not possible to generate all of the permutations and combinations of data from combined task studies.

Research personnel will wear protective eyewear and waterproof gloves while preparing all diluted solutions of Sani-Care Lemon Quat. All information necessary to reconstruct the preparation of each batch of diluted solution, including the amount of test substance and amount of water used, and the beginning and ending amounts of test substance will be documented in the raw data. The temperature of the water in each bucket will be documented at the start and end of use of each bucket. At the Study Director's discretion, the amount of diluted material loaded onto the mop in a

typical immersion/wring cycle shall be recorded and documented in the raw data.

Study personnel will standardize methods in the study by supplying identical brand and model string mops of similar weight to each participant. The diluted solution (1:64) will be prepared at the study location on the day of use and an aliquot will be taken to be analyzed.

The amount of diluted material applied by each volunteer (either by weight in the buckets and weight remaining, or based on measurement of the volume of material initially in the bucket, minus the volume remaining) and the surface area covered by each volunteer will be documented in the raw data. Field personnel will calculate and document the equivalent amount of concentrated test substance applied.

A 5 ml aliquot will be collected from each batch of test solution prior to, and after use in each monitoring event. Unused test substance will be retained in its original container under monitored storage conditions until the release from the study is authorized by the Study Director. Mopping solution remaining in each bucket will be disposed of by the subjects in accordance with Federal and State regulations. Remaining diluted material will be disposed of by research personnel in accordance with Federal and State regulations.

7.5 Application Parameters

Application Equipment:	String Mop and Brite® 6185 Mop Bucket with 6127-01 Wringer
Carrier:	Water
Dilution Factor:	1:64
Target Application Rate:	27 mg ai/m^2
Target Application Volume:	0.2 gal/200 ft^2 = 41 mL/m^2
Target Surface Area:	2,000 ft^2 to 6,000 ft^2
Method of Application:	Mop, vinyl or hard floor
Duration:	30-90 in ~10 minute intervals

Technique: Mopping will be conducted by each participant as they would normally work. Past observation indicates a wide variety of application methods (Figure 8, side to side, back and forth motion), wringing preference (thorough agitation vs. dipping prior to wringing) and degree of wringing (single pull vs. multiple). Each subject will not re-mop any surface during a given monitoring event (ME).

Disposal of the mopping solution remaining in the buckets will be conducted by each participant as they would normally do.

7.6 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 floors.

7.7 Test Material Storage

The concentrated test material (Sani-Care Lemon Quat) will be stored indoors, at room temperature. Storage will be at Golden Pacific Laboratories. Storage conditions will be recorded.

8.0 STUDY DESIGN

8.1 Purposive Diversity Selection

A purposive diversity selection (PDS) design is used for the mopping application study. Synthetic antimicrobial handler-days, called monitoring events (MEs), are designed to capture diversity of the future mopping-conditions expected when professional workers apply an arbitrary antimicrobial by mopping. Diversity is achieved by purposively varying three meta-characteristics that are known to directly or indirectly influence exposure: (1) facility/date, (2) amount of active ingredient handled, and (3) worker. Three different sites (i.e., a facility and range of monitoring dates) are first selected. A cluster of six monitoring events are planned within each site. The MEs within each site have different amounts of AI handled and utilize different workers. AEATF's supporting document regarding the study design of the mopping application scenario (AEATF, 2008b) provides a detailed discussion of the rationale for each component of the PDS design.

8.2 Site Selection

Three experimental sites will be selected randomly from among acceptable experimental sites in Fresno County, CA. First, a real estate broker will be recruited to provide the Field Coordinator with a list of properties that meet the following criteria:

1) the property is within Fresno County;
2) the property is listed and vacant;
3) the building type is an office, retail space, or a meeting facility (school, church, dance hall). These three types provide the

desired architectural diversity.

Next, the properties that meet the above criteria will be placed on one of three lists, depending on the building type. The properties on each building-type list are then randomly ordered. The Field Coordinator or designee will then start with the first (randomly ordered) property on each building-type list and determine its acceptability using additional functional or site-specific qualifying characteristics including:

- A minimal surface area of 10,000 square feet. This amount of available surface area is adequate for conducting MEs for mop application as well as wiping application (i.e, it provides the opportunity for AEATF II to also conduct a similar "wiping application" study using the same buildings as mop application study).
- Acceptable diversity in available surfaces (e.g., unobstructed hallways, bathrooms, stairs, empty rooms, countertops);
- A functional HVAC system;
- The electric service is operating; and,
- The property does not require maintenance prior to use.

The first acceptable property in each of the three building-type categories will be "reserved" with the necessary deposit and paper work. Secondary choices of acceptable properties in each category will also be identified (in random order) but not reserved. If for some reason, one of the selected properties becomes unavailable, unacceptable, or otherwise lost an alternate property in that same category can then be readily selected.

Each site is a single vacant building (or, possibly, a group of adjacent buildings) and a particular range of monitoring dates. One mopping scenario of six MEs each are planned at each site (although as many as eight MEs/scenario per cluster are possible). Monitoring activities for different clusters should be conducted on different days, e.g., separated by several days to one week, as practical, given cluster/site availability constraints and cost considerations.

For purposes of the mop application studies, buildings or facilities must be large enough and have indoor rooms/areas that provide relevant and adequate surface areas for mopping such that subjects will not be in each other's way and no area will be cleaned more than once per day by any subject. Structural variability in surfaces to be mopped is preferred. Thus, buildings are preferred if they

provide diverse indoor room sizes and area configurations, e.g., individual offices, bathrooms, kitchen areas, hallways, dining areas, and stairs.

8.3 Amount of Active Ingredient Handled

In this study all MEs will use the same substance, i.e., Sani-Care Lemon Quat. All subjects will use a string mop and bucket and will use the same 1:64 dilution from concentrate. This is the minimum dilution (i.e., maximum concentration) allowed by label. Based on prior experience, any greater dilution will very likely produce a high frequency of non-detects, especially at the shortest interval.

Because the concentration of active ingredient is the same for all MEs, the amount of active ingredient handled (AaiH) is varied by using MEs with different mopping durations. Mopping duration will range between 30 and 90 minutes. This interval is partitioned into six mopping duration strata as follows:

A. 30 minutes to less than 40 minutes
B. 40 minutes to less than 50 minutes
C. 50 minutes to less than 60 minutes
D. 60 minutes to less than 70 minutes
E. 70 minutes to less than 80 minutes
F. 80 minutes to 90 minutes

At each site, a single ME is targeted for each stratum (see possible exceptions in 8.4 below). As long as the subject is within the correct stratum, it is unnecessary to control the duration more precisely. However, the subject's actual mopping duration will be recorded to the nearest minute.

8.4 Assignment of Surrogate Workers to Sites and MEs

As described in AEATF's rationale for the study design of the mopping application scenario (AEATF, 2008b), , the necessary sample size for this study is N_M=6 monitoring events in each of N_C=3 clusters (i.e., sites). As described in Section 9 below, 24 subjects are recruited randomly from the pool of qualifying volunteers. These 24 subjects are randomly divided into three groups of eight subjects each. The three groups of subjects are then allocated to the three sites. This allocation provides an additional two subjects per site beyond the six MEs needed if all workers are able to complete their assigned mopping tasks.

The eight subjects in each site are ordered randomly. The first subject is then assigned to the ME in the longest mopping duration stratum (i.e., stratum F, 80-90 minutes). No other assignments of subjects to MEs are made until the subject completes the monitoring task in this stratum. When the ME is complete, the next subject in order is assigned to the next longest stratum (E, 70-80 minutes). As long as each subject achieves the target mopping duration, the process is continued down to the shortest duration stratum (A, 30-40 minutes) and six MEs have been obtained, one for each of the six strata. If this process proceeds as expected, the last two subjects are never used for MEs.

It is conceivable that, due to fatigue or other difficulty, a subject might be unable to complete the mopping task for the assigned duration. If this should occur the ME can still be used provided the completed duration falls within one of the other (shorter) duration strata. If the subject's duration was less than 30 minutes, however, then this ME is terminated, and the monitoring media will not be analyzed. Regardless, the next subject in (random) sequence will be assigned to an ME for the uncompleted (longer) mopping duration stratum. This process will be continued until there is at least one ME in all six monitoring duration strata or until all eight subjects have been assigned, whichever occurs first. If such difficulties do occur, then it is possible that some longer-duration strata will not be monitored and that some shorter-duration strata will have more than a single ME. A consistent failure to complete longer-duration mopping would be an indication that such durations are inappropriate and/or unlikely to occur in practice.

8.5 Selection of Within-Site Environmental Conditions

As noted previously test facilities are selected that provide diverse indoor room sizes, surfaces, and area configurations. Conditions of the surfaces to be mopped will also depend on a number of factors including when they were last cleaned, type of HVAC system in the building, and degree of human traffic in the area. This permits each cluster of MEs to span a wide range of mopping conditions. Every attempt is made to insure that different MEs have covered different within-facility environmental conditions and that no two MEs utilize the same areas of the facility on the same day.

Exposure monitoring will be conducted under typical indoor lighting, temperature, humidity and air exchange. Light levels, air temperature, and humidity throughout the study will be documented at each location in the raw data. Measurements will be made at a minimum of 10 minute intervals throughout the course of data

collection. All reasonable efforts will be made to characterize and document the airflow and exchange rate during the study period. The location, architecture, surface composition, dirtiness, and type of HVAC system will be recorded.

9.0 SUBJECTS USED IN MONITORING EVENTS

Twenty-four subjects are required for this study. This includes the planned 18 surrogate workers needed for the design (i.e., three sites and six workers per site). The additional six subjects are included as insurance against subject withdrawal or other failure to complete the assigned mopping tasks.

9.1 Subject Recruitment

9.1.1 Population Base

Adult subjects will be recruited from the janitorial/cleaning service population of Fresno County. 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 represent the ethnic diversity in the Fresno area, recruitment materials and all interactions with potential subjects will be conducted in both English and Spanish.

9.1.2 Recruitment of Surrogate Workers

Janitorial services located in Fresno County and providing professional cleaning services for commercial buildings in the Fresno County, CA area will be contacted and asked to post flyers soliciting study subjects independently from 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).

Those janitorial service managers expressing a willingness to post the flyers will be invited to a meeting (one in the Northern portion of Fresno County and another in the Southern portion of the County). At this meeting, the

managers will be provided with the flyer and the informed consent form. One purpose of these meetings will be to determine if the Spanish translations seems intelligible to the particular dialects that may be represented in the County. Additionally, the managers will be shown the monitoring equipment (long johns, air monitors and wash/wipes) to educate them about the monitoring process. Another purpose will be to impress upon the managers the need to remain neutral (un-coercive) in their interactions with employees regarding study participation. Also, the meeting may provide an opportunity to hear from organized labor, if any of the shops represented are unionized. Finally, this meeting may present the opportunity with a show of hands to estimate the approximate number of employees (1-5, 6-20, 20+) that a particular employer represents.

To avoid the potential for coercion, subjects will not be recruited directly through contract janitorial service companies. Flyers will direct interested workers to contact the study Field Coordinator or Spanish-speaking coordinator directly. Individuals contacting the study representative and expressing an interest in participating in the study will be placed on a primary call-in list. Individuals will be added to this list for a period of four weeks. After this period of time, the primary call-in list will be closed to new volunteers. However, any subsequent call-ins will be added to a secondary list that is kept in case an insufficient number of participants can be obtained from the primary list.

All names on the primary call-in list will be randomized and individuals will be contacted in random order to schedule individual meetings with the Principal Investigator. Interested potential subjects will be asked to come to the laboratory facility and to bring a driver license or State photo identification following the script in Appendix G.

Interested volunteers will be screened and enrolled into the study based on one-on-one conversation held at the office of the Principal Investigator. The recruitment process will terminate when 24 subjects have been recruited for the study. If the entire primary call-in list has been exhausted and fewer than 24 subjects have been recruited, the secondary call-in list can be randomized and these individuals contacted for screening and possible recruitment.

A Spanish translator will be available at recruitment meetings to ensure communication with anyone preferring Spanish over English. The Principal Investigator 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 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 will provide each potential subject with a copy of the product label (Appendix A) and MSDS (Appendix E) and answer any questions regarding the product to be tested. The Principal Investigator will go over the Inclusion and Exclusion Criteria (see 9.1.3 below) for the study and answer any questions that the potential subjects have. They will be provided with copies of the Informed Consent Form (Appendix B), 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 encouraged to take them home with them to discuss with family and friends. The Principal Investigator will explain to potential subjects wishing to remain in consideration that they may withdraw from the research study at any time without penalty to their compensation. The Principal Investigator will then read the "Experimental Subject's Bill of Rights" to the potential subjects. 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 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 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.

The Principal Investigator will retain the final right to refuse participation to any potential subject; however, following signing the informed consent form, any subject not actually monitored will be given the minimum compensation.

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

9.1.3 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. 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, 18 to 65 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
- Reside within Fresno County, California
- Have experience working in janitorial services

Exclusion Criteria

- Skin conditions on the surface of the hands or face/neck (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 or more than 65 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 an employee of Golden Pacific Laboratories or Grayson Research, or is related by blood or marriage to personnel in either company.

9.2 Subject Identification Sequence Number (SISN)

Subjects enrolled into this study will be initially identified by the first and last name printed on the Informed Consent Form. Because the recruitment order was randomized, the final list of 24 enrolled subjects remains in random order. Each subject will then be assigned a unique study identification sequence number (SISN). The first sequential group of eight SISNs will be assigned to the first monitoring 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.

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.

9.3 Compensation

Individuals that are not tested including anyone signing the informed consent form but not subsequently being monitored will be compensated for their time and inconvenience at the rate of $50 per day. This does not include those that meet with PI to discuss the study but do not volunteer. Subjects participating in a monitoring event (ME) will be compensated at $100 for the single day that they are monitored. The values for compensation are 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 in the form of cash (U.S. currency) at the completion of participation.

9.4 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 during the study. The Principal Investigator will discuss the symptoms of heat stress and skin reactions with the subjects prior to participation in the study. Subjects will be instructed to inform the Principal Investigator or research staff immediately if they feel ill, suffer a skin reaction or experience any other unanticipated adverse effects they feel may be related to the study during or following conduct of the study.

If a subject reports an adverse 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 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 11.B describes the procedure for identification and control of heat stress. The poster "Controlling Heat Stress Made Simple" will be posted 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 asked 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 AEATF SOP # AEATF 11.C 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, EPA and California DPR policies for medical event reporting. 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.

10.0 STUDY PROCEDURES

Participation in the study will take about 4 to 6 hours each day, for multiple days. On a day of the study, a subject will change into inner and outer dosimetry clothing and new socks and shoes, and get fitted with an air sampling pump and sampling train. Subjects will then be asked to mop floor surfaces with a dilute solution of Sani-Care Lemon Quat for 30 to 90 minutes. Face wipes and hand washes will be taken at the end of mopping Subjects will then remove the dosimetry clothing with aid of the research team and change into another set of new inner and outer dosimeter clothing, but wear the same shoes and socks, and be asked to empty the buckets containing the remaining mopping solution. Finally, the subjects will remove the second set of dosimetry clothing with the aid of a research team and change back into subjects' own clothes. Following is the sequence of events.

1. On the day of the study, subjects will go to the study location at the time subjects have been told, and meet the researchers.

2. If a subject is female and less than 50 years old, 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 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. All results of the pregnancy test will be kept in confidence, they will not be recorded, and they will be discussed only with subjects.

3. The principal investigator and the research team will review with the subjects their role in the study, and subjects 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. When the subjects are ready, the subject will be directed to a mobile field unit containing the dressing area, field equipment and supplies. The mobile field unit is a 36 foot enclosed trailer containing one 8 ft x 10 ft room at the rear of the trailer, and one 26 x 8 ft room at the front of the trailer. Each room is accessed from a separate exterior door. The subject and one same sex researcher will enter the rear compartment where the subject will be assisted in removing his/her street clothing and donning the study dosimeters and air sampling pump. Subjects will remove their street clothes down to their underwear, and then put on cotton long underwear (long johns), followed by a long sleeved cotton shirt, long cotton pants, and cotton socks and shoes. All clothing articles, including shoes, will be new and provided to subjects by the research team. Care will 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). Cut the large excess off the inner dosimeter pant legs and arms at the wrists so the inner dosimeter will not come out from underneath the outer dosimeter during the performance of the mopping activity. The outer dosimeter pant cuffs may be cut for proper fit. If cutting is necessary, cut the pants at a length so the cuffs do not drag on the floor nor will the worker's socks or inner dosimeter leg be exposed due to a short length. The outer dosimeter pants will not be tucked into the boots/shoes. The outer dosimeter shirt will be tucked into the pants during the mopping activity. A secured locker or similar storage area will be provided for the subjects personal belongings during study participation. Study supplies, including dosimeters of various sizes

will be available in the rear compartment to expedite the process and maintain the subject's privacy. The rear compartment is an air conditioned and heated space, with lighting, seating and work surfaces appropriate for the study activities. In the event the mobile field unit is unexpectedly not available, a separate dressing area with the same functionality, security and privacy will be provided.

5. Subjects will be given safety glasses, and must wear them while mopping the surfaces and emptying the buckets.

6. Before the test begins, subjects will wash their hands and face with Ivory soap and water, and dry them thoroughly using paper towels.

7. An air sampling pump will be attached on a belt around subjects waist, and a flexible tubing with an air sampling tube will be connected from the air pump to subjects shirt collar. Full body front and back photographs will be taken at this time.

8. The air pump will be turned on, and subjects will put on their safety glasses. Subjects will be provided a bucket containing the already diluted SANI-CARE LEMON QUAT solution and a string mop, and asked to start mopping the way they normally do on the job. A researcher will observe each subject as they work, recording how long subjects work and how much surface area they mop, and a designated photographer will take pictures or video.

9. Subjects will be provided with a new diluted test substance-filled bucket every 15 minutes or as necessary or requested by the participant, whichever is shorter. Used equipment will be saved and counted for each subject. This information will be documented in the raw data. The time spent mopping with each bucket, as well as the total time spent mopping will be documented for each volunteer. The floor surface area will be marked in such a way as to provide some measure of how much surface area is mopped with all buckets of diluted mop solution used by a subject.

10. After subjects have been mopping for 30 minutes, the researcher will rinse subjects' hands with a solution of 50% IPA and water, and save the rinse solution for analysis. Subjects will then have a 10-minute rest period. Subjects will not be permitted to smoke during this rest period, but may eat (but must wash their hands with Ivory soap and water before resuming work) and are encouraged to drink lots of fluids. A face wipe will not be collected before eating. Subjects can rest more frequently upon request. Depending on which group subjects are assigned to they may be asked to continue

mopping for up to 2 more 30 minute periods of mopping for a total of 90 minutes, each followed by a 10 minute break.

11. At conclusion of the mopping period, the subject will return to the rear compartment of the trailer with a same sex researcher. 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 sheeting will be used on seating surfaces, and paper sheeting used on counter and floor surfaces at conclusion of each monitoring period to minimize transfer of any residues to clean surfaces. The compartment will be cleaned with cleaning agents appropriate for the study between subjects.

    Samples will be collected in this order as described in SOP AEATF II-10E to minimize cross contamination:

    a. The air sampling pump and the sampling tube will be removed and saved for analysis.

    b. The researcher will rinse subjects' hands with a solution of 50% IPA and water for the last time, and save the rinse solution.

    c. The researcher will wipe subjects face and neck with 50% IPA/water - moistened pads, and save the pads for analysis.

    d. The researcher will help subjects take off the outer shirt and pants, and will save each garment for analysis.

    e. The researchers will help the subject remove shoes and will save the socks.

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

12. Subjects will be assisted in donning a new set of study dosimeters and air sampling pump as described in Section 4. Subjects will be asked to empty the buckets containing the remaining dirty diluted SANI-CARE LEMON QUAT solution.

13. The subjects will return to the rear compartment of the trailer with a same sex researcher and the samples will be collected as described in Point 11. When all samples have been collected, subjects will dress again in their street clothes.

14. The principal investigator will check subjects' hands and face before they leave for redness or other signs of irritation. They will be paid for their time and inconvenience in cash, and will be free to go.

10.1 Preparation of Study Subjects for Exposure Monitoring

SOP's of the AEATF II and cooperating contractors will be used to prepare subjects for exposure monitoring. A brief explanation of the activities follows.

10.1.1 Inner and Outer Dosimeters

Subjects will be taken to a clean private room by same sex study personnel and given the proper size inner and outer dosimeters. If fit is not adequate, other size dosimetry clothing will be available to afford best fit.

The subjects will be asked to remove their street clothes down to their underwear and wear the outer dosimeter on top of the inner dosimeter. The inner dosimeter will consist of 100% cotton long underwear (long johns) provided by AEATF II. The outer garments (long pants and long-sleeved shirts) will be cotton provided by the AEATF II and will be analyzed for DDAC. The inner dosimeter is designed to capture test substance that would normally contact the subject's skin and will act as a collection medium that will also be analyzed. The inner dosimeter will be kept slightly shorter than the outer dosimeter on the arms and legs, either by fit or by trimming to fit to avoid contamination. Both dosimeters will be worn throughout the period of monitoring and removed at the end of the work period, with the assistance of a same-sex member of the monitoring team.

10.1.2 Socks

The socks will consist of 100% cotton socks provided by AEATF II. Two sets of socks will be worn. The inner cotton socks are designed to capture test substance that would normally contact the subject's skin and will act as a collection medium. Both sets of socks will be analyzed. The inner socks will be kept slightly shorter than the outer socks, either by fit or by trimming to fit and to avoid contamination. Both socks will be worn throughout the period of monitoring and removed at the end of exposure period with the assistance of a same sex member of the monitoring team.

10.1.3 Air Sampling Tubes

Suitable low-volume personal air-sampling pumps and an OVS tube with glass filter and XAD2 sorbent will be used. The air flow of the pump will be calibrated to a nominal sample flow rate of approximately 2 L/min. This information will be recorded in the raw data records.

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

10.1.4 Hand/Face Wash

The subjects will be asked to wash their hands and face with Ivory soap and water followed by drying with a paper towel just prior to the exposure-monitoring period.

10.1.5 Eye Wear

Subjects will be given and asked to wear product label-specified protective eye wear.

10.2 Study Conduct

SOP's of the AEATF II and cooperating contractors will be used to document study conduct. A brief explanation of these activities follows.

The subjects will enter the area to be mopped. The air pump will be turned on immediately prior to the start of the monitoring period and will operate continuously until the end of the period. The subjects will be given a bucket containing the diluted SANI-CARE LEMON QUAT and a string mop.

Subjects will each mop approximately 2,700 up to 8,000 ft^2 of flooring surfaces according to label directions. A new diluted solution-filled bucket will be provided to the volunteers every 15 minutes or as necessary, or requested by the participant, whichever is shorter. This use information will be documented in the raw data.

The time spent mopping will be documented for each volunteer. The amount of solution applied using the string mop and the number of buckets used will be documented. The surface area available for mopping will be marked in such a way as to provide an estimate of the surface area mopped by each volunteer at various time points during the monitoring period and the total area mopped at the end of the monitoring period. At the end of the mopping procedure, the volunteer will remove their dosimeters, don new dosimeters and empty the buckets containing the remaining diluted SANI-CARE LEMON QUAT solution.

10.2.1 Inhalation Exposure Sampling

Per SOP AEATF II-10G, prior to study start, each pump will be calibrated to a nominal sample flow rate of approximately 2 L/min and will operate for the duration of the exposure monitoring period. Flow rates will be measured before and after each exposure monitoring period and detailed records of flow rates and sampling durations will be maintained in the raw data records. Air pumps will not be turned off during breaks, and will remain on until the subjects' work duration is complete.

Detailed time logs will be maintained to allow the exposure period to be calculated as either the total time or the time actually spent in the work area (e.g., excluding time for breaks).

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 in it. 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 and connective tubing) will be retained and moved to the second pump if a replacement pump is necessary. At the conclusion of each exposure monitoring period, the final flow rate will be measured and recorded.

10.2.2 Calibration of Air Sampling Pumps

Air flow for air sampling pumps will be determined prior to sample collection and at the end of sampling per SOP AEATF II-10F and -10G.

10.2.3 Air Sampling for Ambient Pre-existing DDAC

Air samples will be collected from the facility for one hour prior to initiating mopping to determine background levels in air each day. Samples will be collected at a height of five feet in the subject dosimetry assembly room, and in the main area where the mopping will be conducted in duplicate.

10.2.4 Hand Wash Sampling During Study Conduct

A hand wash sample will be collected at the end of each 30 minutes of exposure using the method specified in SOP AEATF II-8B. However, hand wash samples will also be collected if a subject interrupts his/her task for using the toilet or taking a break due to fatigue. If this happens, 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 be not be allowed to use tobacco, but may eat and drink following each hand wash. Face wipes will not be taken until the end of the monitoring interval. To prevent sample contamination, subjects will wash their hands with Ivory soap and water after eating.

Due to the need to provide rest breaks at a minimum of 30 minute intervals, the longer duration monitoring intervals (60, but especially 90 minutes) will probably significantly overestimate the contribution of hand exposure to total exposure. The amount transferred to the hands will come to equilibrium with the hand, but hand washes will be summed to indicate a cumulative increase in exposure with time. More discussion of this overestimation bias is presented in the Governing Document.

10.2.5 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.

Work activities described in this protocol 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. The study subjects will not be photographed at any time while changing into or out of the dosimetry clothing.

10.2.6 Environmental Monitoring

Light level, 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. Monitoring equipment will be calibrated or standardized according to the cooperating contractors' SOPs. HVAC will be described in detail and the air turnover rate will be measured or estimated.

10.2.7 Field Study Personnel

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 ending flow rates.
3. Prepare bucket containing diluted formulation and take sampling aliquots.
4. Observe and record all work practices and record site and treatment details.
5. Take a photographic record of representative study-related activities.
6. Observe and document operation and representative output of application equipment.
7. Prepare field fortification samples.

10.3 Sample Collection

At the completion of the mopping monitoring period or the emptying of the buckets, the subjects will be directed to a clean private area by a same sex researcher for removal and collection of exposure samples. Time elapsed between completion of mopping or emptying of the buckets and start of sample collection will be noted.

Sample collection, identification, storage, and transport will be performed in accordance with SOPs AEATF II-10E and -10B. A list of SOPs used in the study will be included in the raw data, and procedures not fully explained in SOPs will be documented in the raw data.

Exposure samples will be taken in the following order to minimize cross contamination: inhalation samples, hand washes, face/neck wipes, outer and inner dosimeters, and finally socks as described below. The samples will be collected by study personnel. New examination gloves will be used for each sample type. For all samples collected in glass jars, the jars will be placed into a re-sealable bag to protect the sample in case of jar breakage.

10.3.1 Inhalation Exposure Sampling

The OVS tube will be disconnected from the tubing leading to the pump per SOP AEATF II-8D. The OVS tube will be sealed at both ends, placed in a pre-labeled re-sealable bag, and 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.

10.3.2 Hand Wash

Hand exposure will be assessed by washing the subjects' hands with a 50% isopropyl alcohol / water solution according to a standardized washing procedure described in SOP AEATF II-8B. The high solubility of DDAC in both IPA and water indicates that this combination of solvents will provide excellent recovery of hand residues.

Hands will be washed with Ivory soap and water just prior to the exposure-monitoring period. If interim hand wash samples are collected (e.g., preceding a break), the interim hand wash samples will be numbered sequentially. After the specified task is completed, one final hand wash will be collected from each subject. Following the final hand wash, the Principal Investigator will examine each subject's hands for irritation or redness. The post-activity hand wash sample for each monitoring event will be the final hand wash sample for the monitoring period and receive the final sequence number for the monitoring event. This sample will be clearly marked as the post-activity hand wash. All hand washes collected during and at the end of the work period will be

treated as separate samples. Additional sample numbers will be generated for additional interim hand wash samples. All hand wash samples will be placed in pre-labeled containers and placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

10.3.3 Face/Neck Wipe

Face/neck exposure will be measured by wiping the exposed areas with two gauze pads that have each been wetted with a 50% isopropyl alcohol/water solution as described in the SOP AEATF II-8C.

After the mopping 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.

10.3.4 Outer and Inner Dosimeter

The outer and inner layer of clothing (outer and inner dosimeter) will be removed with the assistance of a same sex member of the study team and sectioned into upper and lower arms, front and back torso, and upper and lower legs per SOP AEATF II-8G and -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.

10.3.5 Socks

The socks will be removed with the assistance of a same sex member of the study team. The outer or inner socks will be separately 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.

10.4 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 using vialed spikes" 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, socks, hand wash solutions, face/neck wipes, and air sampling matrices) will take place on each day of the study. Field fortification solutions of the test substance diluted in water, or solutions of active ingredient in an appropriate solvent will be prepared and pre-measured into vials by the analytical laboratory and 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 individual vials used for fortifications, and of the fortified OVS tubes, will be specified by the analytical laboratory and the actual storage details will be recorded in the study file. Any unused vials or unused fortified OVS tubes will be returned to the analytical laboratory.

With the exception of OVS tubes, the entire contents of the fortification suspension vials will be applied to the sampling media. Field fortifications will be conducted at the following levels during the study.

Matrix	Fortification Level
Air Sampling Tubes	40 ng/sample and 2.0 µg/sample
Hand Washes	8.0 and 400 ng/mL
Face/Neck Wipes	200 ng/sample and 10 µg/sample
Inner Dosimeter Section	12.0 µg/sample and 1.0 mg/sample
Outer Dosimeter Section	12.0 µg/sample and 1.0 mg/sample
Socks	1.0 µg/sample and 1.0 mg/sample

The lower fortification level in each matrix is the approximate 4X LOQ.

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 mopping tasks being monitored.

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, socks, and OVS tubes will be exposed to ambient conditions (i.e., weathered) for 90 minutes in a location away from possible contamination. Outer, inner dosimeters and socks will be left uncovered per EPA's 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 and socks (single layer) fortified in the field at the highest level, and duplicate OVS tubes fortified in the laboratory at the highest fortification level, will be processed for immediate frozen storage and used as travel spikes. Segments of inner and outer dosimeter representing any body area may be used for fortification samples. These travel 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.

11.0 SAMPLE IDENTIFICATION, SHIPPING AND STORAGE

11.1 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 AEA03-MW-01-ID-LA:

AEA03 = Task Force Study Number
MW = Mop Worker Sample
01 = Subject 1
ID = Inner Dosimeter
LA = Lower Arm

Additional designations are as follows:

PW = Pour Worker
OD = Outer Dosimeter
AR = Air Sampling Tube
FW = Face and Neck Wipe
HW = Hand Wash
IS = Inner Socks
OS = Outer Socks
DM = Diluted Material

Sample identification numbers are appended to this protocol (Appendix K). 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.

11.2 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.

11.3 Storage

All samples will be placed into frozen storage as soon as they are collected, until transported to the analytical laboratory. As soon as the samples arrive at the analytical laboratory, the samples will be stored in a freezer maintained at ≤ -15°C until analyzed.

12.0 ANALYTICAL PROCEDURES

Experimental exposure and laboratory recovery samples will be analyzed according to the analytical methods specified in Section 12.2 of this protocol. The methodology has been validated for use in the relevant matrices.

12.1 Reference Substance and Internal Standard

12.1.1 Reference Substance

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

CAS No.:	7173-51-5
Purity:	80.9%
Source:	Lonza
Lot No.:	D4223025

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(s) (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.

GLP purity analysis (content of active ingredient in the reference substance) will be performed for each lot of reference substance used in the study by the Sponsor prior to the start of sample analysis. Documentation of such analysis will be retained in the study raw data file.

Analytical standards are to be stored under the recommended conditions.

12.1.2 Internal Standard

The Internal Standard (IS), deuterated Didecyl Dimethyl Ammonium Iodide was prepared and supplied by Chemalong Laboratories, LLC (Lemont, IL).

Name:	Deuterated ($^2H_3$)-Didecyl Dimethyl Ammonium Iodide
CAS Number:	Not Applicable
Lot Number:	CA075901
Purity:	>95%
Date Received:	06/02/05
Expiration Date:	Will be documented in study data

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.

12.2 Analytical Method

The analysis of DDAC 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 with very low detection limits. The limit of quantification (LOQ) for air sampling tubes, hand washes, and face and neck wipes are 10 ng, 2.0 ng/mL and 50 ng respectively. The LOQ for inner and outer dosimetry are 3.0 µg/sample. The LOQ for inner and outer socks is 1 µg/sample. The method (GPL-MTH-052) includes the use of deuterated DDAC 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 of the standard solution will be injected prior to the standard solution 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-052 entitled, "Analytical Method for the Determination of Didecyl Dimethyl Ammonium Chloride (DDAC) in Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, and Air-Sampling Tubes" (GPL, 2004).

All samples, except hand washes, 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. 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/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 inner dosimeters will be analyzed in accordance with SOP AEATFII-8A, which states that when the outer dosimeter is below the limit of quantification (<LOQ) the corresponding inner dosimeter 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.

12.3 Storage Stability

A storage stability study to determine the stability of DDAC on the various matrices under freezer storage conditions has been conducted (GPL, 2005). DDAC was shown to be stable for 6 months on all matrices under freezer storage.

12.4 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 squares 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.

12.5 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, 2008a):

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.

We note that the analysis in (1) above may suggest that the realized accuracy bounds differ from the benchmark targets to some extent. This does not invalidate the study since small deviations would be expected and are of little practical concern. However large deviations from the benchmark goals may affect the regulatory usefulness of the data. If large deviations from benchmark goals are observed the AEATF II will, in consultation with regulatory agencies, determine the best course of action to take. This may mean the development of guidance for the use of these data that takes the increased imprecision of the estimates into account. It is possible that collection of additional clusters might be considered.

13.0 STUDY RECORDS

13.1 Field Records

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

1. Test and reference substance lot numbers, receipt and storage location(s), use records;
2. Application equipment details;
3. Environmental conditions for the entire monitoring period;
4. Subjects' demographic information and consent forms;
5. Trial location maps, including description, dimensions, and locations of diluting concentrate;
6. Measurement of active ingredient handled, time exposed and/or volume of liquid applied;
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;
11. Sample information (including inventory, chain of custody);

Field raw data will be recorded directly into a raw data file customized for use in the study. Following the field phase, all data generated during this study will be kept at GPL in 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.

13.2 Analytical Records

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

13.3 Communication with IRB

Prior to conducting studies involving human subjects, written approval from an IRB will be obtained. The package of information that will be submitted to the IRB includes a supplemental document regarding the study design and justification for duration of task and area treated (AEATF, 2008b),,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, test substance MSDS (Appendix E), as well as all recruiting materials, such as flyers (Appendix F), interview scripts (Appendix G), community involvement flyer (Appendix H), and an executive summary of EPA's REDs for ADBAC and DDAC summarizing their risk assessment conclusions (Appendix J). 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 approval 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 approval from the EPA and 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.

14.0 STUDY LOCATIONS

The field study locations will be in Fresno County, CA. Full details of the location will be recorded in the study files. Given the transient nature of availability of vacant commercial real estate, the study location will not be known until a few weeks before study initiation. Criteria for identifying commercial buildings are discussed in the rationale for study design document (AEATF, 2008b) and in Section 8.2 above

The analytical location is at 4720 W. Jennifer Ave., Suite 105, Fresno, CA. The analytical location will be within 30 miles from the field location.

15.0 DATA HANDLING

15.1 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.

15.2 Statistical Methods

Proposed calculations are limited to the calculations specified in Section 12.4 and 12.5.

16.0 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 company 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. A QAU statement will address non-compliance issues, if any. The QA Statement lists dates of inspections, what was inspected and when inspection reports were communicated. A Statement of GLP Compliance will certify the study was/was not conducted in compliance with GLP and, if not, how it differed (i.e., the GLP deviations). 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-5K, inclusive.

17.0 SAMPLE RETENTION

All sample extracts, extracted sample matrices, and analytical standards will be retained until the Principal Investigator 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.

18.0 FINAL STUDY REPORT

One report will be written summarizing the entire study. A final report will be prepared by the Principal Investigator. 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 mixing/loading of concentrate by research staff, and 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 for 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 letter 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.

19.0 PROTOCOL CHANGES

All protocol changes (amendments and deviations) shall be reported to the IIRB in writing by letter, fax or email. The Principal Investigator shall follow written instructions provided by the IIRB for prompt reporting to the IIRB, 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.

19.1 Amendments

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

19.2 Deviations

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

20.0 PERSONNEL

20.1 Study Director (Principal Investigator)

Sami Selim, Ph.D.
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20.2 Study Sponsor Representative

William McCormick
Clorox Product Services Co.
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Phone: (925) 425-4338

20.3 Quality Assurance Unit

Anantdeep K. Kang
Golden Pacific Laboratories, L.L.C.
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Fax: (559) 275-1810

20.4 Field Coordinator

Tami I. Belcher
Grayson Research
211 N. Main Street
Creedmoor, NC 27522
Phone: (919) 528-5508

20.5 Analytical Coordinator

Megan Boatwright
Golden Pacific Laboratories, L.L.C.
4720 W. Jennifer Avenue, Suite 105
Fresno, California 93722
Telephone: (559) 275-9091

21.0 PROTOCOL APPROVAL

_____

William McCormick Date
Sponsor's Representative

_____

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

_____

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

_____

Tami I. Belcher Date
Field Coordinator
Grayson Research, LLC.

_____

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

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APPENDIX A

LABEL FOR PRODUCT TO BE USED IN STUDY

Label for Product to be used in Study

PELIGRO: SI NO SABE LEER INGLÉS, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES SOBRE EL USO APROPIADO ANTES DE TRABAJAR CON ESTE PRODUCTO.

DILUTION 1:64 2 OUNCES PER GALLON OF WATER (660 ppm quat)

Recommended for use in hospitals, nursing homes, schools, colleges, commercial and industrial institutions, office buildings, veterinary clinics, animal life science laboratories, zoos, tack shops, pet shops, airports, kennels, hotels, motels, breeding establishments and grooming establishments. Disinfects, cleans, and deodorizes the following hard, nonporous, inanimate surfaces: floors, walls, (non-medical) metal surfaces, (non-medical) stainless steel surfaces, glazed porcelain, plastic surfaces (such as polypropylene, polystyrene, etc.).

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical devices prior to sterilization or high-level disinfection.

DISINFECTION / CLEANING / DEODORIZING DIRECTIONS: Remove heavy soil deposits from surface, then thoroughly wet surface with a use-solution of 2 ounces of the concentrate per gallon of water. The use-solution can be applied with a cloth, mop, sponge, or coarse spray, or by soaking. For sprayer applications, use a coarse spray device. Spray 6-8 inches from the surface, rub with a brush, cloth or sponge. Do not breathe spray. Let solution remain on surface for a minimum of 10 minutes. Rinse or allow to air dry. Rinsing of floors is not necessary unless they are to be waxed or polished. Food contact surfaces must be thoroughly rinsed with potable water. This product must not be used to clean the following food contact surfaces: utensils, glassware and dishes.

BACTERICIDAL STABILITY OF USE-DILUTION: Tests confirm that Sanicare Lemon Quat, when diluted in 400 ppm hard water (via automatic dispensing devices), remains effective against Pseudomonas aeruginosa, Staphylococcus aureus and Salmonella choleraesuis for up to one month when stored in a sealed container such as a spray bottle. If product becomes visibly dirty or contaminated, the use-dilution must be discarded and fresh product prepared. Always use clean, properly labeled containers when diluting this product. Bactericidal stability of the use-dilution does not apply to open containers such as buckets or pails.

MILDEWSTATIC INSTRUCTIONS: Will effectively control the growth of mold and mildew, plus the odors caused by them when applied to hard, non-porous surfaces such as walls, floors, and table tops. Apply use-solution (2 ounces per gallon of water) with a cloth, mop, sponge, or coarse spray. Make sure to wet all surfaces completely. Let air dry. Repeat application weekly or when growth reappears.

FUNGICIDAL DIRECTIONS: For use in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities follow disinfection directions.

VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP / KENNELS DISINFECTION DIRECTIONS: For cleaning and disinfecting the following hard nonporous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-dilution of 2 oz. of Sanicare Lemon Quat per gallon of water (or equivalent dilution) for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

*KILLS HIV-1 (AIDS VIRUS) AND HBV (HEPATITIS B VIRUS) AND HCV (HEPATITIS C VIRUS) ON PRECLEANED, ENVIRONMENTAL 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/body fluids, and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS) or Hepatitis B Virus (HBV) or Hepatitis C Virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OR HBV OR HCV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Disposable protective gloves, gowns, face masks, or eye coverings as appropriate must be worn during all cleaning of blood/body fluids and during decontamination procedures.

Cleaning Procedures: Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of disinfectant.

Contact Time: HIV-1 (AIDS virus) is inactivated after a contact time of 4 minutes at 25°C (77°F) (room temperature). HBV and HCV are inactivated after a 10 minute contact time. Use a 10-minute contact time for other viruses, fungi, and bacteria listed.

Disposal of Infectious Materials: Blood/body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

Buckeye®

SANI-CARE **LEMON QUAT**™

ONE-STEP DISINFECTANT GERMICIDAL DETERGENT AND DEODORANT

Disinfectant • Pseudomonacidal • Staphylocidal • Salmonellacidal
Bactericidal • Fungicidal • Mildewstatic • *Virucidal

A multi-purpose, neutral pH, germicidal detergent and deodorant effective in hard water up to 400 ppm (calculated as $CaCO_3$) in the presence of a moderate amount of soil (5% organic serum) according to the AOAC Use-dilution Test. Disinfects, cleans, and deodorizes in one labor-saving step. Effective against the following pathogens:

Pseudomonas aeruginosa[1]
Staphylococcus aureus[1]
Salmonella choleraesuis
Acinetobacter calcoaceticus
Bordetella bronchiseptica
Chlamydia psittaci
Enterobacter aerogenes
Enterobacter cloacae
Enterococcus faecalis
Vancomycin Resistant (VRE)
Escherichia coli[1]
Fusobacterium necrophorum
Klebsiella pneumoniae[1]
Legionella pneumophila
Listeria monocytogenes
Pasturella multocida
Proteus mirabilis
Proteus vulgaris
Salmonella enteritidis
Salmonella typhi
Salmonella typhimurium
Serratia marcescens
Shigella flexneri
Shigella sonnei
Staphylococcus aureus-
(Methicillin Resistant) - (MRSA)
Staphylococcus aureus-
Vancomycin Intermediate Resistant - (VISA)
Staphylococcus epidermidis[2]
Streptococcus faecalis[1]
Streptococcus pyogenes
*Adenovirus type 4
*Avian polyomavirus
*Canine distemper
*Feline leukemia
*Feline picornavirus
*Hepatitis B Virus (HBV)
*Hepatitis C Virus (HCV)
*Herpes Simplex Type 1
*Herpes Simplex Type 2
*HIV-1 (AIDS virus)
*Infectious bovine rhinotracheitis
*Infectious bronchitis (Avian IBV)
*Influenza A/Hong Kong
*Pseudorabies (PRV)
*Rabies
*Respiratory Syncytial Virus (RSV)
*Rubella (German Measles)
*Transmissible Gastroenteritis virus (TGE)
*Vaccinia
Aspergillus niger
Candida albicans
Trichophyton mentagrophytes

[1] ATCC & antibiotic-resistant strain
[2] antibiotic-resistant strain only

ACTIVE INGREDIENTS:
Didecyl dimethyl ammonium chloride 2.54%
n-Alkyl (C_{14} 50%, C_{12} 40%, C_{16} 10%)
dimethyl benzyl ammonium chloride.....1.69%
INERT INGREDIENTS: 95.77%
TOTAL:.....100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

(See side panel for Precautionary Statements and First Aid)
EPA Reg. No. 47371-131-559 EPA Est. No. 559-MO-1
NET CONTENTS _____

Buckeye International, Inc.
2700 Wagner Place • Maryland Heights • MO 63043 • USA • (314) 291-1900

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Avoid contact with the skin. Harmful if inhaled. Avoid breathing spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for at least 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.
IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible.

Call a poison control center or doctor immediately for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.
For medical emergencies only, call 800-303-0441. Outside North America call 651-632-8956.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Keep product under locked storage, inaccessible to children. Open dumping is prohibited. Do not reuse empty container.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

PLASTIC CONTAINERS
Triple rinse (or equivalent), then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.

FIBER DRUMS WITH LINER
Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment, then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

APPENDIX B

INFORMED CONSENT FORM

INFORMED CONSENT FORM

Title: A Study For Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using Bucket an Mop Equipment for Cleaning Indoor Surfaces. Study Number (070265).

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

Field Coordinator:
Tami I. Belcher
Grayson Research, LLC.
1040 Grayson Farm Road
Creedmoor, NC 27522
Phone: 919-528-5508

Field Locations: 3 Sites in Fresno County, CA

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

24-Hour Phone Number: 559-447-5364 (Sami Selim)

You are being asked to participate in a research study. 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 participate. If you have any questions, or if you do not understand anything in this form, please ask Dr. Selim, the Principal Investigator, to explain. If you would prefer to discuss participation in either English or Spanish, please ask. This form is available in either English or Spanish, and we can explain the study to you in either language. A translator who can help you understand the research is available as well.

Purpose of this Study

Golden Pacific Laboratories is doing this research to find out how much mop water may reach your skin when you mop a floor. We will measure how much of the mop water 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 mop floors.

The study is being paid for by the Antimicrobial Exposure Assessment Task Force II (AEATF II), a group of companies that make antimicrobial cleaning products. These products kill germs on indoor surfaces, and are currently approved 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. Tami I. Belcher of Grayson Research is the Field Coordinator.

Test Product

The material being tested in this study is a pesticide called SANI-CARE LEMON QUAT, a commercial cleaning product used to clean hard surfaces like floors, walls, and stainless steel. This product is recommended for use in offices and commercial and institutional buildings, such as hospitals, schools, and hotels.

SANI-CARE LEMON QUAT contains two active chemicals: didecyl dimethyl- and n-alkyl dimethyl benzyl- ammonium chlorides, which kill germs. SANI-CARE LEMON QUAT is a strong concentrate, and in this study it will be mixed with water to make the mopping solution.

Subject Selection

People who take part in this research must be healthy adults, between the ages of 18 and 65, who read and speak English or Spanish. They must have experience doing janitorial work; and must be interested in participating in this study and willing to sign a consent form, a form with your personal information and 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 or Grayson Research; if you are pregnant or breast-feeding; if you aren't able to mop floors for 30 minutes at a time between breaks; 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 participate in this study. A few more people will be enrolled than are needed, in case anyone is unexpectedly unable to participate on the day of the test.

The research will be conducted at three different vacant commercial buildings on different days. Six people and two alternates will be asked to participate at each building. You can participate only once, but if you are the alternate and are not selected, you may be able to participate fully on another day.

Study Enrollment

Before you can be enrolled in this study, you will come to the offices of Golden Pacific Laboratories at 4720 W. Jennifer Ave., Suite 105, in Fresno, to meet with the Principal Investigator, Dr. Selim. He will answer all your questions regarding the study, and will 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 meet all eligibility requirements and decide you want to participate in the study, we will ask you to sign this Informed Consent Form and provide some information about your work experience and your general health. We'll ask you for your name and age, about your experience mopping floors, and about your previous use of antimicrobial or pesticide products. We will measure your height and weight, and we will ask you for your clothing and shoe sizes.

If you are accepted as a participant we will ask you to report to one of the three field study locations at a certain day and time, and we'll give you a map with directions to the study location.

We will call you the day before your scheduled test day to confirm your availability. We'll also ask you to be sure to take a shower or a bath before coming to the study location.

Study Procedures

The study itself will take about 4 to 6 hours on one day. During that time you will change into special clothing and shoes for the test and get fitted with a device to sample the air you breathe, then you'll be asked to mop a floor with a diluted solution of SANI-CARE LEMON QUAT for 30 to 90 minutes, and finally you'll give the special clothing to the research team and change back into your own clothes. Here's exactly what will happen on the study day.

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

2. If you are female and less than 50 years old, you will be taken to a private area and asked to take a urine pregnancy test using an over-the-counter pregnancy test kit. After you've taken the pregnancy test you will be asked

if you still want to participate in the test. If you say no, you will be paid for your inconvenience and will be free to go. If you say yes, a female member of the research team will double-check the results of the pregnancy test. All results of the pregnancy test will be kept in confidence, they will not be recorded, and they will be discussed only with you.

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

4. A same-sex member of the research team 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, and then to put on cotton long underwear (long johns), and a long sleeved cotton shirt and long cotton pants. All these clothes will be provided to you. The technician may have to trim the sleeves and trousers of the long underwear so it doesn't stick out. You will also be given special socks and shoes. Your street clothes and valuables will be placed in a locked storage area, and you will be given the key to keep with you.

5. You will be given safety glasses, and you must wear them while you are mopping the floor.

6. Before the test begins, you will wash your hands and face with Ivory soap and water, and dry them thoroughly using paper towels.

7. We will attach a small air sampling pump on a belt around your waist, and attach a small tube connected to the air pump to your shirt collar. This will sample the air you breathe while you are mopping. The pump is small and light-about the size of a portable radio.

8. We will turn on the air pump, and you will put on your safety glasses. We will give you a string mop and a bucket containing the already diluted SANI-CARE LEMON QUAT solution, and ask you to start mopping the floor the way you normally do on your job. A researcher will watch you as you work, keeping track of how long you work and how much floor you mop, and may take pictures or video.

9. We will give you a bucket with fresh cleaning solution every 15 minutes, or more often if you ask for it.

10. After you've been mopping for 30 minutes, the researcher will rinse your hands with a solution of rubbing alcohol and water, and save the rinse solution for analysis. You will then have a 10-minute rest period. You will

not be permitted to smoke during this rest period, but you may eat (if you wash your hands with Ivory soap and water following eating) and are encouraged to drink lots of fluids. You can rest more often if you need to, but before each rest period, the researcher will rinse your hands and save the rinse solution. Depending on which group you are assigned to, you may be asked to continue mopping for up to 2 more 30 minute periods of mopping, for a total of 90 minutes, each followed by a 10 minute break.

11. When you finish mopping, a researcher of your own sex will take you back to the changing area to collect additional samples and remove the special underwear and other clothing. Samples will be collected in this order:

    a. The air sampling pump and the sampling tube will be removed and saved for analysis.

    b. The researcher will rinse your hands with a solution of rubbing alcohol and water for the last time, and save the rinse solution.

    c. The researcher will wipe your face and neck with rubbing alcohol with water moistened pads, to collect any of the mopping solution that might be on your skin, and save the pads for analysis

    d. The researcher will help you take off the outer shirt and pants, and will save each garment for analysis.

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

    f. The researchers will help you remove your shoes and will save the socks for analysis.

12. You will then be asked to put on a set of new cotton long underwear (long Johns), long sleeved cotton shirt, long cotton pants, and cotton socks as described under Point 4 to 7. We will turn on the air pump, and you will put on your safety glasses. You will be asked to empty the buckets containing the diluted SANI-CARE LEMON QUAT solution. If you mopped for 30 minutes, you will have to empty at least 2 buckets. If you mopped for 90 minutes, you will have to empty at least 6 buckets.

13. When you finish emptying the buckets, a researcher of your own sex will take you back to the changing area to remove the special underwear and other clothing and collect the samples as described under Point 11.

14. When all samples have been collected, you will dress again in your street clothes and may take the shoes you wore on study, if you wish.

15. Dr. Selim will check your hands before you leave for redness or other signs of irritation. You will be paid for you time and trouble in cash, and will be free to go.

Risks

Potential risks to you in this study are of several different kinds:

- Risk of a reaction to the test material. EPA requires that the label for the concentrated SANI-CARE LEMON QUAT product bear the signal word "Danger." Direct contact with the concentrated product could damage your eyes permanently, could irritate your skin, and could harm you if you breathe it in. But in this research you will never handle the concentrated product, since it will already be mixed with water in the buckets that are provided to you. You will also be wearing safety glasses to keep the mopping water out of your eyes, and long sleeves, pants, and socks to keep it off your skin. It isn't expected, but you might possibly have an allergic reaction to the mopping water, or it might interact with medicines you are taking. If you have had an allergic reaction to a cleaning product before, or if you are taking medicine, be sure to tell the researchers before you sign this form. The risk of a reaction to the test material is low, but if you do notice any redness or itching or other discomfort, or if you think you may have gotten some of the mopping water in your eye, stop mopping immediately and tell a researcher. A copy of the product label and the Material Safety Data Sheet (MSDS) for SANI-CARE LEMON QUAT will be given to you for reference. A person will be available to help explain these documents to you (in either English or Spanish) and to answer any questions you may have.

- Risk of over-exertion and stroke or heart attack. Mopping continually for 30 minutes is hard physical labor. If you are not in good physical condition, this much work may be dangerous to your health.

- Risk of discomfort. The air pump you will be wearing on your belt and the air hose used to sample the air you breathe may be awkward or uncomfortable for you. Wearing two layers of clothing may also be uncomfortable.

- 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.

- Because you'll be wearing two complete layers of clothing there is a small possibility that you might experience heat stress. The researchers will monitor the temperature and humidity at the test location, and will stop the study if it gets too hot to be safe. If you feel at all faint or overheated, or

are sweating heavily, stop mopping and tell a member of the research team immediately.

- Risk of embarrassment. You may find it embarrassing to have a researcher present with you while you change clothes. This is necessary to make sure the special underwear fits properly, and that it and the outer clothing do not 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 be wearing your own underwear all the time.

- If you are a female, you might be surprised to learn the results of the required pregnancy test on the day of the research. No-one but you and one female researcher will know those results, and they will not be recorded.

Pregnancy Risks

We don't know the risks to the unborn from exposure to SANI-CARE LEMON QUAT, so it is important that you do NOT participate in this study if you are pregnant. That's why on the day of the test all female volunteers under 50 will be given a pregnancy test kit like 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 continue in the study or withdraw; if you decide to withdraw, you won't be asked why. You'll be paid for the inconvenience of coming to the test location, and then you'll be free to go. If you want to continue in the study, a female researcher trained to understand the results of this pregnancy test will check the results with you privately. No-one but you and she will see the results, and they will not be recorded.

Unknown/Unforeseeable Risks

In addition to the risks listed above, there may be some other unknown or unforeseen risks associated with the use of this pesticide, including the possibility of an allergic reaction or interaction with a medication.

Research-Related Injuries

If you are injured as a result of being in this study, medical treatment will be available from a near-by health care facility that knows about this study. The people who are paying for this study will pay any costs of your medical treatment that are not covered by your own insurance or by a third party. If necessary, Golden Pacific Laboratories will transport you to receive medical attention and pay costs associated with reasonable and appropriate treatment for any injuries you get as a result of participating in this study. For more information, or if you think you may have been injured during the research, call Dr. Selim at Golden Pacific Laboratories (559 275-9091).

Alternatives to Participation

If you decide to participate 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

There are no direct benefits to you from your participation. Because what we learn from this study will be used to make sure cleaning products like SANI-CARE LEMON QUAT can be used safely, you and other people who do janitorial work may benefit indirectly from the research. You may benefit if you request results from this study that let you know how your exposure compared to other workers doing your job. The people who are paying for the study will also benefit, since they need to do this study to be able 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. If you have any questions or problems during the study, ask Dr. Selim or any other member of the research team.

As a research volunteer, you have rights. They are spelled out in the attached "Research Subject's Bill of Rights." If you have any questions about your rights as a research volunteer, call Kim Lerner, Chairman of the Independent Investigational Review Board, Inc. toll free at (877-888-4472) during regular working hours. The Independent Investigational Review Board is a committee established to protect the rights of research volunteers. The Independent Investigational Review Board has reviewed and approved the plans for this study and this informed consent document.

Costs and Reimbursement

There will be no cost to you to participate in this study. If you are selected to participate in the study, you will receive $100 in cash at the end of the day of the study, or whenever you withdraw. If you are designated as an alternate subject, you will receive a payment of $50 in cash for your inconvenience in coming to the study location.

Confidentiality

Each volunteer will be assigned an identification number, and all research data will be recorded under that number. All analysis and reporting will be done using data identified only by the identification number. Your name will appear only in the field raw data, and there only once. The document linking your name to the identification number will be stored separately, in a locked cabinet, away from all

other study data. You will not be identified by name or any other personal identifier in any reports of this study.

Golden Pacific Laboratories will retain the records of this study indefinitely. You may obtain a copy of your own records by asking Dr. Selim for it. Representatives from the Sponsor (AEATF II), the U.S. Environmental Protection Agency (EPA), the California Department of Pesticide Regulation, and the Independent Investigational Review Board, Inc., may have access to all non-personal information collected in this study. Because information from this study may be released to these parties, absolute confidentiality cannot be guaranteed.

Right to Withdraw

You are free to withdraw from this study at any time, for any reason. Simply tell Dr. Selim or another member of the research team if you wish to withdraw. Your decision not to participate in this study or to withdraw from this study will not affect your future medical care and will involve no penalty or loss of benefits to which you are otherwise entitled.

Removal from Study

Dr. Selim, the Principal Investigator in charge of this study, can remove you from this study without your consent. He might do this if, for example:

- He thinks staying in the study could put you at risk,
- You fail to follow the instructions of the researchers,
- The temperature and humidity at the test site get so high it would be dangerous to continue the test, or
- The study is stopped for other reasons.

If you are removed from the study, or if the entire study is stopped, you are still entitled to compensation for your time and inconvenience.

Consent and Signature

I have read this Informed Consent Form in [English/Spanish]. I have received satisfactory answers to all of my questions. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this Informed Consent Form. I shall receive a 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 my presence. I have faithfully translated all questions from the volunteer and all the answers provided by the researchers. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____
Translator's Signature

_____
Translator'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

APPENDIX C

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)*, if you have a question about your rights as a research subject.

If I have other questions, I should ask the Principal Investigator or Field Coordinator.

Phone contacts:
Field Coordinator, Tami Belcher: 974-5982
Principal Investigator, Sami Selim: 275-9091

APPENDIX D

SUBJECT SELF-REPORTING DEMOGRAPHIC FORM

Volunteer Name _____

Street Address_____

City, State, Zip Code _____

Telephone number(s)_____

Current age _____ yrs Sex Male Female

Weight _____ lbs Height _____ ft _____ inches

Shirt size: Small Medium Large X Large XX Large XXX Large
Pant size: Small Medium Large X Large XX Large XXX Large
Shoe size: _____(specify)

Years experience mopping indoor surfaces _____

How often do you mop? _____ per week month

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

APPENDIX E

MSDS FOR SANI-CARE LEMON QUAT

Buckeye International, Inc.
2700 Wagner Place
Maryland Heights, MO 63043
314/291-1900

N. F. P. A.
4 = Extreme
3 = High
2 = Moderate
1 = Slight
0 = Insignificant

HEALTH	3
FIRE	0
REACTIVITY	0

Material Safety Data Sheet

24 Hour Medical Emergency Telephone Number: 1-800-303-0441. Outside North America call : 651-632-8956.
24 Hour Transportation Emergency Telephone Number: 1-800-535-5053. Outside North America call : 352-323-3500.

SECTION I - IDENTIFICATION

PRODUCT NAME: BUCKEYE SANICARE LEMON QUAT	DATE PREPARED: April 1, 2005
CHEMICAL FAMILY: Cleaner Disinfectant, Water Based	CODE: 5076
PROPER D.O.T. SHIPPING NAME	Disinfectant, Liquid, NOIBN
D.O.T. HAZARD CLASSIFICATION	None

SECTION II - INGREDIENTS AND IDENTITY INFORMATION

% By WGT	MATERIAL	PEL	T.L.V.	C.A.S. NO.
4.23	Blend of Didecyl Dimethyl and n-Alkyl	NE	NE	7173-51-5
	Dimethyl Benzyl Ammoniun Chlorides			8001-54-5
>90.77	Soft Water	NE	NE	7732-18-5
<4.0	Octyl Dimethyl Amine Oxide	NE	NE	2605-78-9
<1.0	Perfume, coloring and additives less than 1%	NA	NA	NA

ITEMS MARKED * ARE SARA TITLE III SEC 313 REPORTABLES. ALL INGREDIENTS ARE ON TSCA INVENTORY.

SECTION III - PHYSICAL DATA

BOILING POINT °F	212°F	pH (CONC.)	7.6 ± 0.2
SOLUBILITY IN WATER	Infinite	pH (USE DILUTION) 1:64	7.0 ± 0.2
% VOLATILE BY WEIGHT	93.0	EVAPORATION RATE (Water=1)	1.0
SPECIFIC GRAVITY	1.00	PRODUCT FORM	Liquid
APPEARANCE AND ODOR	Lemon, Clear Yellow Solution		

SECTION IV - FIRE AND EXPLOSION DATA

FLASH POINT(Test Method)	Tag Closed Cup: None!	FLAMMABLE LIMITS	
EXTINGUISHING MEDIA	NA	UPPER LIMIT: NA	LOWER LIMIT: NA
SPECIAL FIRE FIGHTING PROCEDURES	None		
UNUSUAL FIRE AND EXPLOSION HAZARDS	Products of combustion. Oxides of carbon and nitrogen.		

SECTION V - REACTIVITY DATA

STABILITY	Stable
CONDITIONS TO AVOID	None known.
INCOMPATIBILITY	Do not mix with chlorine bleach or anionic detergents.
HAZARDOUS DECOMPOSITION PRODUCTS	None known.
HAZARDOUS POLYMERIZATION	Will not occur.

CODE: 5076

SECTION VI - HEALTH HAZARD DATA

ROUTE(S) OF ENTRY: INHALATION? Yes SKIN? Yes INGESTION? No

HEALTH HAZARDS (Acute and Chronic)

Corrosive - causes irreversible eye damage. Causes skin irritation. Harmful if inhaled.

CARCINOGENICITY: NTP? No IARC MONOGRAPHS? No OSHA REGULATED? No

SIGNS AND SYMPTOMS OF OVEREXPOSURE

For Eyes: Redness or burning sensation.
For Skin: Redness of skin or a warming sensation.

MEDICAL CONDITIONS
GENERALLY AGGRAVATED BY EXPOSURE

None known.

EMERGENCY AND FIRST AID PROCEDURES

Call a poison control center or doctor immediately for treatment advice. For Eyes and Skin: In case of contact, immediately flush eyes or skin with plenty of water for 15 - 20 minutes. For Inhalation: Move person to fresh air. If person is not breathing, call 911 or an ambulance and then give artificial respiration. For Ingestion: Give two large glasses of water. DO NOT induce vomiting. Never give anything by mouth to an unconscious person. Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

SECTION VII - SPILL OR LEAK PROCEDURES

SPILL RESPONSE

Pick up with mop, wet/dry vac or absorbent material. Rinse area with clear water and allow floor to dry before allowing traffic.

WASTE DISPOSAL
METHOD Flush to sanitary sewer or send to sanitary landfill, following local, state and federal laws.

SECTION VIII - SPECIAL PROTECTION INFORMATION

EYE PROTECTION	Wear safety glasses or chemical splash goggles.	VENTILATION	Normal room ventilation.
SKIN PROTECTION	Rubber gloves or other impervious gloves.	RESPIRATORY PROTECTION	Avoid breathing spray mist.
OTHER PROTECTION	Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.		

SECTION IX - SPECIAL PRECAUTIONS

PRECAUTIONS IN HANDLING AND STORAGE	**KEEP OUT OF REACH OF CHILDREN!** Rinse container before discarding. Keep container closed when not in use. Store at room temperature.
OTHER PRECAUTIONS NA = Not Applicable NE = Not Established	This product is not regulated under CERCLA or RCRA. If more than 10,000 lbs. are stored in a single day, product may require reporting under SARA Title III, Section 311/312 as an immediate health hazard.

PREPARED BY: Mark Gindling, Director of Research

Disclaimer of Liability

As the conditions or methods of use are beyond our control, we do not assume any responsibility and expressly disclaim any liability for any use of the material. Information contained herein is believed to be true and accurate but all statements or suggestions are made without any warranty, expressed or implied, regarding accuracy of the information, the hazards connected with the use of the material or the results to be obtained from the use thereof. Conforms to OSHA 174, Sept 1985.

APPENDIX F

FLYER SOLICITING RESEARCH SUBJECTS

Research Study Volunteers

The Antimicrobial Exposure Assessment Task Force II (AEATF II) is a group of companies that make antimicrobial cleaning products, doing research to measure how much chemical gets on workers when they use antimicrobial products. We are looking for experienced janitorial workers to do their usual work and let us collect exposure data.

To volunteer you must be:	You are not qualified if you:
• At least 18 years old, but less than 65 • Able to read and speak English or Spanish • In good health • Male or non pregnant, non or nursing female • Experienced and trained in using antimicrobial cleaning products	• 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

You will be asked to do the following:

- Let us monitor you as you do your work for a day, mopping floors and emptying the bucket, using a bucket and string mop
- Sign a consent form before participating (in English or Spanish)
- Wear cotton socks, long underwear under cotton pants and shirt, and shoes 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 periodically with rubbing alcohol (see picture)
- Wear a small air sampler 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 in reducing risks to janitorial workers.

If you are interested,

please contact the Field Coordinator

for English:

Tami Belcher

974-5982

or for Spanish:

275-9091

They can answer any of your questions

APPENDIX G

JANITORIAL SERVICE CONTACT SCRIPT

and

SUBJECT INVITATION TO PARTICIPATE SCRIPT

For English speaking employers -

Introduction

My name is [ ] and I work with Grayson Research. I found your name and number in the phone book *-or-* I was given your name and number by _____ *-or-* I saw your sign on your vehicle *-or-* however the janitorial business came to our attention.

My company has been hired by a group of companies who manufacture and market professional cleaning products to conduct research on a typical cleaning worker's exposure to commercially available cleaning products.

We would like to talk with professional cleaners to see if they would be interested in participating in a study which involves measuring how much product gets on their clothes and skin when cleaning floors using a bucket and string mop.

This study would be conducted outside normal working hours and does not involve your company in any way. I am calling to ask if it would be possible to post a flyer in your place of business which mentions the study and asks anyone interested to contact us directly during non-working hours.

[If yes, appointment made to drop off and post the flyer]

[If no]

I understand. I can provide you with the name and number of the Principal Investigator if you have any questions you'd like to have answered before deciding.

[If still no]

I understand. Can you suggest other cleaning firms I might contact, or suggest a place I might post a flyer that would be seen by professional cleaners? [Document their response for decision if/how to follow-up by Principal Investigator]. Thank you for your time.

[If express interest in further discussion/answering of questions, provide the name and telephone number of Dr. Sami Selim.]

For English speaking potential subjects – Spanish speaking potential subjects will request the person identified in the flyer as the Spanish-speaker contact

Are you calling about the cleaning study?

If yes, ask if they found out about the study by flyer or word of mouth and document response.

Ask the potential subject if he/she would like to receive information on the project.

(If yes, follow with introduction)

Introduction

My name is [ ] and I work with Grayson Research. We are conducting research to find out how much cleaning solution may reach your skin when you clean floors using a bucket and string mop. We will measure how much of the cleaning solution gets on the clothing you wear during the study, on your hands, feet, face and neck, and how much is in the air you breathe while you clean the floors.

The material being tested in this study is a product called SANI-CARE LEMON QUAT, a product used to mop floors.

The project itself will take about 4 to 6 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 mop floors for a period of time between 30 minutes and 90 minutes. You will then give the special clothing to the research team and wear a new set of special clothing and empty the buckets. 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 under age 65 and able to read either English or Spanish.

Would you like to receive additional information on the project?
(If no, thank them for their time.)

(If yes, instruct them to do the following)

If you would like to participate in the project, you will 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. We can make arrangements to meet with you on the weekend as well. The office is just off of Shaw Avenue behind Costco. Dr. Selim will go over the study in great detail and will answer all your questions regarding the study, and will 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.)

APPENDIX H
Community Involvement Flyer

NOTICE

Over the next few weeks you may observe some unusual activity in the vacant building/shop 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 cleaning products very similar to the ones you may use in your home or business. This project will last about one month. 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 (275-9100)
Or
Dr. Has Shah at the American Chemistry Council (703 741-5637)

APPENDIX I
LEMON QUAT CONCENTRATE

APPENDIX J

EPA EXECUTIVE SUMMARIES from ADBAC and DDAC REDs

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

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 then 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 can not 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

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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 then 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 can not 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 K

FIELD SAMPLE IDENTIFICATION CODES

Field Sample Identification Codes

Sample ID Number	Description
AEA03-MW-01-ID-LA	Mop worker sample, rep 01, inner dosimeter, lower arms
AEA03-MW-01-ID-UA	Mop worker sample, rep 01, inner dosimeter, upper arms
AEA03-MW-01-ID-FT	Mop worker sample, rep 01, inner dosimeter, front torso
AEA03-MW-01-ID-RT	Mop worker sample, rep 01, inner dosimeter, rear torso
AEA03-MW-01-ID-LL	Mop worker sample, rep 01, inner dosimeter, lower legs
AEA03-MW-01-ID-UL	Mop worker sample, rep 01, inner dosimeter, upper legs
AEA03-MW-01-OD-LA	Mop worker sample, rep 01, outer dosimeter, lower arms
AEA03-MW-01-OD-UA	Mop worker sample, rep 01, outer dosimeter, upper arms
AEA03-MW-01-OD-FT	Mop worker sample, rep 01, outer dosimeter, front torso
AEA03-MW-01-OD-RT	Mop worker sample, rep 01, outer dosimeter, rear torso
AEA03-MW-01-OD-LL	Mop worker sample, rep 01, outer dosimeter, lower legs
AEA03-MW-01-OD-UL	Mop worker sample, rep 01, outer dosimeter, upper legs
AEA03-MW-01-IS-01	Mop worker sample, rep 01, inner socks
AEA03-MW-01-OS-01	Mop worker sample, rep 01, outer socks
AEA03-MW-01-AR-01	Mop worker sample, rep 01, air sampling tube
AEA03-MW-01-FW-01	Mop worker sample, rep 01, face/neck wipes
AEA03-MW-01-HW-01	Mop worker sample, rep 01, 1st interim hand wash
AEA03-MW-01-HW-02	Mop worker sample, rep 01, 2nd interim hand wash
AEA03-MW-01-HW-03	Mop worker sample, rep 01, 3rd interim hand wash
AEA03-MW-01-HW-04	Mop worker sample, rep 01, 4th interim hand wash
AEA03-MW-01-HW-FR	Mop worker sample, rep 01, final hand wash
AEA03-MW-01-DM-01	Mop worker sample, rep 01, 1st diluted material aliquot
AEA03-MW-01-DM-02	Mop worker sample, rep 01, 2nd diluted material aliquot
AEA03-MW-01-DM-03	Mop worker sample, rep 01, 3rd diluted material aliquot
AEA03-MW-01-DM-04	Mop worker sample, rep 01, 4th diluted material aliquot
AEA03-MW-01-DM-05	Mop worker sample, rep 01, 5th diluted material aliquot
AEA03-MW-01-DM-06	Mop worker sample, rep 01, 6th diluted material aliquot
AEA03-PW-01-ID-LA	Pour worker sample, rep 01, inner dosimeter, lower arms
AEA03-PW-01-ID-UA	Pour worker sample, rep 01, inner dosimeter, upper arms
AEA03-PW-01-ID-FT	Pour worker sample, rep 01, inner dosimeter, front torso
AEA03-PW-01-ID-RT	Pour worker sample, rep 01, inner dosimeter, rear torso
AEA03-PW-01-ID-LL	Pour worker sample, rep 01, inner dosimeter, lower legs
AEA03-PW-01-ID-UL	Pour worker sample, rep 01, inner dosimeter, upper legs
AEA03-PW-01-OD-LA	Pour worker sample, rep 01, outer dosimeter, lower arms
AEA03-PW-01-OD-UA	Pour worker sample, rep 01, outer dosimeter, upper arms
AEA03-PW-01-OD-FT	Pour worker sample, rep 01, outer dosimeter, front torso
AEA03-PW-01-OD-RT	Pour worker sample, rep 01, outer dosimeter, rear torso
AEA03-PW-01-OD-LL	Pour worker sample, rep 01, outer dosimeter, lower legs
AEA03-PW-01-OD-UL	Pour worker sample, rep 01, outer dosimeter, upper legs

Exposure Samples (continued)

Sample ID Number	Description
AEA03-PW-01-IS-01	Pour worker sample, rep 01, inner socks
AEA03-PW-01-OS-01	Pour worker sample, rep 01, outer socks
AEA03-PW-01-AR-01	Pour worker sample, rep 01, air sampling tube
AEA03-PW-01-FW-01	Pour worker sample, rep 01, face/neck wipes
AEA03-PW-01-HW-FR	Pour worker sample, rep 01, hand wash
AEA03-MW-02-ID-LA	Mop worker sample, rep 02, inner dosimeter, lower arms
AEA03-MW-02-ID-UA	Mop worker sample, rep 02, inner dosimeter, upper arms
AEA03-MW-02-ID-FT	Mop worker sample, rep 02, inner dosimeter, front torso
AEA03-MW-02-ID-RT	Mop worker sample, rep 02, inner dosimeter, rear torso
AEA03-MW-02-ID-LL	Mop worker sample, rep 02, inner dosimeter, lower legs
AEA03-MW-02-ID-UL	Mop worker sample, rep 02, inner dosimeter, upper legs
AEA03-MW-02-OD-LA	Mop worker sample, rep 02, outer dosimeter, lower arms
AEA03-MW-02-OD-UA	Mop worker sample, rep 02, outer dosimeter, upper arms
AEA03-MW-02-OD-FT	Mop worker sample, rep 02, outer dosimeter, front torso
AEA03-MW-02-OD-RT	Mop worker sample, rep 02, outer dosimeter, rear torso
AEA03-MW-02-OD-LL	Mop worker sample, rep 02, outer dosimeter, lower legs
AEA03-MW-02-OD-UL	Mop worker sample, rep 02, outer dosimeter, upper legs
AEA03-MW-02-IS-01	Mop worker sample, rep 02, inner socks
AEA03-MW-02-OS-01	Mop worker sample, rep 02, outer socks
AEA03-MW-02-AR-01	Mop worker sample, rep 02, air sampling tube
AEA03-MW-02-FW-01	Mop worker sample, rep 02, face/neck wipes
AEA03-MW-02-HW-01	Mop worker sample, rep 02, 1st interim hand wash
AEA03-MW-02-HW-02	Mop worker sample, rep 02, 2nd interim hand wash
AEA03-MW-02-HW-03	Mop worker sample, rep 02, 3rd interim hand wash
AEA03-MW-02-HW-04	Mop worker sample, rep 02, 4th interim hand wash
AEA03-MW-02-HW-FR	Mop worker sample, rep 02, final hand wash
AEA03-MW-02-DM-01	Mop worker sample, rep 02, 1st diluted material aliquot
AEA03-MW-02-DM-02	Mop worker sample, rep 02, 2nd diluted material aliquot
AEA03-MW-02-DM-03	Mop worker sample, rep 02, 3rd diluted material aliquot
AEA03-MW-02-DM-04	Mop worker sample, rep 02, 4th diluted material aliquot
AEA03-MW-02-DM-05	Mop worker sample, rep 02, 5th diluted material aliquot
AEA03-MW-02-DM-06	Mop worker sample, rep 02, 6th diluted material aliquot
AEA03-PW-02-ID-LA	Pour worker sample, rep 02, inner dosimeter, lower arms
AEA03-PW-02-ID-UA	Pour worker sample, rep 02, inner dosimeter, upper arms
AEA03-PW-02-ID-FT	Pour worker sample, rep 02, inner dosimeter, front torso
AEA03-PW-02-ID-RT	Pour worker sample, rep 02, inner dosimeter, rear torso
AEA03-PW-02-ID-LL	Pour worker sample, rep 02, inner dosimeter, lower legs
AEA03-PW-02-ID-UL	Pour worker sample, rep 02, inner dosimeter, upper legs

Exposure Samples (continued)

Sample ID Number	Description
AEA03-PW-02-OD-LA	Pour worker sample, rep 02, outer dosimeter, lower arms
AEA03-PW-02-OD-UA	Pour worker sample, rep 02, outer dosimeter, upper arms
AEA03-PW-02-OD-FT	Pour worker sample, rep 02, outer dosimeter, front torso
AEA03-PW-02-OD-RT	Pour worker sample, rep 02, outer dosimeter, rear torso
AEA03-PW-02-OD-LL	Pour worker sample, rep 02, outer dosimeter, lower legs
AEA03-PW-02-OD-UL	Pour worker sample, rep 02, outer dosimeter, upper legs
AEA03-PW-02-IS-01	Pour worker sample, rep 02, inner socks
AEA03-PW-02-OS-01	Pour worker sample, rep 02, outer socks
AEA03-PW-02-AR-01	Pour worker sample, rep 02, air sampling tube
AEA03-PW-02-FW-01	Pour worker sample, rep 02, face/neck wipes
AEA03-PW-02-HW-FR	Pour worker sample, rep 02, hand wash
AEA03-MW-03-ID-LA	Mop worker sample, rep 03, inner dosimeter, lower arms
AEA03-MW-03-ID-UA	Mop worker sample, rep 03, inner dosimeter, upper arms
AEA03-MW-03-ID-FT	Mop worker sample, rep 03, inner dosimeter, front torso
AEA03-MW-03-ID-RT	Mop worker sample, rep 03, inner dosimeter, rear torso
AEA03-MW-03-ID-LL	Mop worker sample, rep 03, inner dosimeter, lower legs
AEA03-MW-03-ID-UL	Mop worker sample, rep 03, inner dosimeter, upper legs
AEA03-MW-03-OD-LA	Mop worker sample, rep 03, outer dosimeter, lower arms
AEA03-MW-03-OD-UA	Mop worker sample, rep 03, outer dosimeter, upper arms
AEA03-MW-03-OD-FT	Mop worker sample, rep 03, outer dosimeter, front torso
AEA03-MW-03-OD-RT	Mop worker sample, rep 03, outer dosimeter, rear torso
AEA03-MW-03-OD-LL	Mop worker sample, rep 03, outer dosimeter, lower legs
AEA03-MW-03-OD-UL	Mop worker sample, rep 03, outer dosimeter, upper legs
AEA03-MW-03-IS-01	Mop worker sample, rep 03, inner socks
AEA03-MW-03-OS-01	Mop worker sample, rep 03, outer socks
AEA03-MW-03-AR-01	Mop worker sample, rep 03, air sampling tube
AEA03-MW-03-FW-01	Mop worker sample, rep 03, face/neck wipes
AEA03-MW-03-HW-01	Mop worker sample, rep 03, 1st interim hand wash
AEA03-MW-03-HW-02	Mop worker sample, rep 03, 2nd interim hand wash
AEA03-MW-03-HW-03	Mop worker sample, rep 03, 3rd interim hand wash
AEA03-MW-03-HW-04	Mop worker sample, rep 03, 4th interim hand wash
AEA03-MW-03-HW-FR	Mop worker sample, rep 03, final hand wash
AEA03-MW-03-DM-01	Mop worker sample, rep 03, 1st diluted material aliquot
AEA03-MW-03-DM-02	Mop worker sample, rep 03, 2nd diluted material aliquot
AEA03-MW-03-DM-03	Mop worker sample, rep 03, 3rd diluted material aliquot
AEA03-MW-03-DM-04	Mop worker sample, rep 03, 4th diluted material aliquot
AEA03-MW-03-DM-05	Mop worker sample, rep 03, 5th diluted material aliquot
AEA03-MW-03-DM-06	Mop worker sample, rep 03, 6th diluted material aliquot

Exposure Samples (continued)

Sample ID Number	Description
AEA03-PW-03-ID-LA	Pour worker sample, rep 03, inner dosimeter, lower arms
AEA03-PW-03-ID-UA	Pour worker sample, rep 03, inner dosimeter, upper arms
AEA03-PW-03-ID-FT	Pour worker sample, rep 03, inner dosimeter, front torso
AEA03-PW-03-ID-RT	Pour worker sample, rep 03, inner dosimeter, rear torso
AEA03-PW-03-ID-LL	Pour worker sample, rep 03, inner dosimeter, lower legs
AEA03-PW-03-ID-UL	Pour worker sample, rep 03, inner dosimeter, upper legs
AEA03-PW-03-OD-LA	Pour worker sample, rep 03, outer dosimeter, lower arms
AEA03-PW-03-OD-UA	Pour worker sample, rep 03, outer dosimeter, upper arms
AEA03-PW-03-OD-FT	Pour worker sample, rep 03, outer dosimeter, front torso
AEA03-PW-03-OD-RT	Pour worker sample, rep 03, outer dosimeter, rear torso
AEA03-PW-03-OD-LL	Pour worker sample, rep 03, outer dosimeter, lower legs
AEA03-PW-03-OD-UL	Pour worker sample, rep 03, outer dosimeter, upper legs
AEA03-PW-03-IS-01	Pour worker sample, rep 03, inner socks
AEA03-PW-03-OS-01	Pour worker sample, rep 03, outer socks
AEA03-PW-03-AR-01	Pour worker sample, rep 03, air sampling tube
AEA03-PW-03-FW-01	Pour worker sample, rep 03, face/neck wipes
AEA03-PW-03-HW-FR	Pour worker sample, rep 03, hand wash
AEA03-MW-04-ID-LA	Mop worker sample, rep 04, inner dosimeter, lower arms
AEA03-MW-04-ID-UA	Mop worker sample, rep 04, inner dosimeter, upper arms
AEA03-MW-04-ID-FT	Mop worker sample, rep 04, inner dosimeter, front torso
AEA03-MW-04-ID-RT	Mop worker sample, rep 04, inner dosimeter, rear torso
AEA03-MW-04-ID-LL	Mop worker sample, rep 04, inner dosimeter, lower legs
AEA03-MW-04-ID-UL	Mop worker sample, rep 04, inner dosimeter, upper legs
AEA03-MW-04-OD-LA	Mop worker sample, rep 04, outer dosimeter, lower arms
AEA03-MW-01-OD-UA	Mop worker sample, rep 04, outer dosimeter, upper arms
AEA03-MW-04-OD-FT	Mop worker sample, rep 04, outer dosimeter, front torso
AEA03-MW-04-OD-RT	Mop worker sample, rep 04, outer dosimeter, rear torso
AEA03-MW-04-OD-LL	Mop worker sample, rep 04, outer dosimeter, lower legs
AEA03-MW-04-OD-UL	Mop worker sample, rep 04, outer dosimeter, upper legs
AEA03-MW-04-IS-01	Mop worker sample, rep 04, inner socks
AEA03-MW-04-OS-01	Mop worker sample, rep 04, outer socks
AEA03-MW-04-AR-01	Mop worker sample, rep 04, air sampling tube
AEA03-MW-04-FW-01	Mop worker sample, rep 04, face/neck wipes
AEA03-MW-04-HW-01	Mop worker sample, rep 04, 1st interim hand wash
AEA03-MW-04-HW-02	Mop worker sample, rep 04, 2nd interim hand wash
AEA03-MW-04-HW-03	Mop worker sample, rep 04, 3rd interim hand wash
AEA03-MW-04-HW-04	Mop worker sample, rep 04, 4th interim hand wash
AEA03-MW-04-HW-FR	Mop worker sample, rep 04, final hand wash

Exposure Samples (continued)

Sample ID Number	Description
AEA03-MW-04-DM-01	Mop worker sample, rep 04, 1st diluted material aliquot
AEA03-MW-04-DM-02	Mop worker sample, rep 04, 2nd diluted material aliquot
AEA03-MW-04-DM-03	Mop worker sample, rep 04, 3rd diluted material aliquot
AEA03-MW-04-DM-04	Mop worker sample, rep 04, 4th diluted material aliquot
AEA03-MW-04-DM-05	Mop worker sample, rep 04, 5th diluted material aliquot
AEA03-MW-04-DM-06	Mop worker sample, rep 04, 6th diluted material aliquot
AEA03-PW-04-ID-LA	Pour worker sample, rep 04, inner dosimeter, lower arms
AEA03-PW-04-ID-UA	Pour worker sample, rep 04, inner dosimeter, upper arms
AEA03-PW-04-ID-FT	Pour worker sample, rep 04, inner dosimeter, front torso
AEA03-PW-04-ID-RT	Pour worker sample, rep 04, inner dosimeter, rear torso
AEA03-PW-04-ID-LL	Pour worker sample, rep 04, inner dosimeter, lower legs
AEA03-PW-04-ID-UL	Pour worker sample, rep 04, inner dosimeter, upper legs
AEA03-PW-04-OD-LA	Pour worker sample, rep 04, outer dosimeter, lower arms
AEA03-PW-04-OD-UA	Pour worker sample, rep 04, outer dosimeter, upper arms
AEA03-PW-04-OD-FT	Pour worker sample, rep 04, outer dosimeter, front torso
AEA03-PW-04-OD-RT	Pour worker sample, rep 04, outer dosimeter, rear torso
AEA03-PW-04-OD-LL	Pour worker sample, rep 04, outer dosimeter, lower legs
AEA03-PW-04-OD-UL	Pour worker sample, rep 04, outer dosimeter, upper legs
AEA03-PW-04-IS-01	Pour worker sample, rep 04, inner socks
AEA03-PW-04-OS-01	Pour worker sample, rep 04, outer socks
AEA03-PW-04-AR-01	Pour worker sample, rep 04, air sampling tube
AEA03-PW-04-FW-01	Pour worker sample, rep 04, face/neck wipes
AEA03-PW-04-HW-FR	Pour worker sample, rep 04, hand wash
AEA03-MW-05-ID-LA	Mop worker sample, rep 05, inner dosimeter, lower arms
AEA03-MW-05-ID-UA	Mop worker sample, rep 05, inner dosimeter, upper arms
AEA03-MW-05-ID-FT	Mop worker sample, rep 05, inner dosimeter, front torso
AEA03-MW-05-ID-RT	Mop worker sample, rep 05, inner dosimeter, rear torso
AEA03-MW-05-ID-LL	Mop worker sample, rep 05, inner dosimeter, lower legs
AEA03-MW-05-ID-UL	Mop worker sample, rep 05, inner dosimeter, upper legs
AEA03-MW-05-OD-LA	Mop worker sample, rep 05, outer dosimeter, lower arms
AEA03-MW-05-OD-UA	Mop worker sample, rep 05, outer dosimeter, upper arms
AEA03-MW-05-OD-FT	Mop worker sample, rep 05, outer dosimeter, front torso
AEA03-MW-05-OD-RT	Mop worker sample, rep 05, outer dosimeter, rear torso
AEA03-MW-05-OD-LL	Mop worker sample, rep 05, outer dosimeter, lower legs
AEA03-MW-01-OD-UL	Mop worker sample, rep 05, outer dosimeter, upper legs
AEA03-MW-05-IS-01	Mop worker sample, rep 05, inner socks
AEA03-MW-05-OS-01	Mop worker sample, rep 05, outer socks
AEA03-MW-05-AR-01	Mop worker sample, rep 05, air sampling tube

Exposure Samples (continued)

Sample ID Number	Description
AEA03-MW-05-FW-01	Mop worker sample, rep 05, face/neck wipes
AEA03-MW-05-HW-01	Mop worker sample, rep 05, 1st interim hand wash
AEA03-MW-05-HW-02	Mop worker sample, rep 05, 2nd interim hand wash
AEA03-MW-05-HW-03	Mop worker sample, rep 05, 3rd interim hand wash
AEA03-MW-05-HW-04	Mop worker sample, rep 05, 4th interim hand wash
AEA03-MW-05-HW-FR	Mop worker sample, rep 05, final hand wash
AEA03-MW-05-DM-01	Mop worker sample, rep 05, 1st diluted material aliquot
AEA03-MW-05-DM-02	Mop worker sample, rep 05, 2nd diluted material aliquot
AEA03-MW-05-DM-03	Mop worker sample, rep 05, 3rd diluted material aliquot
AEA03-MW-05-DM-04	Mop worker sample, rep 05, 4th diluted material aliquot
AEA03-MW-05-DM-05	Mop worker sample, rep 05, 5th diluted material aliquot
AEA03-MW-05-DM-06	Mop worker sample, rep 05, 6th diluted material aliquot
AEA03-PW-05-ID-LA	Pour worker sample, rep 05, inner dosimeter, lower arms
AEA03-PW-05-ID-UA	Pour worker sample, rep 05, inner dosimeter, upper arms
AEA03-PW-05-ID-FT	Pour worker sample, rep 05, inner dosimeter, front torso
AEA03-PW-05-ID-RT	Pour worker sample, rep 05, inner dosimeter, rear torso
AEA03-PW-05-ID-LL	Pour worker sample, rep 05, inner dosimeter, lower legs
AEA03-PW-05-ID-UL	Pour worker sample, rep 05, inner dosimeter, upper legs
AEA03-PW-05-OD-LA	Pour worker sample, rep 05, outer dosimeter, lower arms
AEA03-PW-05-OD-UA	Pour worker sample, rep 05, outer dosimeter, upper arms
AEA03-PW-05-OD-FT	Pour worker sample, rep 05, outer dosimeter, front torso
AEA03-PW-05-OD-RT	Pour worker sample, rep 05, outer dosimeter, rear torso
AEA03-PW-05-OD-LL	Pour worker sample, rep 05, outer dosimeter, lower legs
AEA03-PW-05-OD-UL	Pour worker sample, rep 05, outer dosimeter, upper legs
AEA03-PW-05-IS-01	Pour worker sample, rep 05, inner socks
AEA03-PW-05-OS-01	Pour worker sample, rep 05, outer socks
AEA03-PW-05-AR-01	Pour worker sample, rep 05, air sampling tube
AEA03-PW-05-FW-01	Pour worker sample, rep 05, face/neck wipes
AEA03-PW-05-HW-FR	Pour worker sample, rep 05, hand wash
AEA03-MW-06-ID-LA	Mop worker sample, rep 06, inner dosimeter, lower arms
AEA03-MW-06-ID-UA	Mop worker sample, rep 06, inner dosimeter, upper arms
AEA03-MW-06-ID-FT	Mop worker sample, rep 06, inner dosimeter, front torso
AEA03-MW-06-ID-RT	Mop worker sample, rep 06, inner dosimeter, rear torso
AEA03-MW-06-ID-LL	Mop worker sample, rep 06, inner dosimeter, lower legs
AEA03-MW-06-ID-UL	Mop worker sample, rep 06, inner dosimeter, upper legs
AEA03-MW-06-OD-LA	Mop worker sample, rep 06, outer dosimeter, lower arms
AEA03-MW-06-OD-UA	Mop worker sample, rep 06, outer dosimeter, upper arms
AEA03-MW-06-OD-FT	Mop worker sample, rep 06, outer dosimeter, front torso
AEA03-MW-06-OD-RT	Mop worker sample, rep 06, outer dosimeter, rear torso

Exposure Samples (continued)

Sample ID Number	Description
AEA03-MW-06-OD-LL	Mop worker sample, rep 06, outer dosimeter, lower legs
AEA03-MW-06-OD-UL	Mop worker sample, rep 06, outer dosimeter, upper legs
AEA03-MW-06-IS-01	Mop worker sample, rep 06, inner socks
AEA03-MW-06-OS-01	Mop worker sample, rep 06, outer socks
AEA03-MW-06-AR-01	Mop worker sample, rep 06, air sampling tube
AEA03-MW-06-FW-01	Mop worker sample, rep 06, face/neck wipes
AEA03-MW-06-HW-01	Mop worker sample, rep 06, 1st interim hand wash
AEA03-MW-06-HW-02	Mop worker sample, rep 06, 2nd interim hand wash
AEA03-MW-06-HW-03	Mop worker sample, rep 06, 3rd interim hand wash
AEA03-MW-06-HW-04	Mop worker sample, rep 06, 4th interim hand wash
AEA03-MW-06-HW-FR	Mop worker sample, rep 06, final hand wash
AEA03-MW-06-DM-01	Mop worker sample, rep 06, 1st diluted material aliquot
AEA03-MW-06-DM-02	Mop worker sample, rep 06, 2nd diluted material aliquot
AEA03-MW-06-DM-03	Mop worker sample, rep 06, 3rd diluted material aliquot
AEA03-MW-06-DM-04	Mop worker sample, rep 06, 4th diluted material aliquot
AEA03-MW-06-DM-05	Mop worker sample, rep 06, 5th diluted material aliquot
AEA03-MW-06-DM-06	Mop worker sample, rep 06, 6th diluted material aliquot
AEA03-PW-06-ID-LA	Pour worker sample, rep 06, inner dosimeter, lower arms
AEA03-PW-06-ID-UA	Pour worker sample, rep 06, inner dosimeter, upper arms
AEA03-PW-06-ID-FT	Pour worker sample, rep 06, inner dosimeter, front torso
AEA03-PW-06-ID-RT	Pour worker sample, rep 06, inner dosimeter, rear torso
AEA03-PW-06-ID-LL	Pour worker sample, rep 06, inner dosimeter, lower legs
AEA03-PW-06-ID-UL	Pour worker sample, rep 06, inner dosimeter, upper legs
AEA03-PW-06-OD-LA	Pour worker sample, rep 06, outer dosimeter, lower arms
AEA03-PW-06-OD-UA	Pour worker sample, rep 06, outer dosimeter, upper arms
AEA03-PW-06-OD-FT	Pour worker sample, rep 06, outer dosimeter, front torso
AEA03-PW-06-OD-RT	Pour worker sample, rep 06, outer dosimeter, rear torso
AEA03-PW-06-OD-LL	Pour worker sample, rep 06, outer dosimeter, lower legs
AEA03-PW-06-OD-UL	Pour worker sample, rep 06, outer dosimeter, upper legs
AEA03-PW-06-IS-01	Pour worker sample, rep 06, inner socks
AEA03-PW-06-OS-01	Pour worker sample, rep 06, outer socks
AEA03-PW-06-AR-01	Pour worker sample, rep 06, air sampling tube
AEA03-PW-06-FW-01	Pour worker sample, rep 06, face/neck wipes
AEA03-PW-06-HW-FR	Pour worker sample, rep 06, hand wash
AEA03-MW-07-ID-LA	Mop worker sample, rep 07, inner dosimeter, lower arms
AEA03-MW-07-ID-UA	Mop worker sample, rep 07, inner dosimeter, upper arms
AEA03-MW-07-ID-FT	Mop worker sample, rep 07, inner dosimeter, front torso
AEA03-MW-07-ID-RT	Mop worker sample, rep 07, inner dosimeter, rear torso

Exposure Samples (continued)

Sample ID Number	Description
AEA03-MW-07-ID-LL	Mop worker sample, rep 07, inner dosimeter, lower legs
AEA03-MW-07-ID-UL	Mop worker sample, rep 07, inner dosimeter, upper legs
AEA03-MW-07-OD-LA	Mop worker sample, rep 07, outer dosimeter, lower arms
AEA03-MW-07-OD-UA	Mop worker sample, rep 07, outer dosimeter, upper arms
AEA03-MW-07-OD-FT	Mop worker sample, rep 07, outer dosimeter, front torso
AEA03-MW-07-OD-RT	Mop worker sample, rep 07, outer dosimeter, rear torso
AEA03-MW-07-OD-LL	Mop worker sample, rep 07, outer dosimeter, lower legs
AEA03-MW-07-OD-UL	Mop worker sample, rep 07, outer dosimeter, upper legs
AEA03-MW-07-IS-01	Mop worker sample, rep 07, inner socks
AEA03-MW-07-OS-01	Mop worker sample, rep 07, outer socks
AEA03-MW-07-AR-01	Mop worker sample, rep 07, air sampling tube
AEA03-MW-07-FW-01	Mop worker sample, rep 07, face/neck wipes
AEA03-MW-07-HW-01	Mop worker sample, rep 07, 1st interim hand wash
AEA03-MW-07-HW-02	Mop worker sample, rep 07, 2nd interim hand wash
AEA03-MW-07-HW-03	Mop worker sample, rep 07, 3rd interim hand wash
AEA03-MW-07-HW-04	Mop worker sample, rep 07, 4th interim hand wash
AEA03-MW-07-HW-FR	Mop worker sample, rep 07, final hand wash
AEA03-MW-07-DM-01	Mop worker sample, rep 07, 1st diluted material aliquot
AEA03-MW-07-DM-02	Mop worker sample, rep 07, 2nd diluted material aliquot
AEA03-MW-07-DM-03	Mop worker sample, rep 07, 3rd diluted material aliquot
AEA03-MW-07-DM-04	Mop worker sample, rep 07, 4th diluted material aliquot
AEA03-MW-07-DM-05	Mop worker sample, rep 07, 5th diluted material aliquot
AEA03-MW-07-DM-06	Mop worker sample, rep 07, 6th diluted material aliquot
AEA03-PW-07-ID-LA	Pour worker sample, rep 07, inner dosimeter, lower arms
AEA03-PW-07-ID-UA	Pour worker sample, rep 07, inner dosimeter, upper arms
AEA03-PW-07-ID-FT	Pour worker sample, rep 07, inner dosimeter, front torso
AEA03-PW-07-ID-RT	Pour worker sample, rep 07, inner dosimeter, rear torso
AEA03-PW-07-ID-LL	Pour worker sample, rep 07, inner dosimeter, lower legs
AEA03-PW-07-ID-UL	Pour worker sample, rep 07, inner dosimeter, upper legs
AEA03-PW-07-OD-LA	Pour worker sample, rep 07, outer dosimeter, lower arms
AEA03-PW-07-OD-UA	Pour worker sample, rep 07, outer dosimeter, upper arms
AEA03-PW-07-OD-FT	Pour worker sample, rep 07, outer dosimeter, front torso
AEA03-PW-07-OD-RT	Pour worker sample, rep 07, outer dosimeter, rear torso
AEA03-PW-07-OD-LL	Pour worker sample, rep 07, outer dosimeter, lower legs
AEA03-PW-07-OD-UL	Pour worker sample, rep 07, outer dosimeter, upper legs
AEA03-PW-07-IS-01	Pour worker sample, rep 07, inner socks
AEA03-PW-07-OS-01	Pour worker sample, rep 07, outer socks
AEA03-PW-07-AR-01	Pour worker sample, rep 07, air sampling tube

Exposure Samples (continued)

Sample ID Number	Description
AEA03-PW-07-FW-01	Pour worker sample, rep 07, face/neck wipes
AEA03-PW-07-HW-FR	Pour worker sample, rep 07 , hand wash
AEA03-MW-08-ID-LA	Mop worker sample, rep 08, inner dosimeter, lower arms
AEA03-MW-08-ID-UA	Mop worker sample, rep 08, inner dosimeter, upper arms
AEA03-MW-08-ID-FT	Mop worker sample, rep 08, inner dosimeter, front torso
AEA03-MW-08-ID-RT	Mop worker sample, rep 08, inner dosimeter, rear torso
AEA03-MW-08-ID-LL	Mop worker sample, rep 08, inner dosimeter, lower legs
AEA03-MW-08-ID-UL	Mop worker sample, rep 08, inner dosimeter, upper legs
AEA03-MW-08-OD-LA	Mop worker sample, rep 08, outer dosimeter, lower arms
AEA03-MW-08-OD-UA	Mop worker sample, rep 08, outer dosimeter, upper arms
AEA03-MW-08-OD-FT	Mop worker sample, rep 08, outer dosimeter, front torso
AEA03-MW-08-OD-RT	Mop worker sample, rep 08, outer dosimeter, rear torso
AEA03-MW-08-OD-LL	Mop worker sample, rep 08, outer dosimeter, lower legs
AEA03-MW-08-OD-UL	Mop worker sample, rep 08, outer dosimeter, upper legs
AEA03-MW-08-IS-01	Mop worker sample, rep 08, inner socks
AEA03-MW-08-OS-01	Mop worker sample, rep 08, outer socks
AEA03-MW-08-AR-01	Mop worker sample, rep 08, air sampling tube
AEA03-MW-08-FW-01	Mop worker sample, rep 08, face/neck wipes
AEA03-MW-08-HW-01	Mop worker sample, rep 08, 1st interim hand wash
AEA03-MW-08-HW-02	Mop worker sample, rep 08, 2nd interim hand wash
AEA03-MW-08-HW-03	Mop worker sample, rep 08, 3rd interim hand wash
AEA03-MW-08-HW-04	Mop worker sample, rep 08, 4th interim hand wash
AEA03-MW-08-HW-FR	Mop worker sample, rep 08, final hand wash
AEA03-MW-08-DM-01	Mop worker sample, rep 08, 1st diluted material aliquot
AEA03-MW-08-DM-02	Mop worker sample, rep 08, 2nd diluted material aliquot
AEA03-MW-08-DM-03	Mop worker sample, rep 08, 3rd diluted material aliquot
AEA03-MW-08-DM-04	Mop worker sample, rep 08, 4th diluted material aliquot
AEA03-MW-08-DM-05	Mop worker sample, rep 08, 5th diluted material aliquot
AEA03-MW-08-DM-06	Mop worker sample, rep 08, 6th diluted material aliquot
AEA03-PW-08-ID-LA	Pour worker sample, rep 08, inner dosimeter, lower arms
AEA03-PW-08-ID-UA	Pour worker sample, rep 08, inner dosimeter, upper arms
AEA03-PW-08-ID-FT	Pour worker sample, rep 08, inner dosimeter, front torso
AEA03-PW-08-ID-RT	Pour worker sample, rep 08, inner dosimeter, rear torso
AEA03-PW-08-ID-LL	Pour worker sample, rep 08, inner dosimeter, lower legs
AEA03-PW-08-ID-UL	Pour worker sample, rep 08, inner dosimeter, upper legs
AEA03-PW-08-OD-LA	Pour worker sample, rep 08, outer dosimeter, lower arms
AEA03-PW-08-OD-UA	Pour worker sample, rep 08, outer dosimeter, upper arms
AEA03-PW-08-OD-FT	Pour worker sample, rep 08, outer dosimeter, front torso
AEA03-PW-08-OD-RT	Pour worker sample, rep 08, outer dosimeter, rear torso

Exposure Samples (continued)

Sample ID Number	Description
AEA03-PW-08-OD-LL	Pour worker sample, rep 08, outer dosimeter, lower legs
AEA03-PW-08-OD-UL	Pour worker sample, rep 08, outer dosimeter, upper legs
AEA03-PW-08-IS-01	Pour worker sample, rep 08, inner socks
AEA03-PW-08-OS-01	Pour worker sample, rep 08, outer socks
AEA03-PW-08-AR-01	Pour worker sample, rep 08, air sampling tube
AEA03-PW-08-FW-01	Pour worker sample, rep 08, face/neck wipes
AEA03-PW-08-HW-FR	Pour worker sample, rep 08, hand wash
AEA03-MW-09-ID-LA	Mop worker sample, rep 09, inner dosimeter, lower arms
AEA03-MW-09-ID-UA	Mop worker sample, rep 09, inner dosimeter, upper arms
AEA03-MW-09-ID-FT	Mop worker sample, rep 09, inner dosimeter, front torso
AEA03-MW-09-ID-RT	Mop worker sample, rep 09, inner dosimeter, rear torso
AEA03-MW-09-ID-LL	Mop worker sample, rep 09, inner dosimeter, lower legs
AEA03-MW-09-ID-UL	Mop worker sample, rep 09, inner dosimeter, upper legs
AEA03-MW-09-OD-LA	Mop worker sample, rep 09, outer dosimeter, lower arms
AEA03-MW-09-OD-UA	Mop worker sample, rep 09, outer dosimeter, upper arms
AEA03-MW-09-OD-FT	Mop worker sample, rep 09, outer dosimeter, front torso
AEA03-MW-09-OD-RT	Mop worker sample, rep 09, outer dosimeter, rear torso
AEA03-MW-09-OD-LL	Mop worker sample, rep 09, outer dosimeter, lower legs
AEA03-MW-09-OD-UL	Mop worker sample, rep 09, outer dosimeter, upper legs
AEA03-MW-09-IS-01	Mop worker sample, rep 09, inner socks
AEA03-MW-09-OS-01	Mop worker sample, rep 09, outer socks
AEA03-MW-09-AR-01	Mop worker sample, rep 09, air sampling tube
AEA03-MW-09-FW-01	Mop worker sample, rep 09, face/neck wipes
AEA03-MW-09-HW-01	Mop worker sample, rep 09, 1st interim hand wash
AEA03-MW-09-HW-02	Mop worker sample, rep 09, 2nd interim hand wash
AEA03-MW-09-HW-03	Mop worker sample, rep 09, 3rd interim hand wash
AEA03-MW-09-HW-04	Mop worker sample, rep 09, 4th interim hand wash
AEA03-MW-09-HW-FR	Mop worker sample, rep 09, final hand wash
AEA03-MW-09-DM-01	Mop worker sample, rep 09, 1st diluted material aliquot
AEA03-MW-09-DM-02	Mop worker sample, rep 09, 2nd diluted material aliquot
AEA03-MW-09-DM-03	Mop worker sample, rep 09, 3rd diluted material aliquot
AEA03-MW-09-DM-04	Mop worker sample, rep 09, 4th diluted material aliquot
AEA03-MW-09-DM-05	Mop worker sample, rep 09, 5th diluted material aliquot
AEA03-MW-09-DM-06	Mop worker sample, rep 09, 6th diluted material aliquot
AEA03-PW-09-ID-LA	Pour worker sample, rep 09, inner dosimeter, lower arms
AEA03-PW-09-ID-UA	Pour worker sample, rep 09, inner dosimeter, upper arms
AEA03-PW-09-ID-FT	Pour worker sample, rep 09, inner dosimeter, front torso
AEA03-PW-09-ID-RT	Pour worker sample, rep 09, inner dosimeter, rear torso

Exposure Samples (continued)

Sample ID Number	Description
AEA03-PW-09-ID-LL	Pour worker sample, rep 09, inner dosimeter, lower legs
AEA03-PW-09-ID-UL	Pour worker sample, rep 09, inner dosimeter, upper legs
AEA03-PW-09-OD-LA	Pour worker sample, rep 09, outer dosimeter, lower arms
AEA03-PW-09-OD-UA	Pour worker sample, rep 09, outer dosimeter, upper arms
AEA03-PW-09-OD-FT	Pour worker sample, rep 09, outer dosimeter, front torso
AEA03-PW-09-OD-RT	Pour worker sample, rep 09, outer dosimeter, rear torso
AEA03-PW-09-OD-LL	Pour worker sample, rep 09, outer dosimeter, lower legs
AEA03-PW-09-OD-UL	Pour worker sample, rep 09, outer dosimeter, upper legs
AEA03-PW-09-IS-01	Pour worker sample, rep 09, inner socks
AEA03-PW-09-OS-01	Pour worker sample, rep 09, outer socks
AEA03-PW-09-AR-01	Pour worker sample, rep 09, air sampling tube
AEA03-PW-09-FW-01	Pour worker sample, rep 09, face/neck wipes
AEA03-PW-09-HW-FR	Pour worker sample, rep 09, hand wash
AEA03-MW-10-ID-LA	Mop worker sample, rep 10, inner dosimeter, lower arms
AEA03-MW-10-ID-UA	Mop worker sample, rep 10, inner dosimeter, upper arms
AEA03-MW-10-ID-FT	Mop worker sample, rep 10, inner dosimeter, front torso
AEA03-MW-10-ID-RT	Mop worker sample, rep 10, inner dosimeter, rear torso
AEA03-MW-10-ID-LL	Mop worker sample, rep 10, inner dosimeter, lower legs
AEA03-MW-10-ID-UL	Mop worker sample, rep 10, inner dosimeter, upper legs
AEA03-MW-10-OD-LA	Mop worker sample, rep 10, outer dosimeter, lower arms
AEA03-MW-10-OD-UA	Mop worker sample, rep 10, outer dosimeter, upper arms
AEA03-MW-10-OD-FT	Mop worker sample, rep 10, outer dosimeter, front torso
AEA03-MW-10-OD-RT	Mop worker sample, rep 10, outer dosimeter, rear torso
AEA03-MW-10-OD-LL	Mop worker sample, rep 10, outer dosimeter, lower legs
AEA03-MW-10-OD-UL	Mop worker sample, rep 10, outer dosimeter, upper legs
AEA03-MW-10-IS-01	Mop worker sample, rep 10, inner socks
AEA03-MW-10-OS-01	Mop worker sample, rep 10, outer socks
AEA03-MW-10-AR-01	Mop worker sample, rep 10, air sampling tube
AEA03-MW-10-FW-01	Mop worker sample, rep 10, face/neck wipes
AEA03-MW-10-HW-01	Mop worker sample, rep 10, 1st interim hand wash
AEA03-MW-10-HW-02	Mop worker sample, rep 10, 2nd interim hand wash
AEA03-MW-10-HW-03	Mop worker sample, rep 10, 3rd interim hand wash
AEA03-MW-10-HW-04	Mop worker sample, rep 10, 4th interim hand wash
AEA03-MW-10-HW-FR	Mop worker sample, rep 10, final hand wash
AEA03-MW-10-DM-01	Mop worker sample, rep 10, 1st diluted material aliquot
AEA03-MW-10-DM-02	Mop worker sample, rep 10, 2nd diluted material aliquot
AEA03-MW-10-DM-03	Mop worker sample, rep 10, 3rd diluted material aliquot
AEA03-MW-10-DM-04	Mop worker sample, rep 10, 4th diluted material aliquot

Exposure Samples (continued)

Sample ID Number	Description
AEA03-MW-10-DM-05	Mop worker sample, rep 10, 5th diluted material aliquot
AEA03-MW-10-DM-06	Mop worker sample, rep 10, 6th diluted material aliquot
AEA03-PW-10-ID-LA	Pour worker sample, rep 10, inner dosimeter, lower arms
AEA03-PW-10-ID-UA	Pour worker sample, rep 10, inner dosimeter, upper arms
AEA03-PW-10-ID-FT	Pour worker sample, rep 10, inner dosimeter, front torso
AEA03-PW-10-ID-RT	Pour worker sample, rep 10, inner dosimeter, rear torso
AEA03-PW-10-ID-LL	Pour worker sample, rep 10, inner dosimeter, lower legs
AEA03-PW-10-ID-UL	Pour worker sample, rep 10, inner dosimeter, upper legs
AEA03-PW-10-OD-LA	Pour worker sample, rep 10, outer dosimeter, lower arms
AEA03-PW-10-OD-UA	Pour worker sample, rep 10, outer dosimeter, upper arms
AEA03-PW-10-OD-FT	Pour worker sample, rep 10, outer dosimeter, front torso
AEA03-PW-10-OD-RT	Pour worker sample, rep 10, outer dosimeter, rear torso
AEA03-PW-10-OD-LL	Pour worker sample, rep 10, outer dosimeter, lower legs
AEA03-PW-10-OD-UL	Pour worker sample, rep 10, outer dosimeter, upper legs
AEA03-PW-10-IS-01	Pour worker sample, rep 10, inner socks
AEA03-PW-10-OS-01	Pour worker sample, rep 10, outer socks
AEA03-PW-10-AR-01	Pour worker sample, rep 10, air sampling tube
AEA03-PW-10-FW-01	Pour worker sample, rep 10, face/neck wipes
AEA03-PW-10-HW-FR	Pour worker sample, rep 10, hand wash
AEA03-MW-11-ID-LA	Mop worker sample, rep 11, inner dosimeter, lower arms
AEA03-MW-11-ID-UA	Mop worker sample, rep 11, inner dosimeter, upper arms
AEA03-MW-11-ID-FT	Mop worker sample, rep 11, inner dosimeter, front torso
AEA03-MW-11-ID-RT	Mop worker sample, rep 11, inner dosimeter, rear torso
AEA03-MW-11-ID-LL	Mop worker sample, rep 11, inner dosimeter, lower legs
AEA03-MW-11-ID-UL	Mop worker sample, rep 11, inner dosimeter, upper legs
AEA03-MW-11-OD-LA	Mop worker sample, rep 11, outer dosimeter, lower arms
AEA03-MW-11-OD-UA	Mop worker sample, rep 11, outer dosimeter, upper arms
AEA03-MW-11-OD-FT	Mop worker sample, rep 11, outer dosimeter, front torso
AEA03-MW-11-OD-RT	Mop worker sample, rep 11, outer dosimeter, rear torso
AEA03-MW-11-OD-LL	Mop worker sample, rep 11, outer dosimeter, lower legs
AEA03-MW-11-OD-UL	Mop worker sample, rep 11, outer dosimeter, upper legs
AEA03-MW-11-IS-01	Mop worker sample, rep 11, inner socks
AEA03-MW-11-OS-01	Mop worker sample, rep 11, outer socks
AEA03-MW-11-AR-01	Mop worker sample, rep 11, air sampling tube
AEA03-MW-11-FW-01	Mop worker sample, rep 11, face/neck wipes
AEA03-MW-11-HW-01	Mop worker sample, rep 11, 1st interim hand wash
AEA03-MW-11-HW-02	Mop worker sample, rep 11, 2nd interim hand wash
AEA03-MW-11-HW-03	Mop worker sample, rep 11, 3rd interim hand wash

Exposure Samples (continued)

Sample ID Number	Description
AEA03-MW-11-HW-04	Mop worker sample, rep 11, 4th interim hand wash
AEA03-MW-11-HW-FR	Mop worker sample, rep 11, final hand wash
AEA03-MW-11-DM-01	Mop worker sample, rep 11, 1st diluted material aliquot
AEA03-MW-11-DM-02	Mop worker sample, rep 11, 2nd diluted material aliquot
AEA03-MW-11-DM-03	Mop worker sample, rep 11, 3rd diluted material aliquot
AEA03-MW-11-DM-04	Mop worker sample, rep 11, 4th diluted material aliquot
AEA03-MW-11-DM-05	Mop worker sample, rep 11, 5th diluted material aliquot
AEA03-MW-11-DM-06	Mop worker sample, rep 11, 6th diluted material aliquot
AEA03-PW-11-ID-LA	Pour worker sample, rep 11, inner dosimeter, lower arms
AEA03-PW-11-ID-UA	Pour worker sample, rep 11, inner dosimeter, upper arms
AEA03-PW-11-ID-FT	Pour worker sample, rep 11, inner dosimeter, front torso
AEA03-PW-11-ID-RT	Pour worker sample, rep 11, inner dosimeter, rear torso
AEA03-PW-11-ID-LL	Pour worker sample, rep 11, inner dosimeter, lower legs
AEA03-PW-11-ID-UL	Pour worker sample, rep 11, inner dosimeter, upper legs
AEA03-PW-11-OD-LA	Pour worker sample, rep 11, outer dosimeter, lower arms
AEA03-PW-11-OD-UA	Pour worker sample, rep 11, outer dosimeter, upper arms
AEA03-PW-11-OD-FT	Pour worker sample, rep 11, outer dosimeter, front torso
AEA03-PW-11-OD-RT	Pour worker sample, rep 11, outer dosimeter, rear torso
AEA03-PW-11-OD-LL	Pour worker sample, rep 11, outer dosimeter, lower legs
AEA03-PW-11-OD-UL	Pour worker sample, rep 11, outer dosimeter, upper legs
AEA03-PW-11-IS-01	Pour worker sample, rep 11, inner socks
AEA03-PW-11-OS-01	Pour worker sample, rep 11, outer socks
AEA03-PW-11-AR-01	Pour worker sample, rep 11, air sampling tube
AEA03-PW-11-FW-01	Pour worker sample, rep 11, face/neck wipes
AEA03-PW-11-HW-FR	Pour worker sample, rep 11, hand wash
AEA03-MW-12-ID-LA	Mop worker sample, rep 12, inner dosimeter, lower arms
AEA03-MW-12-ID-UA	Mop worker sample, rep 12, inner dosimeter, upper arms
AEA03-MW-12-ID-FT	Mop worker sample, rep 12, inner dosimeter, front torso
AEA03-MW-12-ID-RT	Mop worker sample, rep 12, inner dosimeter, rear torso
AEA03-MW-12-ID-LL	Mop worker sample, rep 12, inner dosimeter, lower legs
AEA03-MW-12-ID-UL	Mop worker sample, rep 12, inner dosimeter, upper legs
AEA03-MW-12-OD-LA	Mop worker sample, rep 12, outer dosimeter, lower arms
AEA03-MW-12-OD-UA	Mop worker sample, rep 12, outer dosimeter, upper arms
AEA03-MW-12-OD-FT	Mop worker sample, rep 12, outer dosimeter, front torso
AEA03-MW-12-OD-RT	Mop worker sample, rep 12, outer dosimeter, rear torso
AEA03-MW-12-OD-LL	Mop worker sample, rep 12, outer dosimeter, lower legs
AEA03-MW-12-OD-UL	Mop worker sample, rep 12, outer dosimeter, upper legs
AEA03-MW-12-IS-01	Mop worker sample, rep 12, inner socks

Exposure Samples (continued)

Sample ID Number	Description
AEA03-MW-12-OS-01	Mop worker sample, rep 12, outer socks
AEA03-MW-12-AR-01	Mop worker sample, rep 12, air sampling tube
AEA03-MW-12-FW-01	Mop worker sample, rep 12, face/neck wipes
AEA03-MW-12-HW-01	Mop worker sample, rep 12, 1st interim hand wash
AEA03-MW-12-HW-02	Mop worker sample, rep 12, 2nd interim hand wash
AEA03-MW-12-HW-03	Mop worker sample, rep 12, 3rd interim hand wash
AEA03-MW-12-HW-04	Mop worker sample, rep 12, 4th interim hand wash
AEA03-MW-12-HW-FR	Mop worker sample, rep 12, final hand wash
AEA03-MW-12-DM-01	Mop worker sample, rep 12, 1st diluted material aliquot
AEA03-MW-12-DM-02	Mop worker sample, rep 12, 2nd diluted material aliquot
AEA03-MW-12-DM-03	Mop worker sample, rep 12, 3rd diluted material aliquot
AEA03-MW-12-DM-04	Mop worker sample, rep 12, 4th diluted material aliquot
AEA03-MW-12-DM-05	Mop worker sample, rep 12, 5th diluted material aliquot
AEA03-MW-12-DM-06	Mop worker sample, rep 12, 6th diluted material aliquot
AEA03-PW-12-ID-LA	Pour worker sample, rep 12, inner dosimeter, lower arms
AEA03-PW-12-ID-UA	Pour worker sample, rep 12, inner dosimeter, upper arms
AEA03-PW-12-ID-FT	Pour worker sample, rep 12, inner dosimeter, front torso
AEA03-PW-12-ID-RT	Pour worker sample, rep 12, inner dosimeter, rear torso
AEA03-PW-12-ID-LL	Pour worker sample, rep 12, inner dosimeter, lower legs
AEA03-PW-12-ID-UL	Pour worker sample, rep 12, inner dosimeter, upper legs
AEA03-PW-12-OD-LA	Pour worker sample, rep 12, outer dosimeter, lower arms
AEA03-PW-12-OD-UA	Pour worker sample, rep 12, outer dosimeter, upper arms
AEA03-PW-12-OD-FT	Pour worker sample, rep 12, outer dosimeter, front torso
AEA03-PW-12-OD-RT	Pour worker sample, rep 12, outer dosimeter, rear torso
AEA03-PW-12-OD-LL	Pour worker sample, rep 12, outer dosimeter, lower legs
AEA03-PW-12-OD-UL	Pour worker sample, rep 12, outer dosimeter, upper legs
AEA03-PW-12-IS-01	Pour worker sample, rep 12, inner socks
AEA03-PW-12-OS-01	Pour worker sample, rep 12, outer socks
AEA03-PW-12-AR-01	Pour worker sample, rep 12, air sampling tube
AEA03-PW-12-FW-01	Pour worker sample, rep 12, face/neck wipes
AEA03-PW-12-HW-FR	Pour worker sample, rep 12, hand wash
AEA03-MW-13-ID-LA	Mop worker sample, rep 13, inner dosimeter, lower arms
AEA03-MW-13-ID-UA	Mop worker sample, rep 13, inner dosimeter, upper arms
AEA03-MW-13-ID-FT	Mop worker sample, rep 13, inner dosimeter, front torso
AEA03-MW-13-ID-RT	Mop worker sample, rep 13, inner dosimeter, rear torso
AEA03-MW-13-ID-LL	Mop worker sample, rep 13, inner dosimeter, lower legs
AEA03-MW-13-ID-UL	Mop worker sample, rep 13, inner dosimeter, upper legs
AEA03-MW-13-OD-LA	Mop worker sample, rep 13, outer dosimeter, lower arms

Exposure Samples (continued)

Sample ID Number	Description
AEA03-MW-13-OD-UA	Mop worker sample, rep 13, outer dosimeter, upper arms
AEA03-MW-13-OD-FT	Mop worker sample, rep 13, outer dosimeter, front torso
AEA03-MW-13-OD-RT	Mop worker sample, rep 13, outer dosimeter, rear torso
AEA03-MW-13-OD-LL	Mop worker sample, rep 13, outer dosimeter, lower legs
AEA03-MW-13-OD-UL	Mop worker sample, rep 13, outer dosimeter, upper legs
AEA03-MW-13-IS-01	Mop worker sample, rep 13, inner socks
AEA03-MW-13-OS-01	Mop worker sample, rep 13, outer socks
AEA03-MW-13-AR-01	Mop worker sample, rep 13, air sampling tube
AEA03-MW-13-FW-01	Mop worker sample, rep 13, face/neck wipes
AEA03-MW-13-HW-01	Mop worker sample, rep 13, 1st interim hand wash
AEA03-MW-13-HW-02	Mop worker sample, rep 13, 2nd interim hand wash
AEA03-MW-13-HW-03	Mop worker sample, rep 13, 3rd interim hand wash
AEA03-MW-13-HW-04	Mop worker sample, rep 13, 4th interim hand wash
AEA03-MW-13-HW-FR	Mop worker sample, rep 13, final hand wash
AEA03-MW-13-DM-01	Mop worker sample, rep 13, 1st diluted material aliquot
AEA03-MW-13-DM-02	Mop worker sample, rep 13, 2nd diluted material aliquot
AEA03-MW-13-DM-03	Mop worker sample, rep 13, 3rd diluted material aliquot
AEA03-MW-13-DM-04	Mop worker sample, rep 13, 4th diluted material aliquot
AEA03-MW-13-DM-05	Mop worker sample, rep 13, 5th diluted material aliquot
AEA03-MW-13-DM-06	Mop worker sample, rep 13, 6th diluted material aliquot
AEA03-PW-13-ID-LA	Pour worker sample, rep 13, inner dosimeter, lower arms
AEA03-PW-13-ID-UA	Pour worker sample, rep 13, inner dosimeter, upper arms
AEA03-PW-13-ID-FT	Pour worker sample, rep 13, inner dosimeter, front torso
AEA03-PW-13-ID-RT	Pour worker sample, rep 13, inner dosimeter, rear torso
AEA03-PW-13-ID-LL	Pour worker sample, rep 13, inner dosimeter, lower legs
AEA03-PW-13-ID-UL	Pour worker sample, rep 13, inner dosimeter, upper legs
AEA03-PW-13-OD-LA	Pour worker sample, rep 13, outer dosimeter, lower arms
AEA03-PW-13-OD-UA	Pour worker sample, rep 13, outer dosimeter, upper arms
AEA03-PW-13-OD-FT	Pour worker sample, rep 13, outer dosimeter, front torso
AEA03-PW-13-OD-RT	Pour worker sample, rep 13, outer dosimeter, rear torso
AEA03-PW-13-OD-LL	Pour worker sample, rep 13, outer dosimeter, lower legs
AEA03-PW-13-OD-UL	Pour worker sample, rep 13, outer dosimeter, upper legs
AEA03-PW-13-IS-01	Pour worker sample, rep 13, inner socks
AEA03-PW-13-OS-01	Pour worker sample, rep 13, outer socks
AEA03-PW-13-AR-01	Pour worker sample, rep 13, air sampling tube
AEA03-PW-13-FW-01	Pour worker sample, rep 13, face/neck wipes
AEA03-PW-13-HW-FR	Pour worker sample, rep 13, hand wash

Exposure Samples (continued)

Sample ID Number	Description
AEA03-MW-14-ID-LA	Mop worker sample, rep 14, inner dosimeter, lower arms
AEA03-MW-14-ID-UA	Mop worker sample, rep 14, inner dosimeter, upper arms
AEA03-MW-14-ID-FT	Mop worker sample, rep 14, inner dosimeter, front torso
AEA03-MW-14-ID-RT	Mop worker sample, rep 14, inner dosimeter, rear torso
AEA03-MW-14-ID-LL	Mop worker sample, rep 14, inner dosimeter, lower legs
AEA03-MW-14-ID-UL	Mop worker sample, rep 14, inner dosimeter, upper legs
AEA03-MW-14-OD-LA	Mop worker sample, rep 14, outer dosimeter, lower arms
AEA03-MW-14-OD-UA	Mop worker sample, rep 14, outer dosimeter, upper arms
AEA03-MW-14-OD-FT	Mop worker sample, rep 14, outer dosimeter, front torso
AEA03-MW-14-OD-RT	Mop worker sample, rep 14, outer dosimeter, rear torso
AEA03-MW-14-OD-LL	Mop worker sample, rep 14, outer dosimeter, lower legs
AEA03-MW-14-OD-UL	Mop worker sample, rep 14, outer dosimeter, upper legs
AEA03-MW-14-IS-01	Mop worker sample, rep 14, inner socks
AEA03-MW-14-OS-01	Mop worker sample, rep 14, outer socks
AEA03-MW-14-AR-01	Mop worker sample, rep 14, air sampling tube
AEA03-MW-14-FW-01	Mop worker sample, rep 14, face/neck wipes
AEA03-MW-14-HW-01	Mop worker sample, rep 14, 1st interim hand wash
AEA03-MW-14-HW-02	Mop worker sample, rep 14, 2nd interim hand wash
AEA03-MW-14-HW-03	Mop worker sample, rep 14, 3rd interim hand wash
AEA03-MW-14-HW-04	Mop worker sample, rep 14, 4th interim hand wash
AEA03-MW-14-HW-FR	Mop worker sample, rep 14, final hand wash
AEA03-MW-14-DM-01	Mop worker sample, rep 14, 1st diluted material aliquot
AEA03-MW-14-DM-02	Mop worker sample, rep 14, 2nd diluted material aliquot
AEA03-MW-14-DM-03	Mop worker sample, rep 14, 3rd diluted material aliquot
AEA03-MW-14-DM-04	Mop worker sample, rep 14, 4th diluted material aliquot
AEA03-MW-14-DM-05	Mop worker sample, rep 14, 5th diluted material aliquot
AEA03-MW-14-DM-06	Mop worker sample, rep 14, 6th diluted material aliquot
AEA03-PW-14-ID-LA	Pour worker sample, rep 14, inner dosimeter, lower arms
AEA03-PW-14-ID-UA	Pour worker sample, rep 14, inner dosimeter, upper arms
AEA03-PW-14-ID-FT	Pour worker sample, rep 14, inner dosimeter, front torso
AEA03-PW-14-ID-RT	Pour worker sample, rep 14, inner dosimeter, rear torso
AEA03-PW-14-ID-LL	Pour worker sample, rep 14, inner dosimeter, lower legs
AEA03-PW-14-ID-UL	Pour worker sample, rep 14, inner dosimeter, upper legs
AEA03-PW-14-OD-LA	Pour worker sample, rep 14, outer dosimeter, lower arms
AEA03-PW-14-OD-UA	Pour worker sample, rep 14, outer dosimeter, upper arms
AEA03-PW-14-OD-FT	Pour worker sample, rep 14, outer dosimeter, front torso
AEA03-PW-14-OD-RT	Pour worker sample, rep 14, outer dosimeter, rear torso
AEA03-PW-14-OD-LL	Pour worker sample, rep 14, outer dosimeter, lower legs
AEA03-PW-14-OD-UL	Pour worker sample, rep 14, outer dosimeter, upper legs

AEA03-PW-14-IS-01	Pour worker sample, rep 14, inner socks
AEA03-PW-14-OS-01	Pour worker sample, rep 14, outer socks
AEA03-PW-14-AR-01	Pour worker sample, rep 14, air sampling tube
AEA03-PW-14-FW-01	Pour worker sample, rep 14, face/neck wipes
AEA03-PW-14-HW-FR	Pour worker sample, rep 14, hand wash
AEA03-MW-15-ID-LA	Mop worker sample, rep 15, inner dosimeter, lower arms
AEA03-MW-15-ID-UA	Mop worker sample, rep 15, inner dosimeter, upper arms
AEA03-MW-15-ID-FT	Mop worker sample, rep 15, inner dosimeter, front torso
AEA03-MW-15-ID-RT	Mop worker sample, rep 15, inner dosimeter, rear torso
AEA03-MW-15-ID-LL	Mop worker sample, rep 15, inner dosimeter, lower legs
AEA03-MW-15-ID-UL	Mop worker sample, rep 15, inner dosimeter, upper legs
AEA03-MW-15-OD-LA	Mop worker sample, rep 15, outer dosimeter, lower arms
AEA03-MW-15-OD-UA	Mop worker sample, rep 15, outer dosimeter, upper arms
AEA03-MW-15-OD-FT	Mop worker sample, rep 15, outer dosimeter, front torso
AEA03-MW-15-OD-RT	Mop worker sample, rep 15, outer dosimeter, rear torso
AEA03-MW-15-OD-LL	Mop worker sample, rep 15, outer dosimeter, lower legs
AEA03-MW-15-OD-UL	Mop worker sample, rep 15, outer dosimeter, upper legs
AEA03-MW-15-IS-01	Mop worker sample, rep 15, inner socks
AEA03-MW-15-OS-01	Mop worker sample, rep 15, outer socks
AEA03-MW-15-AR-01	Mop worker sample, rep 15, air sampling tube
AEA03-MW-15-FW-01	Mop worker sample, rep 15, face/neck wipes
AEA03-MW-15-HW-01	Mop worker sample, rep 15, 1st interim hand wash
AEA03-MW-15-HW-02	Mop worker sample, rep 15, 2nd interim hand wash
AEA03-MW-15-HW-03	Mop worker sample, rep 15, 3rd interim hand wash
AEA03-MW-15-HW-04	Mop worker sample, rep 15, 4th interim hand wash
AEA03-MW-15-HW-FR	Mop worker sample, rep 15, final hand wash
AEA03-MW-15-DM-01	Mop worker sample, rep 15, 1st diluted material aliquot
AEA03-MW-15-DM-02	Mop worker sample, rep 15, 2nd diluted material aliquot
AEA03-MW-15-DM-03	Mop worker sample, rep 15, 3rd diluted material aliquot
AEA03-MW-15-DM-04	Mop worker sample, rep 15, 4th diluted material aliquot
AEA03-MW-15-DM-05	Mop worker sample, rep 15, 5th diluted material aliquot
AEA03-MW-15-DM-06	Mop worker sample, rep 15, 6th diluted material aliquot
AEA03-PW-15-ID-LA	Pour worker sample, rep 15, inner dosimeter, lower arms
AEA03-PW-15-ID-UA	Pour worker sample, rep 15, inner dosimeter, upper arms
AEA03-PW-15-ID-FT	Pour worker sample, rep 15, inner dosimeter, front torso
AEA03-PW-15-ID-RT	Pour worker sample, rep 15, inner dosimeter, rear torso
AEA03-PW-15-ID-LL	Pour worker sample, rep 15, inner dosimeter, lower legs
AEA03-PW-15-ID-UL	Pour worker sample, rep 15, inner dosimeter, upper legs
AEA03-PW-15-OD-LA	Pour worker sample, rep 15, outer dosimeter, lower arms
AEA03-PW-15-OD-UA	Pour worker sample, rep 15, outer dosimeter, upper arms
AEA03-PW-15-OD-FT	Pour worker sample, rep 15, outer dosimeter, front torso
AEA03-PW-15-OD-RT	Pour worker sample, rep 15, outer dosimeter, rear torso

Exposure Samples (continued)

Sample ID Number	Description
AEA03-PW-15-OD-LL	Pour worker sample, rep 15, outer dosimeter, lower legs
AEA03-PW-15-OD-UL	Pour worker sample, rep 15, outer dosimeter, upper legs
AEA03-PW-15-IS-01	Pour worker sample, rep 15, inner socks
AEA03-PW-15-OS-01	Pour worker sample, rep 15, outer socks
AEA03-PW-15-AR-01	Pour worker sample, rep 15, air sampling tube
AEA03-PW-15-FW-01	Pour worker sample, rep 15, face/neck wipes
AEA03-PW-15-HW-FR	Pour worker sample, rep 15, hand wash
AEA03-MW-16-ID-LA	Mop worker sample, rep 16, inner dosimeter, lower arms
AEA03-MW-16-ID-UA	Mop worker sample, rep 16, inner dosimeter, upper arms
AEA03-MW-16-ID-FT	Mop worker sample, rep 16, inner dosimeter, front torso
AEA03-MW-16-ID-RT	Mop worker sample, rep 16, inner dosimeter, rear torso
AEA03-MW-16-ID-LL	Mop worker sample, rep 16, inner dosimeter, lower legs
AEA03-MW-16-ID-UL	Mop worker sample, rep 16, inner dosimeter, upper legs
AEA03-MW-16-OD-LA	Mop worker sample, rep 16, outer dosimeter, lower arms
AEA03-MW-16-OD-UA	Mop worker sample, rep 16, outer dosimeter, upper arms
AEA03-MW-16-OD-FT	Mop worker sample, rep 16, outer dosimeter, front torso
AEA03-MW-16-OD-RT	Mop worker sample, rep 16, outer dosimeter, rear torso
AEA03-MW-16-OD-LL	Mop worker sample, rep 16, outer dosimeter, lower legs
AEA03-MW-16-OD-UL	Mop worker sample, rep 16, outer dosimeter, upper legs
AEA03-MW-16-IS-01	Mop worker sample, rep 16, inner socks
AEA03-MW-16-OS-01	Mop worker sample, rep 16, outer socks
AEA03-MW-16-AR-01	Mop worker sample, rep 16, air sampling tube
AEA03-MW-16-FW-01	Mop worker sample, rep 16, face/neck wipes
AEA03-MW-16-HW-01	Mop worker sample, rep 16, 1st interim hand wash
AEA03-MW-16-HW-02	Mop worker sample, rep 16, 2nd interim hand wash
AEA03-MW-16-HW-03	Mop worker sample, rep 16, 3rd interim hand wash
AEA03-MW-16-HW-04	Mop worker sample, rep 16, 4th interim hand wash
AEA03-MW-16-HW-FR	Mop worker sample, rep 16, final hand wash
AEA03-MW-16-DM-01	Mop worker sample, rep 16, 1st diluted material aliquot
AEA03-MW-16-DM-02	Mop worker sample, rep 16, 2nd diluted material aliquot
AEA03-MW-16-DM-03	Mop worker sample, rep 16, 3rd diluted material aliquot
AEA03-MW-16-DM-04	Mop worker sample, rep 16, 4th diluted material aliquot
AEA03-MW-16-DM-05	Mop worker sample, rep 16, 5th diluted material aliquot
AEA03-MW-16-DM-06	Mop worker sample, rep 16, 6th diluted material aliquot
AEA03-PW-16-ID-LA	Pour worker sample, rep 16, inner dosimeter, lower arms
AEA03-PW-16-ID-UA	Pour worker sample, rep 16, inner dosimeter, upper arms
AEA03-PW-16-ID-FT	Pour worker sample, rep 16, inner dosimeter, front torso
AEA03-PW-16-ID-RT	Pour worker sample, rep 16, inner dosimeter, rear torso

Exposure Samples (continued)

Sample ID Number	Description
AEA03-PW-16-ID-LL	Pour worker sample, rep 16, inner dosimeter, lower legs
AEA03-PW-16-ID-UL	Pour worker sample, rep 16, inner dosimeter, upper legs
AEA03-PW-16-OD-LA	Pour worker sample, rep 16, outer dosimeter, lower arms
AEA03-PW-16-OD-UA	Pour worker sample, rep 16, outer dosimeter, upper arms
AEA03-PW-16-OD-FT	Pour worker sample, rep 16, outer dosimeter, front torso
AEA03-PW-16-OD-RT	Pour worker sample, rep 16, outer dosimeter, rear torso
AEA03-PW-16-OD-LL	Pour worker sample, rep 16, outer dosimeter, lower legs
AEA03-PW-16-OD-UL	Pour worker sample, rep 16, outer dosimeter, upper legs
AEA03-PW-16-IS-01	Pour worker sample, rep 16, inner socks
AEA03-PW-16-OS-01	Pour worker sample, rep 16, outer socks
AEA03-PW-16-AR-01	Pour worker sample, rep 16, air sampling tube
AEA03-PW-16-FW-01	Pour worker sample, rep 16, face/neck wipes
AEA03-PW-16-HW-FR	Pour worker sample, rep 16, hand wash
AEA03-MW-17-ID-LA	Mop worker sample, rep 17, inner dosimeter, lower arms
AEA03-MW-17-ID-UA	Mop worker sample, rep 17, inner dosimeter, upper arms
AEA03-MW-17-ID-FT	Mop worker sample, rep 17, inner dosimeter, front torso
AEA03-MW-17-ID-RT	Mop worker sample, rep 17, inner dosimeter, rear torso
AEA03-MW-17-ID-LL	Mop worker sample, rep 17, inner dosimeter, lower legs
AEA03-MW-17-ID-UL	Mop worker sample, rep 17, inner dosimeter, upper legs
AEA03-MW-17-OD-LA	Mop worker sample, rep 17, outer dosimeter, lower arms
AEA03-MW-17-OD-UA	Mop worker sample, rep 17, outer dosimeter, upper arms
AEA03-MW-17-OD-FT	Mop worker sample, rep 17, outer dosimeter, front torso
AEA03-MW-17-OD-RT	Mop worker sample, rep 17, outer dosimeter, rear torso
AEA03-MW-17-OD-LL	Mop worker sample, rep 17, outer dosimeter, lower legs
AEA03-MW-17-OD-UL	Mop worker sample, rep 17, outer dosimeter, upper legs
AEA03-MW-17-IS-01	Mop worker sample, rep 17, inner socks
AEA03-MW-17-OS-01	Mop worker sample, rep 17, outer socks
AEA03-MW-17-AR-01	Mop worker sample, rep 17, air sampling tube
AEA03-MW-17-FW-01	Mop worker sample, rep 17, face/neck wipes
AEA03-MW-17-HW-01	Mop worker sample, rep 17, 1st interim hand wash
AEA03-MW-17-HW-02	Mop worker sample, rep 17, 2nd interim hand wash
AEA03-MW-17-HW-03	Mop worker sample, rep 17, 3rd interim hand wash
AEA03-MW-17-HW-04	Mop worker sample, rep 17, 4th interim hand wash
AEA03-MW-17-HW-FR	Mop worker sample, rep 17, final hand wash
AEA03-MW-17-DM-01	Mop worker sample, rep 17, 1st diluted material aliquot
AEA03-MW-17-DM-02	Mop worker sample, rep 17, 2nd diluted material aliquot
AEA03-MW-17-DM-03	Mop worker sample, rep 17, 3rd diluted material aliquot
AEA03-MW-17-DM-04	Mop worker sample, rep 17, 4th diluted material aliquot

Exposure Samples (continued)

Sample ID Number	Description
AEA03-MW-17-DM-05	Mop worker sample, rep 17, 5th diluted material aliquot
AEA03-MW-17-DM-06	Mop worker sample, rep 17, 6th diluted material aliquot
AEA03-PW-17-ID-LA	Pour worker sample, rep 17, inner dosimeter, lower arms
AEA03-PW-17-ID-UA	Pour worker sample, rep 17, inner dosimeter, upper arms
AEA03-PW-17-ID-FT	Pour worker sample, rep 17, inner dosimeter, front torso
AEA03-PW-17-ID-RT	Pour worker sample, rep 17, inner dosimeter, rear torso
AEA03-PW-17-ID-LL	Pour worker sample, rep 17, inner dosimeter, lower legs
AEA03-PW-17-ID-UL	Pour worker sample, rep 17, inner dosimeter, upper legs
AEA03-PW-17-OD-LA	Pour worker sample, rep 17, outer dosimeter, lower arms
AEA03-PW-17-OD-UA	Pour worker sample, rep 17, outer dosimeter, upper arms
AEA03-PW-17-OD-FT	Pour worker sample, rep 17, outer dosimeter, front torso
AEA03-PW-17-OD-RT	Pour worker sample, rep 17, outer dosimeter, rear torso
AEA03-PW-17-OD-LL	Pour worker sample, rep 17, outer dosimeter, lower legs
AEA03-PW-17-OD-UL	Pour worker sample, rep 17, outer dosimeter, upper legs
AEA03-PW-17-IS-01	Pour worker sample, rep 17, inner socks
AEA03-PW-17-OS-01	Pour worker sample, rep 17, outer socks
AEA03-PW-17-AR-01	Pour worker sample, rep 17, air sampling tube
AEA03-PW-17-FW-01	Pour worker sample, rep 17, face/neck wipes
AEA03-PW-17-HW-FR	Pour worker sample, rep 17, hand wash
AEA03-MW-18-ID-LA	Mop worker sample, rep 18, inner dosimeter, lower arms
AEA03-MW-18-ID-UA	Mop worker sample, rep 18, inner dosimeter, upper arms
AEA03-MW-18-ID-FT	Mop worker sample, rep 18, inner dosimeter, front torso
AEA03-MW-18-ID-RT	Mop worker sample, rep 18, inner dosimeter, rear torso
AEA03-MW-18-ID-LL	Mop worker sample, rep 18, inner dosimeter, lower legs
AEA03-MW-18-ID-UL	Mop worker sample, rep 18, inner dosimeter, upper legs
AEA03-MW-18-OD-LA	Mop worker sample, rep 18, outer dosimeter, lower arms
AEA03-MW-18-OD-UA	Mop worker sample, rep 18, outer dosimeter, upper arms
AEA03-MW-18-OD-FT	Mop worker sample, rep 18, outer dosimeter, front torso
AEA03-MW-18-OD-RT	Mop worker sample, rep 18, outer dosimeter, rear torso
AEA03-MW-18-OD-LL	Mop worker sample, rep 18, outer dosimeter, lower legs
AEA03-MW-18-OD-UL	Mop worker sample, rep 18, outer dosimeter, upper legs
AEA03-MW-18-IS-01	Mop worker sample, rep 18, inner socks
AEA03-MW-18-OS-01	Mop worker sample, rep 18, outer socks
AEA03-MW-18-AR-01	Mop worker sample, rep 18, air sampling tube
AEA03-MW-18-FW-01	Mop worker sample, rep 18, face/neck wipes
AEA03-MW-18-HW-01	Mop worker sample, rep 18, 1st interim hand wash
AEA03-MW-18-HW-02	Mop worker sample, rep 18, 2nd interim hand wash
AEA03-MW-18-HW-03	Mop worker sample, rep 18, 3rd interim hand wash

Exposure Samples (continued)

Sample ID Number	Description
AEA03-MW-18-HW-04	Mop worker sample, rep 18, 4th interim hand wash
AEA03-MW-18-HW-FR	Mop worker sample, rep 18, final hand wash
AEA03-MW-18-DM-01	Mop worker sample, rep 18, 1st diluted material aliquot
AEA03-MW-18-DM-02	Mop worker sample, rep 18, 2nd diluted material aliquot
AEA03-MW-18-DM-03	Mop worker sample, rep 18, 3rd diluted material aliquot
AEA03-MW-18-DM-04	Mop worker sample, rep 18, 4th diluted material aliquot
AEA03-MW-18-DM-05	Mop worker sample, rep 18, 5th diluted material aliquot
AEA03-MW-18-DM-06	Mop worker sample, rep 18, 6th diluted material aliquot
AEA03-PW-18-ID-LA	Pour worker sample, rep 18, inner dosimeter, lower arms
AEA03-PW-18-ID-UA	Pour worker sample, rep 18, inner dosimeter, upper arms
AEA03-PW-18-ID-FT	Pour worker sample, rep 18, inner dosimeter, front torso
AEA03-PW-18-ID-RT	Pour worker sample, rep 18, inner dosimeter, rear torso
AEA03-PW-18-ID-LL	Pour worker sample, rep 18, inner dosimeter, lower legs
AEA03-PW-18-ID-UL	Pour worker sample, rep 18, inner dosimeter, upper legs
AEA03-PW-18-OD-LA	Pour worker sample, rep 18, outer dosimeter, lower arms
AEA03-PW-18-OD-UA	Pour worker sample, rep 18, outer dosimeter, upper arms
AEA03-PW-18-OD-FT	Pour worker sample, rep 18, outer dosimeter, front torso
AEA03-PW-18-OD-RT	Pour worker sample, rep 18, outer dosimeter, rear torso
AEA03-PW-18-OD-LL	Pour worker sample, rep 18, outer dosimeter, lower legs
AEA03-PW-18-OD-UL	Pour worker sample, rep 18, outer dosimeter, upper legs
AEA03-PW-18-IS-01	Pour worker sample, rep 18, inner socks
AEA03-PW-18-OS-01	Pour worker sample, rep 18, outer socks
AEA03-PW-18-AR-01	Pour worker sample, rep 18, air sampling tube
AEA03-PW-18-FW-01	Pour worker sample, rep 18, face/neck wipes
AEA03-PW-18-HW-FR	Pour worker sample, rep 18, hand wash
AEA03-FF-01-AR-L1	Fortification sample, Day 01, air sampling tube, 1st low level
AEA03-FF-01-AR-L2	Fortification sample, Day 01, air sampling tube, 2nd low level
AEA03-FF-01-AR-L3	Fortification sample, Day 01, air sampling tube, 3rd low level
AEA03-FF-01-AR-H1	Fortification sample, Day 01, air sampling tube, 1st high level
AEA03-FF-01-AR-H2	Fortification sample, Day 01, air sampling tube, 2nd high level
AEA03-FF-01-AR-H3	Fortification sample, Day 01, air sampling tube, 3rd high level
AEA03-FF-01-HW-L1	Fortification sample, Day 01, hand wash, 1st low level
AEA03-FF-01-HW-L2	Fortification sample, Day 01, hand wash, 2nd low level
AEA03-FF-01-HW-L3	Fortification sample, Day 01, hand wash, 3rd low level
AEA03-FF-01-HW-H1	Fortification sample, Day 01, hand wash, 1st high level
AEA03-FF-01-HW-H2	Fortification sample, Day 01, hand wash, 2nd high level
AEA03-FF-01-HW-H3	Fortification sample, Day 01, hand wash, 3rd high level
AEA03-FF-01-FW-L1	Fortification sample, Day 01, face/neck wipe, 1st low level

Exposure Samples (continued)

Sample ID Number	Description
AEA03-FF-01-FW-L2	Fortification sample, Day 01, face/neck wipe, 2nd low level
AEA03-FF-01-FW-L3	Fortification sample, Day 01, face/neck wipe, 3rd low level
AEA03-FF-01-FW-H1	Fortification sample, Day 01, face/neck wipe, 1st high level
AEA03-FF-01-FW-H2	Fortification sample, Day 01, face/neck wipe, 2nd high level
AEA03-FF-01-FW-H3	Fortification sample, Day 01, face/neck wipe, 3rd high level
AEA03-FF-01-ID-L1	Fortification sample, Day 01, inner dosimeter, 1st low level
AEA03-FF-01-ID-L2	Fortification sample, Day 01, inner dosimeter, 2nd low level
AEA03-FF-01-ID-L3	Fortification sample, Day 01, inner dosimeter, 3rd low level
AEA03-FF-01-ID-H1	Fortification sample, Day 01, inner dosimeter, 1st high level
AEA03-FF-01-ID-H2	Fortification sample, Day 01, inner dosimeter, 2nd high level
AEA03-FF-01-ID-H3	Fortification sample, Day 01, inner dosimeter, 3rd high level
AEA03-FF-01-OD-L1	Fortification sample, Day 01, outer dosimeter, 1st low level
AEA03-FF-01-OD-L2	Fortification sample, Day 01, outer dosimeter, 2nd low level
AEA03-FF-01-OD-L3	Fortification sample, Day 01, outer dosimeter, 3rd low level
AEA03-FF-01-OD-H1	Fortification sample, Day 01, outer dosimeter, 1st high level
AEA03-FF-01-OD-H2	Fortification sample, Day 01, outer dosimeter, 2nd high level
AEA03-FF-01-OD-H3	Fortification sample, Day 01, outer dosimeter, 3rd high level
AEA03-FF-01-CS-L1	Fortification sample, Day 01, cotton socks, 1st low level
AEA03-FF-01-CS-L2	Fortification sample, Day 01, cotton socks, 2nd low level
AEA03-FF-01-CS-L3	Fortification sample, Day 01, cotton socks, 3rd low level
AEA03-FF-01-CS-H1	Fortification sample, Day 01, cotton socks, 1st high level
AEA03-FF-01-CS-H2	Fortification sample, Day 01, cotton socks, 2nd high level
AEA03-FF-01-CS-H3	Fortification sample, Day 01, cotton socks, 3rd high level
AEA03-FF-01-AR-C1	Fortification sample, Day 01, air sampling tube, 1st control
AEA03-FF-01-AR-C2	Fortification sample, Day 01, air sampling tube, 2nd control
AEA03-FF-01-HW-C1	Fortification sample, Day 01, hand wash, 1st control
AEA03-FF-01-HW-C2	Fortification sample, Day 01, hand wash, 2nd control
AEA03-FF-01-FW-C1	Fortification sample, Day 01, face/neck wipe, 1st control
AEA03-FF-01-FW-C2	Fortification sample, Day 01, face/neck wipe, 2nd control
AEA03-FF-01-ID-C1	Fortification sample, Day 01, inner dosimeter, 1st control
AEA03-FF-01-ID-C2	Fortification sample, Day 01, inner dosimeter, 2nd control
AEA03-FF-01-OD-C1	Fortification sample, Day 01, outer dosimeter, 1st control
AEA03-FF-01-OD-C2	Fortification sample, Day 01, outer dosimeter, 2nd control
AEA03-FF-01-CS-C1	Fortification sample, Day 01, cotton socks, 1st control
AEA03-FF-01-CS-C2	Fortification sample, Day 01, cotton socks, 2nd control
AEA03-FF-01-AR-T1	Fortification sample, Day 01, air sampling tube, 1st travel spike

Exposure Samples (continued)

Sample ID Number	Description
AEA03-FF-01-AR-T2	Fortification sample, Day 01, air sampling tube, 2nd travel spike
AEA03-FF-01-HW-T1	Fortification sample, Day 01, hand wash, 1st travel spike
AEA03-FF-01-HW-T2	Fortification sample, Day 01, hand wash, 2nd travel spike
AEA03-FF-01-FW-T1	Fortification sample, Day 01, face/neck wipe, 1st travel spike
AEA03-FF-01-FW-T2	Fortification sample, Day 01, face/neck wipe, 2nd travel spike
AEA03-FF-01-ID-T1	Fortification sample, Day 01, inner dosimeter, 1st travel spike
AEA03-FF-01-ID-T2	Fortification sample, Day 01, inner dosimeter, 2nd travel spike
AEA03-FF-01-OD-T1	Fortification sample, Day 01, outer dosimeter, 1st travel spike
AEA03-FF-01-OD-T2	Fortification sample, Day 01, outer dosimeter, 2nd travel spike
AEA03-FF-01-CS-T1	Fortification sample, Day 01, cotton socks, 1st travel spike
AEA03-FF-01-CS-T2	Fortification sample, Day 01, cotton socks, 2nd travel spike
AEA03-FF-02-AR-L1	Fortification sample, Day 02, air sampling tube, 1st low level
AEA03-FF-02-AR-L2	Fortification sample, Day 02, air sampling tube, 2nd low level
AEA03-FF-02-AR-L3	Fortification sample, Day 02, air sampling tube, 3rd low level
AEA03-FF-02-AR-H1	Fortification sample, Day 02, air sampling tube, 1st high level
AEA03-FF-02-AR-H2	Fortification sample, Day 02, air sampling tube, 2nd high level
AEA03-FF-02-AR-H3	Fortification sample, Day 02, air sampling tube, 3rd high level
AEA03-FF-02-HW-L1	Fortification sample, Day 02, hand wash, 1st low level
AEA03-FF-02-HW-L2	Fortification sample, Day 02, hand wash, 2nd low level
AEA03-FF-02-HW-L3	Fortification sample, Day 02, hand wash, 3rd low level
AEA03-FF-02-HW-H1	Fortification sample, Day 02, hand wash, 1st high level
AEA03-FF-02-HW-H2	Fortification sample, Day 02, hand wash, 2nd high level
AEA03-FF-02-HW-H3	Fortification sample, Day 02, hand wash, 3rd high level
AEA03-FF-02-FW-L1	Fortification sample, Day 02, face/neck wipe, 1st low level
AEA03-FF-02-FW-L2	Fortification sample, Day 02, face/neck wipe, 2nd low level
AEA03-FF-02-FW-L3	Fortification sample, Day 02, face/neck wipe, 3rd low level
AEA03-FF-02-FW-H1	Fortification sample, Day 02, face/neck wipe, 1st high level
AEA03-FF-02-FW-H2	Fortification sample, Day 02, face/neck wipe, 2nd high level
AEA03-FF-02-FW-H3	Fortification sample, Day 02, face/neck wipe, 3rd high level
AEA03-FF-02-ID-L1	Fortification sample, Day 02, inner dosimeter, 1st low level
AEA03-FF-02-ID-L2	Fortification sample, Day 02, inner dosimeter, 2nd low level
AEA03-FF-02-ID-L3	Fortification sample, Day 02, inner dosimeter, 3rd low level
AEA03-FF-02-ID-H1	Fortification sample, Day 02, inner dosimeter, 1st high level
AEA03-FF-02-ID-H2	Fortification sample, Day 02, inner dosimeter, 2nd high level
AEA03-FF-02-ID-H3	Fortification sample, Day 02, inner dosimeter, 3rd high level
AEA03-FF-02-OD-L1	Fortification sample, Day 02, outer dosimeter, 1st low level

Exposure Samples (continued)

Sample ID Number	Description
AEA03-FF-02-OD-L2	Fortification sample, Day 02, outer dosimeter, 2nd low level
AEA03-FF-02-OD-L3	Fortification sample, Day 02, outer dosimeter, 3rd low level
AEA03-FF-02-OD-H1	Fortification sample, Day 02, outer dosimeter, 1st high level
AEA03-FF-02-OD-H2	Fortification sample, Day 02, outer dosimeter, 2nd high level
AEA03-FF-02-OD-H3	Fortification sample, Day 02, outer dosimeter, 3rd high level
AEA03-FF-02-CS-L1	Fortification sample, Day 02, cotton socks, 1st low level
AEA03-FF-02-CS-L2	Fortification sample, Day 02, cotton socks, 2nd low level
AEA03-FF-02-CS-L3	Fortification sample, Day 02, cotton socks, 3rd low level
AEA03-FF-02-CS-H1	Fortification sample, Day 02, cotton socks, 1st high level
AEA03-FF-02-CS-H2	Fortification sample, Day 02, cotton socks, 2nd high level
AEA03-FF-02-CS-H3	Fortification sample, Day 02, cotton socks, 3rd high level
AEA03-FF-02-AR-C1	Fortification sample, Day 02, air sampling tube, 1st control
AEA03-FF-02-AR-C2	Fortification sample, Day 02, air sampling tube, 2nd control
AEA03-FF-02-HW-C1	Fortification sample, Day 02, hand wash, 1st control
AEA03-FF-02-HW-C2	Fortification sample, Day 02, hand wash, 2nd control
AEA03-FF-02-FW-C1	Fortification sample, Day 02, face/neck wipe, 1st control
AEA03-FF-02-FW-C2	Fortification sample, Day 02, face/neck wipe, 2nd control
AEA03-FF-02-ID-C1	Fortification sample, Day 02, inner dosimeter, 1st control
AEA03-FF-02-ID-C2	Fortification sample, Day 02, inner dosimeter, 2nd control
AEA03-FF-02-OD-C1	Fortification sample, Day 02, outer dosimeter, 1st control
AEA03-FF-02-OD-C2	Fortification sample, Day 02, outer dosimeter, 2nd control
AEA03-FF-02-CS-C1	Fortification sample, Day 02, cotton socks, 1st control
AEA03-FF-02-CS-C2	Fortification sample, Day 02, cotton socks, 2nd control
AEA03-FF-02-AR-T1	Fortification sample, Day 02, air sampling tube, 1st travel spike
AEA03-FF-02-AR-T2	Fortification sample, Day 02, air sampling tube, 2nd travel spike
AEA03-FF-02-HW-T1	Fortification sample, Day 02, hand wash, 1st travel spike
AEA03-FF-02-HW-T2	Fortification sample, Day 02, hand wash, 2nd travel spike
AEA03-FF-02-FW-T1	Fortification sample, Day 02, face/neck wipe, 1st travel spike
AEA03-FF-02-FW-T2	Fortification sample, Day 02, face/neck wipe, 2nd travel spike
AEA03-FF-02-ID-T1	Fortification sample, Day 02, inner dosimeter, 1st travel spike
AEA03-FF-02-ID-T2	Fortification sample, Day 02, inner dosimeter, 2nd travel spike
AEA03-FF-02-OD-T1	Fortification sample, Day 02, outer dosimeter, 1st travel spike
AEA03-FF-02-OD-T2	Fortification sample, Day 02, outer dosimeter, 2nd travel spike

Exposure Samples (continued)

Sample ID Number	Description
AEA03-FF-02-CS-T1	Fortification sample, Day 02, cotton socks, 1st travel spike
AEA03-FF-02-CS-T2	Fortification sample, Day 02, cotton socks, 2nd travel spike
AEA03-FF-03-AR-L1	Fortification sample, Day 03, air sampling tube, 1st low level
AEA03-FF-03-AR-L2	Fortification sample, Day 03, air sampling tube, 2nd low level
AEA03-FF-03-AR-L3	Fortification sample, Day 03, air sampling tube, 3rd low level
AEA03-FF-03-AR-H1	Fortification sample, Day 03, air sampling tube, 1st high level
AEA03-FF-03-AR-H2	Fortification sample, Day 03, air sampling tube, 2nd high level
AEA03-FF-03-AR-H3	Fortification sample, Day 03, air sampling tube, 3rd high level
AEA03-FF-03-HW-L1	Fortification sample, Day 03, hand wash, 1st low level
AEA03-FF-03-HW-L2	Fortification sample, Day 03, hand wash, 2nd low level
AEA03-FF-03-HW-L3	Fortification sample, Day 03, hand wash, 3rd low level
AEA03-FF-03-HW-H1	Fortification sample, Day 03, hand wash, 1st high level
AEA03-FF-03-HW-H2	Fortification sample, Day 03, hand wash, 2nd high level
AEA03-FF-03-HW-H3	Fortification sample, Day 03, hand wash, 3rd high level
AEA03-FF-03-FW-L1	Fortification sample, Day 03, face/neck wipe, 1st low level
AEA03-FF-03-FW-L2	Fortification sample, Day 03, face/neck wipe, 2nd low level
AEA03-FF-03-FW-L3	Fortification sample, Day 03, face/neck wipe, 3rd low level
AEA03-FF-03-FW-H1	Fortification sample, Day 03, face/neck wipe, 1st high level
AEA03-FF-03-FW-H2	Fortification sample, Day 03, face/neck wipe, 2nd high level
AEA03-FF-03-FW-H3	Fortification sample, Day 03, face/neck wipe, 3rd high level
AEA03-FF-03-ID-L1	Fortification sample, Day 03, inner dosimeter, 1st low level
AEA03-FF-03-ID-L2	Fortification sample, Day 03, inner dosimeter, 2nd low level
AEA03-FF-03-ID-L3	Fortification sample, Day 03, inner dosimeter, 3rd low level
AEA03-FF-03-ID-H1	Fortification sample, Day 03, inner dosimeter, 1st high level
AEA03-FF-03-ID-H2	Fortification sample, Day 03, inner dosimeter, 2nd high level
AEA03-FF-03-ID-H3	Fortification sample, Day 03, inner dosimeter, 3rd high level
AEA03-FF-03-OD-L1	Fortification sample, Day 03, outer dosimeter, 1st low level
AEA03-FF-03-OD-L2	Fortification sample, Day 03, outer dosimeter, 2nd low level
AEA03-FF-03-OD-L3	Fortification sample, Day 03, outer dosimeter, 3rd low level
AEA03-FF-03-OD-H1	Fortification sample, Day 03, outer dosimeter, 1st high level
AEA03-FF-03-OD-H2	Fortification sample, Day 03, outer dosimeter, 2nd high level
AEA03-FF-03-OD-H3	Fortification sample, Day 03, outer dosimeter, 3rd high level
AEA03-FF-03-CS-L1	Fortification sample, Day 03, cotton socks, 1st low level
AEA03-FF-03-CS-L2	Fortification sample, Day 03, cotton socks, 2nd low level
AEA03-FF-03-CS-L3	Fortification sample, Day 03, cotton socks, 3rd low level
AEA03-FF-03-CS-H1	Fortification sample, Day 03, cotton socks, 1st high level
AEA03-FF-03-CS-H2	Fortification sample, Day 03, cotton socks, 2nd high level
AEA03-FF-03-CS-H3	Fortification sample, Day 03, cotton socks, 3rd high level
AEA03-FF-03-AR-C1	Fortification sample, Day 03, air sampling tube, 1st control

Exposure Samples (continued)

Sample ID Number	Description
AEA03-FF-03-AR-C2	Fortification sample, Day 03, air sampling tube, 2nd control
AEA03-FF-03-HW-C1	Fortification sample, Day 03, hand wash, 1st control
AEA03-FF-03-HW-C2	Fortification sample, Day 03, hand wash, 2nd control
AEA03-FF-03-FW-C1	Fortification sample, Day 03, face/neck wipe, 1st control
AEA03-FF-03-FW-C2	Fortification sample, Day 03, face/neck wipe, 2nd control
AEA03-FF-03-ID-C1	Fortification sample, Day 03, inner dosimeter, 1st control
AEA03-FF-03-ID-C2	Fortification sample, Day 03, inner dosimeter, 2nd control
AEA03-FF-01-OD-C1	Fortification sample, Day 03, outer dosimeter, 1st control
AEA03-FF-03-OD-C2	Fortification sample, Day 03, outer dosimeter, 2nd control
AEA03-FF-03-CS-C1	Fortification sample, Day 03, cotton socks, 1st control
AEA03-FF-03-CS-C2	Fortification sample, Day 03, cotton socks, 2nd control
AEA03-FF-03-AR-T1	Fortification sample, Day 03, air sampling tube, 1st travel spike
AEA03-FF-03-AR-T2	Fortification sample, Day 03, air sampling tube, 2nd travel spike
AEA03-FF-03-HW-T1	Fortification sample, Day 03, hand wash, 1st travel spike
AEA03-FF-03-HW-T2	Fortification sample, Day 03, hand wash, 2nd travel spike
AEA03-FF-03-FW-T1	Fortification sample, Day 03, face/neck wipe, 1st travel spike
AEA03-FF-03-FW-T2	Fortification sample, Day 03, face/neck wipe, 2nd travel spike
AEA03-FF-03-ID-T1	Fortification sample, Day 03, inner dosimeter, 1st travel spike
AEA03-FF-03-ID-T2	Fortification sample, Day 03, inner dosimeter, 2nd travel spike
AEA03-FF-03-OD-T1	Fortification sample, Day 03, outer dosimeter, 1st travel spike
AEA03-FF-03-OD-T2	Fortification sample, Day 03, outer dosimeter, 2nd travel spike
AEA03-FF-03-CS-T1	Fortification sample, Day 03, cotton socks, 1st travel spike
AEA03-FF-03-CS-T2	Fortification sample, Day 03, cotton socks, 2nd travel spike
AEA03-FF-04-AR-L1	Fortification sample, Day 04, air sampling tube, 1st low level
AEA03-FF-04-AR-L2	Fortification sample, Day 04, air sampling tube, 2nd low level
AEA03-FF-04-AR-L3	Fortification sample, Day 04, air sampling tube, 3rd low level
AEA03-FF-04-AR-H1	Fortification sample, Day 04, air sampling tube, 1st high level
AEA03-FF-04-AR-H2	Fortification sample, Day 04, air sampling tube, 2nd high level
AEA03-FF-04-AR-H3	Fortification sample, Day 04, air sampling tube, 3rd high level
AEA03-FF-04-HW-L1	Fortification sample, Day 04, hand wash, 1st low level
AEA03-FF-04-HW-L2	Fortification sample, Day 04, hand wash, 2nd low level
AEA03-FF-04-HW-L3	Fortification sample, Day 04, hand wash, 3rd low level
AEA03-FF-04-HW-H1	Fortification sample, Day 04, hand wash, 1st high level

Exposure Samples (continued)

Sample ID Number	Description
AEA03-FF-04-HW-H2	Fortification sample, Day 04, hand wash, 2nd high level
AEA03-FF-04-HW-H3	Fortification sample, Day 04, hand wash, 3rd high level
AEA03-FF-04-FW-L1	Fortification sample, Day 04, face/neck wipe, 1st low level
AEA03-FF-04-FW-L2	Fortification sample, Day 04, face/neck wipe, 2nd low level
AEA03-FF-04-FW-L3	Fortification sample, Day 04, face/neck wipe, 3rd low level
AEA03-FF-04-FW-H1	Fortification sample, Day 04, face/neck wipe, 1st high level
AEA03-FF-04-FW-H2	Fortification sample, Day 04, face/neck wipe, 2nd high level
AEA03-FF-04-FW-H3	Fortification sample, Day 04, face/neck wipe, 3rd high level
AEA03-FF-04-ID-L1	Fortification sample, Day 04, inner dosimeter, 1st low level
AEA03-FF-04-ID-L2	Fortification sample, Day 04, inner dosimeter, 2nd low level
AEA03-FF-04-ID-L3	Fortification sample, Day 04, inner dosimeter, 3rd low level
AEA03-FF-04-ID-H1	Fortification sample, Day 04, inner dosimeter, 1st high level
AEA03-FF-04-ID-H2	Fortification sample, Day 04, inner dosimeter, 2nd high level
AEA03-FF-04-ID-H3	Fortification sample, Day 04, inner dosimeter, 3rd high level
AEA03-FF-04-OD-L1	Fortification sample, Day 04, outer dosimeter, 1st low level
AEA03-FF-04-OD-L2	Fortification sample, Day 04, outer dosimeter, 2nd low level
AEA03-FF-04-OD-L3	Fortification sample, Day 04, outer dosimeter, 3rd low level
AEA03-FF-04-OD-H1	Fortification sample, Day 04, outer dosimeter, 1st high level
AEA03-FF-04-OD-H2	Fortification sample, Day 04, outer dosimeter, 2nd high level
AEA03-FF-04-OD-H3	Fortification sample, Day 04, outer dosimeter, 3rd high level
AEA03-FF-04-CS-L1	Fortification sample, Day 04, cotton socks, 1st low level
AEA03-FF-04-CS-L2	Fortification sample, Day 04, cotton socks, 2nd low level
AEA03-FF-04-CS-L3	Fortification sample, Day 04, cotton socks, 3rd low level
AEA03-FF-04-CS-H1	Fortification sample, Day 04, cotton socks, 1st high level
AEA03-FF-04-CS-H2	Fortification sample, Day 04, cotton socks, 2nd high level
AEA03-FF-04-CS-H3	Fortification sample, Day 04, cotton socks, 3rd high level
AEA03-FF-04-AR-C1	Fortification sample, Day 04, air sampling tube, 1st control
AEA03-FF-04-AR-C2	Fortification sample, Day 04, air sampling tube, 2nd control
AEA03-FF-04-HW-C1	Fortification sample, Day 04, hand wash, 1st control
AEA03-FF-04-HW-C2	Fortification sample, Day 04, hand wash, 2nd control
AEA03-FF-04-FW-C1	Fortification sample, Day 04, face/neck wipe, 1st control
AEA03-FF-04-FW-C2	Fortification sample, Day 04, face/neck wipe, 2nd control
AEA03-FF-04-ID-C1	Fortification sample, Day 04, inner dosimeter, 1st control
AEA03-FF-04-ID-C2	Fortification sample, Day 04, inner dosimeter, 2nd control
AEA03-FF-04-OD-C1	Fortification sample, Day 04, outer dosimeter, 1st control
AEA03-FF-04-OD-C2	Fortification sample, Day 04, outer dosimeter, 2nd control

Exposure Samples (continued)

Sample ID Number	Description
AEA03-FF-04-CS-C1	Fortification sample, Day 04, cotton socks, 1st control
AEA03-FF-04-CS-C2	Fortification sample, Day 04, cotton socks, 2nd control
AEA03-FF-04-AR-T1	Fortification sample, Day 04, air sampling tube, 1st travel spike
AEA03-FF-04-AR-T2	Fortification sample, Day 04, air sampling tube, 2nd travel spike
AEA03-FF-04-HW-T1	Fortification sample, Day 04, hand wash, 1st travel spike
AEA03-FF-04-HW-T2	Fortification sample, Day 04, hand wash, 2nd travel spike
AEA03-FF-04-FW-T1	Fortification sample, Day 04, face/neck wipe, 1st travel spike
AEA03-FF-04-FW-T2	Fortification sample, Day 04, face/neck wipe, 2nd travel spike
AEA03-FF-04-ID-T1	Fortification sample, Day 04, inner dosimeter, 1st travel spike
AEA03-FF-04-ID-T2	Fortification sample, Day 04, inner dosimeter, 2nd travel spike
AEA03-FF-04-OD-T1	Fortification sample, Day 04, outer dosimeter, 1st travel spike
AEA03-FF-04-OD-T2	Fortification sample, Day 04, outer dosimeter, 2nd travel spike
AEA03-FF-04-CS-T1	Fortification sample, Day 04, cotton socks, 1st travel spike
AEA03-FF-04-CS-T2	Fortification sample, Day 04, cotton socks, 2nd travel spike
AEA03-FF-05-AR-L1	Fortification sample, Day 05, air sampling tube, 1st low level
AEA03-FF-05-AR-L2	Fortification sample, Day 05, air sampling tube, 2nd low level
AEA03-FF-05-AR-L3	Fortification sample, Day 05, air sampling tube, 3rd low level
AEA03-FF-05-AR-H1	Fortification sample, Day 05, air sampling tube, 1st high level
AEA03-FF-05-AR-H2	Fortification sample, Day 05, air sampling tube, 2nd high level
AEA03-FF-05-AR-H3	Fortification sample, Day 05, air sampling tube, 3rd high level
AEA03-FF-05-HW-L1	Fortification sample, Day 05, hand wash, 1st low level
AEA03-FF-05-HW-L2	Fortification sample, Day 05, hand wash, 2nd low level
AEA03-FF-05-HW-L3	Fortification sample, Day 05, hand wash, 3rd low level
AEA03-FF-05-HW-H1	Fortification sample, Day 05, hand wash, 1st high level
AEA03-FF-05-HW-H2	Fortification sample, Day 05, hand wash, 2nd high level
AEA03-FF-05-HW-H3	Fortification sample, Day 05, hand wash, 3rd high level
AEA03-FF-05-FW-L1	Fortification sample, Day 05, face/neck wipe, 1st low level
AEA03-FF-05-FW-L2	Fortification sample, Day 05, face/neck wipe, 2nd low level
AEA03-FF-05-FW-L3	Fortification sample, Day 05, face/neck wipe, 3rd low level
AEA03-FF-05-FW-H1	Fortification sample, Day 05, face/neck wipe, 1st high level
AEA03-FF-05-FW-H2	Fortification sample, Day 05, face/neck wipe, 2nd high level
AEA03-FF-05-FW-H3	Fortification sample, Day 05, face/neck wipe, 3rd high level
AEA03-FF-05-ID-L1	Fortification sample, Day 05, inner dosimeter, 1st low level
AEA03-FF-05-ID-L2	Fortification sample, Day 05, inner dosimeter, 2nd low level
AEA03-FF-05-ID-L3	Fortification sample, Day 01, inner dosimeter, 3rd low level

Exposure Samples (continued)

Sample ID Number	Description
AEA03-FF-05-ID-H1	Fortification sample, Day 01, inner dosimeter, 1st high level
AEA03-FF-05-ID-H2	Fortification sample, Day 01, inner dosimeter, 2nd high level
AEA03-FF-05-ID-H3	Fortification sample, Day 01, inner dosimeter, 3rd high level
AEA03-FF-05-OD-L1	Fortification sample, Day 05, outer dosimeter, 1st low level
AEA03-FF-05-OD-L2	Fortification sample, Day 05, outer dosimeter, 2nd low level
AEA03-FF-05-OD-L3	Fortification sample, Day 05, outer dosimeter, 3rd low level
AEA03-FF-05-OD-H1	Fortification sample, Day 05, outer dosimeter, 1st high level
AEA03-FF-05-OD-H2	Fortification sample, Day 05, outer dosimeter, 2nd high level
AEA03-FF-05-OD-H3	Fortification sample, Day 05, outer dosimeter, 3rd high level
AEA03-FF-05-CS-L1	Fortification sample, Day 05, cotton socks, 1st low level
AEA03-FF-05-CS-L2	Fortification sample, Day 05, cotton socks, 2nd low level
AEA03-FF-05-CS-L3	Fortification sample, Day 05, cotton socks, 3rd low level
AEA03-FF-05-CS-H1	Fortification sample, Day 05, cotton socks, 1st high level
AEA03-FF-05-CS-H2	Fortification sample, Day 05, cotton socks, 2nd high level
AEA03-FF-05-CS-H3	Fortification sample, Day 05, cotton socks, 3rd high level
AEA03-FF-05-AR-C1	Fortification sample, Day 05, air sampling tube, 1st control
AEA03-FF-05-AR-C2	Fortification sample, Day 05, air sampling tube, 2nd control
AEA03-FF-05-HW-C1	Fortification sample, Day 05, hand wash, 1st control
AEA03-FF-05-HW-C2	Fortification sample, Day 05, hand wash, 2nd control
AEA03-FF-05-FW-C1	Fortification sample, Day 05, face/neck wipe, 1st control
AEA03-FF-05-FW-C2	Fortification sample, Day 05, face/neck wipe, 2nd control
AEA03-FF-05-ID-C1	Fortification sample, Day 05, inner dosimeter, 1st control
AEA03-FF-05-ID-C2	Fortification sample, Day 05, inner dosimeter, 2nd control
AEA03-FF-05-OD-C1	Fortification sample, Day 05, outer dosimeter, 1st control
AEA03-FF-05-OD-C2	Fortification sample, Day 05, outer dosimeter, 2nd control
AEA03-FF-05-CS-C1	Fortification sample, Day 05, cotton socks, 1st control
AEA03-FF-05-CS-C2	Fortification sample, Day 05, cotton socks, 2nd control
AEA03-FF-05-AR-T1	Fortification sample, Day 05, air sampling tube, 1st travel spike
AEA03-FF-05-AR-T2	Fortification sample, Day 05, air sampling tube, 2nd travel spike
AEA03-FF-05-HW-T1	Fortification sample, Day 05, hand wash, 1st travel spike
AEA03-FF-05-HW-T2	Fortification sample, Day 05, hand wash, 2nd travel spike
AEA03-FF-05-FW-T1	Fortification sample, Day 05, face/neck wipe, 1st travel spike
AEA03-FF-05-FW-T2	Fortification sample, Day 05, face/neck wipe, 2nd travel spike

Exposure Samples (continued)

Sample ID Number	Description
AEA03-FF-05-ID-T1	Fortification sample, Day 05, inner dosimeter, 1st travel spike
AEA03-FF-05-ID-T2	Fortification sample, Day 05, inner dosimeter, 2nd travel spike
AEA03-FF-05-OD-T1	Fortification sample, Day 01, outer dosimeter, 1st travel spike
AEA03-FF-05-OD-T2	Fortification sample, Day 05, outer dosimeter, 2nd travel spike
AEA03-FF-05-CS-T1	Fortification sample, Day 05, cotton socks, 1st travel spike
AEA03-FF-05-CS-T2	Fortification sample, Day 05, cotton socks, 2nd travel spike
AEA03-FF-06-AR-L1	Fortification sample, Day 06, air sampling tube, 1st low level
AEA03-FF-06-AR-L2	Fortification sample, Day 06, air sampling tube, 2nd low level
AEA03-FF-06-AR-L3	Fortification sample, Day 06, air sampling tube, 3rd low level
AEA03-FF-06-AR-H1	Fortification sample, Day 06, air sampling tube, 1st high level
AEA03-FF-06-AR-H2	Fortification sample, Day 06, air sampling tube, 2nd high level
AEA03-FF-06-AR-H3	Fortification sample, Day 06, air sampling tube, 3rd high level
AEA03-FF-06-HW-L1	Fortification sample, Day 06, hand wash, 1st low level
AEA03-FF-06-HW-L2	Fortification sample, Day 06, hand wash, 2nd low level
AEA03-FF-06-HW-L3	Fortification sample, Day 06, hand wash, 3rd low level
AEA03-FF-06-HW-H1	Fortification sample, Day 06, hand wash, 1st high level
AEA03-FF-06-HW-H2	Fortification sample, Day 06, hand wash, 2nd high level
AEA03-FF-06-HW-H3	Fortification sample, Day 06, hand wash, 3rd high level
AEA03-FF-06-FW-L1	Fortification sample, Day 06, face/neck wipe, 1st low level
AEA03-FF-06-FW-L2	Fortification sample, Day 06, face/neck wipe, 2nd low level
AEA03-FF-06-FW-L3	Fortification sample, Day 06, face/neck wipe, 3rd low level
AEA03-FF-06-FW-H1	Fortification sample, Day 06, face/neck wipe, 1st high level
AEA03-FF-06-FW-H2	Fortification sample, Day 06, face/neck wipe, 2nd high level
AEA03-FF-06-FW-H3	Fortification sample, Day 06, face/neck wipe, 3rd high level
AEA03-FF-06-ID-L1	Fortification sample, Day 06, inner dosimeter, 1st low level
AEA03-FF-06-ID-L2	Fortification sample, Day 06, inner dosimeter, 2nd low level
AEA03-FF-06-ID-L3	Fortification sample, Day 06, inner dosimeter, 3rd low level
AEA03-FF-06-ID-H1	Fortification sample, Day 06, inner dosimeter, 1st high level
AEA03-FF-06-ID-H2	Fortification sample, Day 06, inner dosimeter, 2nd high level
AEA03-FF-06-ID-H3	Fortification sample, Day 06, inner dosimeter, 3rd high level
AEA03-FF-06-OD-L1	Fortification sample, Day 06, outer dosimeter, 1st low level
AEA03-FF-06-OD-L2	Fortification sample, Day 06, outer dosimeter, 2nd low level
AEA03-FF-06-OD-L3	Fortification sample, Day 06, outer dosimeter, 3rd low level
AEA03-FF-06-OD-H1	Fortification sample, Day 06, outer dosimeter, 1st high level
AEA03-FF-06-OD-H2	Fortification sample, Day 06, outer dosimeter, 2nd high level
AEA03-FF-06-OD-H3	Fortification sample, Day 06, outer dosimeter, 3rd high level
AEA03-FF-06-CS-L1	Fortification sample, Day 06, cotton socks, 1st low level
AEA03-FF-06-CS-L2	Fortification sample, Day 06, cotton socks, 2nd low level

Exposure Samples (continued)

Sample ID Number	Description
AEA03-FF-06-CS-L3	Fortification sample, Day 06, cotton socks, 3rd low level
AEA03-FF-06-CS-H1	Fortification sample, Day 06, cotton socks, 1st high level
AEA03-FF-06-CS-H2	Fortification sample, Day 06, cotton socks, 2nd high level
AEA03-FF-06-CS-H3	Fortification sample, Day 06, cotton socks, 3rd high level
AEA03-FF-06-AR-C1	Fortification sample, Day 06, air sampling tube, 1st control
AEA03-FF-06-AR-C2	Fortification sample, Day 06, air sampling tube, 2nd control
AEA03-FF-06-HW-C1	Fortification sample, Day 06, hand wash, 1st control
AEA03-FF-06-HW-C2	Fortification sample, Day 06, hand wash, 2nd control
AEA03-FF-06-FW-C1	Fortification sample, Day 06, face/neck wipe, 1st control
AEA03-FF-06-FW-C2	Fortification sample, Day 06, face/neck wipe, 2nd control
AEA03-FF-06-ID-C1	Fortification sample, Day 06, inner dosimeter, 1st control
AEA03-FF-06-ID-C2	Fortification sample, Day 01, inner dosimeter, 2nd control
AEA03-FF-06-OD-C1	Fortification sample, Day 06, outer dosimeter, 1st control
AEA03-FF-06-OD-C2	Fortification sample, Day 06, outer dosimeter, 2nd control
AEA03-FF-06-CS-C1	Fortification sample, Day 06, cotton socks, 1st control
AEA03-FF-06-CS-C2	Fortification sample, Day 06, cotton socks, 2nd control
AEA03-FF-06-AR-T1	Fortification sample, Day 06, air sampling tube, 1st travel spike
AEA03-FF-06-AR-T2	Fortification sample, Day 06, air sampling tube, 2nd travel spike
AEA03-FF-06-HW-T1	Fortification sample, Day 06, hand wash, 1st travel spike
AEA03-FF-06-HW-T2	Fortification sample, Day 06, hand wash, 2nd travel spike
AEA03-FF-06-FW-T1	Fortification sample, Day 06, face/neck wipe, 1st travel spike
AEA03-FF-06-FW-T2	Fortification sample, Day 06, face/neck wipe, 2nd travel spike
AEA03-FF-06-ID-T1	Fortification sample, Day 06, inner dosimeter, 1st travel spike
AEA03-FF-06-ID-T2	Fortification sample, Day 06, inner dosimeter, 2nd travel spike
AEA03-FF-06-OD-T1	Fortification sample, Day 06, outer dosimeter, 1st travel spike
AEA03-FF-06-OD-T2	Fortification sample, Day 06, outer dosimeter, 2nd travel spike
AEA03-FF-06-CS-T1	Fortification sample, Day 06, cotton socks, 1st travel spike
AEA03-FF-06-CS-T2	Fortification sample, Day 06, cotton socks, 2nd travel spike
AEA03-FF-07-AR-L1	Fortification sample, Day 07, air sampling tube, 1st low level
AEA03-FF-07-AR-L2	Fortification sample, Day 07, air sampling tube, 2nd low level
AEA03-FF-07-AR-L3	Fortification sample, Day 07, air sampling tube, 3rd low level
AEA03-FF-07-AR-H1	Fortification sample, Day 07, air sampling tube, 1st high level
AEA03-FF-07-AR-H2	Fortification sample, Day 07, air sampling tube, 2nd high level

Exposure Samples (continued)

Sample ID Number	Description
AEA03-FF-07-AR-H3	Fortification sample, Day 07, air sampling tube, 3rd high level
AEA03-FF-07-HW-L1	Fortification sample, Day 07, hand wash, 1st low level
AEA03-FF-07-HW-L2	Fortification sample, Day 07, hand wash, 2nd low level
AEA03-FF-07-HW-L3	Fortification sample, Day 07, hand wash, 3rd low level
AEA03-FF-07-HW-H1	Fortification sample, Day 07, hand wash, 1st high level
AEA03-FF-07-HW-H2	Fortification sample, Day 07, hand wash, 2nd high level
AEA03-FF-07-HW-H3	Fortification sample, Day 07, hand wash, 3rd high level
AEA03-FF-07-FW-L1	Fortification sample, Day 07, face/neck wipe, 1st low level
AEA03-FF-07-FW-L2	Fortification sample, Day 07, face/neck wipe, 2nd low level
AEA03-FF-07-FW-L3	Fortification sample, Day 07, face/neck wipe, 3rd low level
AEA03-FF-07-FW-H1	Fortification sample, Day 07, face/neck wipe, 1st high level
AEA03-FF-07-FW-H2	Fortification sample, Day 07, face/neck wipe, 2nd high level
AEA03-FF-07-FW-H3	Fortification sample, Day 07, face/neck wipe, 3rd high level
AEA03-FF-07-ID-L1	Fortification sample, Day 07, inner dosimeter, 1st low level
AEA03-FF-07-ID-L2	Fortification sample, Day 07, inner dosimeter, 2nd low level
AEA03-FF-07-ID-L3	Fortification sample, Day 07, inner dosimeter, 3rd low level
AEA03-FF-07-ID-H1	Fortification sample, Day 07, inner dosimeter, 1st high level
AEA03-FF-07-ID-H2	Fortification sample, Day 07, inner dosimeter, 2nd high level
AEA03-FF-07-ID-H3	Fortification sample, Day 07, inner dosimeter, 3rd high level
AEA03-FF-07-OD-L1	Fortification sample, Day 07, outer dosimeter, 1st low level
AEA03-FF-07-OD-L2	Fortification sample, Day 07, outer dosimeter, 2nd low level
AEA03-FF-07-OD-L3	Fortification sample, Day 07, outer dosimeter, 3rd low level
AEA03-FF-07-OD-H1	Fortification sample, Day 07, outer dosimeter, 1st high level
AEA03-FF-07-OD-H2	Fortification sample, Day 07, outer dosimeter, 2nd high level
AEA03-FF-07-OD-H3	Fortification sample, Day 07, outer dosimeter, 3rd high level
AEA03-FF-07-CS-L1	Fortification sample, Day 07, cotton socks, 1st low level
AEA03-FF-07-CS-L2	Fortification sample, Day 07, cotton socks, 2nd low level
AEA03-FF-07-CS-L3	Fortification sample, Day 07, cotton socks, 3rd low level
AEA03-FF-07-CS-H1	Fortification sample, Day 07, cotton socks, 1st high level
AEA03-FF-07-CS-H2	Fortification sample, Day 07, cotton socks, 2nd high level
AEA03-FF-07-CS-H3	Fortification sample, Day 07, cotton socks, 3rd high level
AEA03-FF-07-AR-C1	Fortification sample, Day 07, air sampling tube, 1st control
AEA03-FF-07-AR-C2	Fortification sample, Day 07, air sampling tube, 2nd control
AEA03-FF-07-HW-C1	Fortification sample, Day 07, hand wash, 1st control
AEA03-FF-07-HW-C2	Fortification sample, Day 07, hand wash, 2nd control
AEA03-FF-07-FW-C1	Fortification sample, Day 07, face/neck wipe, 1st control
AEA03-FF-07-FW-C2	Fortification sample, Day 07, face/neck wipe, 2nd control

Exposure Samples (continued)

Sample ID Number	Description
AEA03-FF-07-ID-C1	Fortification sample, Day 07, inner dosimeter, 1st control
AEA03-FF-07-ID-C2	Fortification sample, Day 07, inner dosimeter, 2nd control
AEA03-FF-07-OD-C1	Fortification sample, Day 07, outer dosimeter, 1st control
AEA03-FF-07-OD-C2	Fortification sample, Day 07, outer dosimeter, 2nd control
AEA03-FF-07-CS-C1	Fortification sample, Day 07, cotton socks, 1st control
AEA03-FF-07-CS-C2	Fortification sample, Day 07, cotton socks, 2nd control
AEA03-FF-07-AR-T1	Fortification sample, Day 07, air sampling tube, 1st travel spike
AEA03-FF-07-AR-T2	Fortification sample, Day 07, air sampling tube, 2nd travel spike
AEA03-FF-07-HW-T1	Fortification sample, Day 07, hand wash, 1st travel spike
AEA03-FF-07-HW-T2	Fortification sample, Day 07, hand wash, 2nd travel spike
AEA03-FF-07-FW-T1	Fortification sample, Day 07, face/neck wipe, 1st travel spike
AEA03-FF-07-FW-T2	Fortification sample, Day 07, face/neck wipe, 2nd travel spike
AEA03-FF-07-ID-T1	Fortification sample, Day 07, inner dosimeter, 1st travel spike
AEA03-FF-07-ID-T2	Fortification sample, Day 07, inner dosimeter, 2nd travel spike
AEA03-FF-07-OD-T1	Fortification sample, Day 07, outer dosimeter, 1st travel spike
AEA03-FF-07-OD-T2	Fortification sample, Day 07, outer dosimeter, 2nd travel spike
AEA03-FF-07-CS-T1	Fortification sample, Day 07, cotton socks, 1st travel spike
AEA03-FF-07-CS-T2	Fortification sample, Day 07, cotton socks, 2nd travel spike
AEA03-FF-08-AR-L1	Fortification sample, Day 08, air sampling tube, 1st low level
AEA03-FF-08-AR-L2	Fortification sample, Day 08, air sampling tube, 2nd low level
AEA03-FF-08-AR-L3	Fortification sample, Day 08, air sampling tube, 3rd low level
AEA03-FF-08-AR-H1	Fortification sample, Day 08, air sampling tube, 1st high level
AEA03-FF-08-AR-H2	Fortification sample, Day 08, air sampling tube, 2nd high level
AEA03-FF-08-AR-H3	Fortification sample, Day 08, air sampling tube, 3rd high level
AEA03-FF-08-HW-L1	Fortification sample, Day 08, hand wash, 1st low level
AEA03-FF-08-HW-L2	Fortification sample, Day 08, hand wash, 2nd low level
AEA03-FF-08-HW-L3	Fortification sample, Day 08, hand wash, 3rd low level
AEA03-FF-08-HW-H1	Fortification sample, Day 08, hand wash, 1st high level
AEA03-FF-08-HW-H2	Fortification sample, Day 08, hand wash, 2nd high level
AEA03-FF-08-HW-H3	Fortification sample, Day 08, hand wash, 3rd high level
AEA03-FF-08-FW-L1	Fortification sample, Day 08, face/neck wipe, 1st low level
AEA03-FF-08-FW-L2	Fortification sample, Day 08, face/neck wipe, 2nd low level
AEA03-FF-08-FW-L3	Fortification sample, Day 08, face/neck wipe, 3rd low level
AEA03-FF-08-FW-H1	Fortification sample, Day 08, face/neck wipe, 1st high level
AEA03-FF-08-FW-H2	Fortification sample, Day 08, face/neck wipe, 2nd high level

Exposure Samples (continued)

Sample ID Number	Description
AEA03-FF-08-FW-H3	Fortification sample, Day 08, face/neck wipe, 3rd high level
AEA03-FF-08-ID-L1	Fortification sample, Day 08, inner dosimeter, 1st low level
AEA03-FF-08-ID-L2	Fortification sample, Day 08, inner dosimeter, 2nd low level
AEA03-FF-08-ID-L3	Fortification sample, Day 08, inner dosimeter, 3rd low level
AEA03-FF-08-ID-H1	Fortification sample, Day 08, inner dosimeter, 1st high level
AEA03-FF-08-ID-H2	Fortification sample, Day 08, inner dosimeter, 2nd high level
AEA03-FF-08-ID-H3	Fortification sample, Day 08, inner dosimeter, 3rd high level
AEA03-FF-08-OD-L1	Fortification sample, Day 08, outer dosimeter, 1st low level
AEA03-FF-08-OD-L2	Fortification sample, Day 08, outer dosimeter, 2nd low level
AEA03-FF-08-OD-L3	Fortification sample, Day 08, outer dosimeter, 3rd low level
AEA03-FF-08-OD-H1	Fortification sample, Day 08, outer dosimeter, 1st high level
AEA03-FF-08-OD-H2	Fortification sample, Day 08, outer dosimeter, 2nd high level
AEA03-FF-08-OD-H3	Fortification sample, Day 08, outer dosimeter, 3rd high level
AEA03-FF-08-CS-L1	Fortification sample, Day 08, cotton socks, 1st low level
AEA03-FF-08-CS-L2	Fortification sample, Day 08, cotton socks, 2nd low level
AEA03-FF-08-CS-L3	Fortification sample, Day 08, cotton socks, 3rd low level
AEA03-FF-08-CS-H1	Fortification sample, Day 08, cotton socks, 1st high level
AEA03-FF-08-CS-H2	Fortification sample, Day 08, cotton socks, 2nd high level
AEA03-FF-08-CS-H3	Fortification sample, Day 08, cotton socks, 3rd high level
AEA03-FF-08-AR-C1	Fortification sample, Day 08, air sampling tube, 1st control
AEA03-FF-08-AR-C2	Fortification sample, Day 08, air sampling tube, 2nd control
AEA03-FF-08-HW-C1	Fortification sample, Day 08, hand wash, 1st control
AEA03-FF-08-HW-C2	Fortification sample, Day 08, hand wash, 2nd control
AEA03-FF-08-FW-C1	Fortification sample, Day 08, face/neck wipe, 1st control
AEA03-FF-08-FW-C2	Fortification sample, Day 08, face/neck wipe, 2nd control
AEA03-FF-08-ID-C1	Fortification sample, Day 08, inner dosimeter, 1st control
AEA03-FF-08-ID-C2	Fortification sample, Day 08, inner dosimeter, 2nd control
AEA03-FF-08-OD-C1	Fortification sample, Day 08, outer dosimeter, 1st control
AEA03-FF-08-OD-C2	Fortification sample, Day 08, outer dosimeter, 2nd control
AEA03-FF-08-CS-C1	Fortification sample, Day 08, cotton socks, 1st control
AEA03-FF-08-CS-C2	Fortification sample, Day 08, cotton socks, 2nd control
AEA03-FF-08-AR-T1	Fortification sample, Day 08, air sampling tube, 1st travel spike
AEA03-FF-08-AR-T2	Fortification sample, Day 08, air sampling tube, 2nd travel spike
AEA03-FF-08-HW-T1	Fortification sample, Day 08, hand wash, 1st travel spike
AEA03-FF-08-HW-T2	Fortification sample, Day 08, hand wash, 2nd travel spike

Exposure Samples (continued)

Sample ID Number	Description
AEA03-FF-08-FW-T1	Fortification sample, Day 08, face/neck wipe, 1st travel spike
AEA03-FF-08-FW-T2	Fortification sample, Day 08, face/neck wipe, 2nd travel spike
AEA03-FF-08-ID-T1	Fortification sample, Day 08, inner dosimeter, 1st travel spike
AEA03-FF-08-ID-T2	Fortification sample, Day 08, inner dosimeter, 2nd travel spike
AEA03-FF-08-OD-T1	Fortification sample, Day 08, outer dosimeter, 1st travel spike
AEA03-FF-08-OD-T2	Fortification sample, Day 08, outer dosimeter, 2nd travel spike
AEA03-FF-08-CS-T1	Fortification sample, Day 08, cotton socks, 1st travel spike
AEA03-FF-08-CS-T2	Fortification sample, Day 08, cotton socks, 2nd travel spike
AEA03-FF-09-AR-L1	Fortification sample, Day 09, air sampling tube, 1st low level
AEA03-FF-09-AR-L2	Fortification sample, Day 09, air sampling tube, 2nd low level
AEA03-FF-09-AR-L3	Fortification sample, Day 09, air sampling tube, 3rd low level
AEA03-FF-09-AR-H1	Fortification sample, Day 09, air sampling tube, 1st high level
AEA03-FF-09-AR-H2	Fortification sample, Day 09, air sampling tube, 2nd high level
AEA03-FF-09-AR-H3	Fortification sample, Day 09, air sampling tube, 3rd high level
AEA03-FF-09-HW-L1	Fortification sample, Day 09, hand wash, 1st low level
AEA03-FF-09-HW-L2	Fortification sample, Day 09, hand wash, 2nd low level
AEA03-FF-09-HW-L3	Fortification sample, Day 09, hand wash, 3rd low level
AEA03-FF-09-HW-H1	Fortification sample, Day 09, hand wash, 1st high level
AEA03-FF-09-HW-H2	Fortification sample, Day 09, hand wash, 2nd high level
AEA03-FF-09-HW-H3	Fortification sample, Day 09, hand wash, 3rd high level
AEA03-FF-09-FW-L1	Fortification sample, Day 09, face/neck wipe, 1st low level
AEA03-FF-09-FW-L2	Fortification sample, Day 09, face/neck wipe, 2nd low level
AEA03-FF-09-FW-L3	Fortification sample, Day 09, face/neck wipe, 3rd low level
AEA03-FF-09-FW-H1	Fortification sample, Day 09, face/neck wipe, 1st high level
AEA03-FF-09-FW-H2	Fortification sample, Day 09, face/neck wipe, 2nd high level
AEA03-FF-09-FW-H3	Fortification sample, Day 09, face/neck wipe, 3rd high level
AEA03-FF-09-ID-L1	Fortification sample, Day 09, inner dosimeter, 1st low level
AEA03-FF-09-ID-L2	Fortification sample, Day 09, inner dosimeter, 2nd low level
AEA03-FF-09-ID-L3	Fortification sample, Day 09, inner dosimeter, 3rd low level
AEA03-FF-09-ID-H1	Fortification sample, Day 09, inner dosimeter, 1st high level
AEA03-FF-09-ID-H2	Fortification sample, Day 09, inner dosimeter, 2nd high level
AEA03-FF-09-ID-H3	Fortification sample, Day 09, inner dosimeter, 3rd high level
AEA03-FF-09-OD-L1	Fortification sample, Day 09, outer dosimeter, 1st low level
AEA03-FF-09-OD-L2	Fortification sample, Day 09, outer dosimeter, 2nd low level
AEA03-FF-09-OD-L3	Fortification sample, Day 09, outer dosimeter, 3rd low level
AEA03-FF-09-OD-H1	Fortification sample, Day 09, outer dosimeter, 1st high level
AEA03-FF-09-OD-H2	Fortification sample, Day 09, outer dosimeter, 2nd high level
AEA03-FF-09-OD-H3	Fortification sample, Day 09, outer dosimeter, 3rd high level

Exposure Samples (continued)

Sample ID Number	Description
AEA03-FF-09-CS-L1	Fortification sample, Day 09, cotton socks, 1st low level
AEA03-FF-09-CS-L2	Fortification sample, Day 09, cotton socks, 2nd low level
AEA03-FF-09-CS-L3	Fortification sample, Day 09, cotton socks, 3rd low level
AEA03-FF-09-CS-H1	Fortification sample, Day 09, cotton socks, 1st high level
AEA03-FF-09-CS-H2	Fortification sample, Day 09, cotton socks, 2nd high level
AEA03-FF-09-CS-H3	Fortification sample, Day 09, cotton socks, 3rd high level
AEA03-FF-09-AR-C1	Fortification sample, Day 09, air sampling tube, 1st control
AEA03-FF-09-AR-C2	Fortification sample, Day 09, air sampling tube, 2nd control
AEA03-FF-09-HW-C1	Fortification sample, Day 09, hand wash, 1st control
AEA03-FF-09-HW-C2	Fortification sample, Day 09, hand wash, 2nd control
AEA03-FF-09-FW-C1	Fortification sample, Day 09, face/neck wipe, 1st control
AEA03-FF-09-FW-C2	Fortification sample, Day 09, face/neck wipe, 2nd control
AEA03-FF-09-ID-C1	Fortification sample, Day 09, inner dosimeter, 1st control
AEA03-FF-09-ID-C2	Fortification sample, Day 09, inner dosimeter, 2nd control
AEA03-FF-09-OD-C1	Fortification sample, Day 09, outer dosimeter, 1st control
AEA03-FF-09-OD-C2	Fortification sample, Day 09, outer dosimeter, 2nd control
AEA03-FF-09-CS-C1	Fortification sample, Day 09, cotton socks, 1st control
AEA03-FF-09-CS-C2	Fortification sample, Day 09, cotton socks, 2nd control
AEA03-FF-09-AR-T1	Fortification sample, Day 09, air sampling tube, 1st travel spike
AEA03-FF-09-AR-T2	Fortification sample, Day 09, air sampling tube, 2nd travel spike
AEA03-FF-09-HW-T1	Fortification sample, Day 09, hand wash, 1st travel spike
AEA03-FF-09-HW-T2	Fortification sample, Day 09, hand wash, 2nd travel spike
AEA03-FF-09-FW-T1	Fortification sample, Day 09, face/neck wipe, 1st travel spike
AEA03-FF-09-FW-T2	Fortification sample, Day 09, face/neck wipe, 2nd travel spike
AEA03-FF-09-ID-T1	Fortification sample, Day 09, inner dosimeter, 1st travel spike
AEA03-FF-09-ID-T2	Fortification sample, Day 09, inner dosimeter, 2nd travel spike
AEA03-FF-09-OD-T1	Fortification sample, Day 09, outer dosimeter, 1st travel spike
AEA03-FF-09-OD-T2	Fortification sample, Day 09, outer dosimeter, 2nd travel spike
AEA03-FF-09-CS-T1	Fortification sample, Day 09, cotton socks, 1st travel spike
AEA03-FF-09-CS-T2	Fortification sample, Day 09, cotton socks, 2nd travel spike

Part 5 Independent Review Board Approval and Translated Informed Consent

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

DATE: January 22, 2008

TO: Sami Selim, Ph.D.
Principal Investigator

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

SUBJECT: Approval Clinical Research Protocol dated: 1/16/2008
- English/Certified Spanish Translation Informed Consent Form (Ver. 1/22/2008)
- Mopping Application Scenarios: Rational for Study Design dated 1/14/2008
- English/Certified Spanish Translation Experimental Subject's Bill of Rights
- Site Questionnaire

PROTOCOL: (070265) A Study For Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using Bucket an Mop Equipment for Cleaning Indoor Surfaces.

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

At the meeting held on January 22, 2008, the Committee reviewed and unanimously approved the Research Protocol, the Investigators, Mopping Application Scenarios: Rational for Study Design, Experimental Subject's Bill of Rights and Informed Consent Form for the above noted research study. The Site Questionnaire was reviewed and unanimously accepted.

The Informed Consent Form is unanimously approved. The Committee recommended that changes be made to the Informed Consent Form. The approved English/Certified Spanish Translation Informed Consent Forms are identified as Version 1/22/2008 and stamped, "Approved 1/22/2008. The Informed Consent Form contains all regulatory required consent elements. The English/Certified Spanish Translation Experimental Subject's Bill of Rights are stamped "Approved 1/22/2008".

phone 954-327-0778 • fax 954-327-5778 • 6738 West Sunrise Blvd., Suite 102 • Plantation, FL 33313 • info@iirb.com (email) • www.iirb.com

The study has been approved for a 12 month period. Prior to the end of approval on 1/21/2009, you are required to provide the Independent Investigational Review Board with a written progress report for this research and obtain approval for continuing the research. Changes to the protocol or use of non-approved recruitment materials cannot be initiated without IIRB review and approval.

In the event of any serious adverse events, significant deviations from the protocol or problems in the research, written notice to the Independent Investigational Review Board is required. Please provide this reporting to the above-noted address so that appropriate follow-up will be initiated.

Thank you for your cooperation.

KL/AMS/yc:rr

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the study.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the study may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of a signed and dated written consent form when one is required.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

APPROVED BY
Independent IRB

Signature 1/22/08
Date

CARTA DE LOS DERECHOS DEL SUJETO EXPERIMENTAL

Cualquier persona a quien se le solicite que consienta a participar como sujeto de un estudio de investigación científica que implique un experimento médico, o a quien se le solicite que consienta en nombre de otro, tiene el derecho de:

1. Estar informado acerca de la naturaleza y del propósito del estudio.

2. Que se le dé una explicación de los procedimientos a seguir en el experimento médico y sobre cualquier fármaco o dispositivo a ser usado.

3. Que se le dé una descripción acerca de cualquier molestia y riesgo del asistente, los cuales se esperen que razonablemente resulten del experimento.

4. Que se le dé una explicación acerca de cualquier beneficio al sujeto, que se espere que razonablemente resulte del experimento, si es pertinente.

5. Que se le divulgue cualquier procedimiento(s) alternativo apropiado, fármaco(s), o dispositivo(s) que pudiera serle ventajoso al sujeto, y sus riesgos y beneficios relativos.

6. Que se le informe acerca de las avenidas de tratamiento médico, si existen, a disposición del sujeto, después del experimento, si surgieran complicaciones.

7. Que se le dé una oportunidad de hacer cualquier pregunta concerniente al experimento o a los procedimientos implicados.

8. Que se le instruya que el consentimiento para participar en el estudio podría ser retirado en cualquier momento, y que el sujeto puede discontinuar la participación en el experimento médico, sin perjuicios.

9. Que se le dé un ejemplar [una copia] de un formulario de consentimiento escrito, firmado y fechado, cuando se requiera uno.

10. Que se le dé la oportunidad de decidir a dar o no, el consentimiento a un experimento médico, sin la intervención de ningún elemento de fuerza, fraude, engaño, coacción, coerción, o la indebida influencia sobre la decisión del sujeto.

_____ _____

Firma del Sujeto Fecha

_____ _____

Firma del Testigo Fecha

APROBADO POR
Independent IRB

Firma 1/22/08
Fecha

INFORMED CONSENT FORM

Title: (Protocol # 070265) A Study For Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using Bucket an Mop Equipment for Cleaning Indoor Surfaces.

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

Field Coordinator:
Tami I. Belcher
Grayson Research, LLC.
1040 Grayson Farm Road
Creedmoor, NC 27522
Phone: 919-528-5508

Field Locations: 3 Sites in Fresno County, CA

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

24-Hour Phone Number: 559-447-5364 (Sami Selim)

You are being asked to participate in a research study. 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 participate. If you have any questions, or if you do not understand anything in this form, please ask Dr. Selim, the Principal Investigator, to explain. If you would prefer to discuss participation in either English or Spanish, please ask. This form is available in either English or Spanish, and we can explain the study to you in either language. A translator who can help you understand the research is available as well.

Purpose of this Study
Golden Pacific Laboratories is doing this research to find out how much mop water may reach your skin when you mop a floor. We will measure how much of

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Independent IRB
Signature 1/22/08 Date

Initials: _____
Date: _____

the mop water 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 mop floors.

The study is being paid for by the Antimicrobial Exposure Assessment Task Force II (AEATF II), a group of companies that make antimicrobial cleaning products. These products kill germs on indoor surfaces, and are currently approved 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. Tami I. Belcher of Grayson Research is the Field Coordinator.

Test Product
The material being tested in this study is a pesticide called SANI-CARE LEMON QUAT, a commercial cleaning product used to clean hard surfaces like floors, walls, and stainless steel. This product is recommended for use in offices and commercial and institutional buildings, such as hospitals, schools, and hotels.

SANI-CARE LEMON QUAT contains two active chemicals: didecyl dimethyl- and n-alkyl dimethyl benzyl- ammonium chlorides, which kill germs. SANI-CARE LEMON QUAT is a strong concentrate, and in this study it will be mixed with water to make the mopping solution.

Subject Selection
People who take part in this research must be healthy adults, between the ages of 18 and 65, who read and speak English or Spanish. They must have experience doing janitorial work; and must be interested in participating in this study and willing to sign a consent form, a form with your personal information and 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 or Grayson Research; if you are pregnant or breast-feeding; if you aren't able to mop floors for 30 minutes at a time between breaks; 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.

Approximately 24 people will participate in this study. A few more people will be enrolled than are needed, in case anyone is unexpectedly unable to participate on the day of the test.

APPROVED BY
Independent IRB
Signature 1/22/08 Date

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Date: _____

The research will be conducted at three different vacant commercial buildings on different days. Six people and two alternates will be asked to participate at each building. You can participate only once, but if you are the alternate and are not selected, you may be able to participate fully on another day.

Study Enrollment

Before you can be enrolled in this study, you will come to the offices of Golden Pacific Laboratories at 4720 W. Jennifer Ave., Suite 105, in Fresno, to meet with the Principal Investigator, Dr. Selim. He will answer all your questions regarding the study, and will 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 meet all eligibility requirements and decide you want to participate in the study, we will ask you to sign this Informed Consent Form and provide some information about your work experience and your general health. We'll ask you for your name and age, about your experience mopping floors, and about your previous use of antimicrobial or pesticide products. We will measure your height and weight, and we will ask you for your clothing and shoe sizes.

If you are accepted as a participant we will ask you to report to one of the three field study locations at a certain day and time, and we'll give you a map with directions to the study location.

We will call you the day before your scheduled test day to confirm your availability. We'll also ask you to be sure to take a shower or a bath before coming to the study location.

Study Procedures

The study itself will take about 4 to 6 hours on one day. During that time you will change into special clothing and shoes for the test and get fitted with a device to sample the air you breathe, then you'll be asked to mop a floor with a diluted solution of SANI-CARE LEMON QUAT for 30 to 90 minutes, and finally you'll give the special clothing to the research team and change back into your own clothes. Here's exactly what will happen on the study day.

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

2. If you are female and less than 50 years old, you will be taken to a private area and asked to take a urine pregnancy test using an over-the-counter pregnancy test kit. After you've taken the pregnancy test you will be asked if you still want to participate in the test. If you say no, you will be paid for your inconvenience and will be free to go. If you say yes, a female member of the research team will double-check the results of the

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pregnancy test. All results of the pregnancy test will be kept in confidence, they will not be recorded, and they will be discussed only with you.

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

4. A same-sex member of the research team 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, and then to put on cotton long underwear (long johns), and a long sleeved cotton shirt and long cotton pants. All these clothes will be provided to you. The technician may have to trim the sleeves and trousers of the long underwear so it doesn't stick out. You will also be given special socks and shoes. Your street clothes and valuables will be placed in a locked storage area, and you will be given the key to keep with you.

5. You will be given safety glasses, and you must wear them while you are mopping the floor.

6. Before the test begins, you will wash your hands and face with Ivory soap and water, and dry them thoroughly using paper towels.

7. We will attach a small air sampling pump on a belt around your waist, and attach a small tube connected to the air pump to your shirt collar. This will sample the air you breathe while you are mopping. The pump is small and light-about the size of a portable radio.

8. We will turn on the air pump, and you will put on your safety glasses. We will give you a string mop and a bucket containing the already diluted SANI-CARE LEMON QUAT solution, and ask you to start mopping the floor the way you normally do on your job. A researcher will watch you as you work, keeping track of how long you work and how much floor you mop, and may take pictures or video. **If you do not want to be photographed or recorded do not participate in this study.**

9. We will give you a bucket with fresh cleaning solution every 15 minutes, or more often if you ask for it.

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10. After you've been mopping for 30 minutes, the researcher will rinse your hands with a solution of rubbing alcohol and water, and save the rinse solution for analysis. You will then have a 10-minute rest period. You will not be permitted to smoke during this rest period, but you may eat (if you wash your hands with Ivory soap and water following eating) and are encouraged to drink lots of fluids. You can rest more often if you need to, but before each rest period, the researcher will rinse your hands and save the rinse solution. Depending on which group you are assigned to, you may be asked to continue mopping for up to 2 more 30 minute periods of mopping, for a total of 90 minutes, each followed by a 10 minute break.

11. When you finish mopping, a researcher of your own sex will take you back to the changing area to collect additional samples and remove the special underwear and other clothing. Samples will be collected in this order:

    a. The air sampling pump and the sampling tube will be removed and saved for analysis.

    b. The researcher will rinse your hands with a solution of rubbing alcohol and water for the last time, and save the rinse solution.

    c. The researcher will wipe your face and neck with rubbing alcohol with water moistened pads, to collect any of the mopping solution that might be on your skin, and save the pads for analysis

    d. The researcher will help you take off the outer shirt and pants, and will save each garment for analysis.

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

    f. The researchers will help you remove your shoes and will save the socks for analysis.

12. You will then be asked to put on a set of new cotton long underwear (long Johns), long sleeved cotton shirt, long cotton pants, and cotton socks as described under Point 4 to 7. We will turn on the air pump, and you will put on your safety glasses. You will be asked to empty the buckets containing the diluted SANI-CARE LEMON QUAT solution. If you mopped for 30 minutes, you will have to empty at least 2 buckets. If you mopped for 90 minutes, you will have to empty at least 6 buckets.

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13. When you finish emptying the buckets, a researcher of your own sex will take you back to the changing area to remove the special underwear and other clothing and collect the samples as described under Point 11.

14. When all samples have been collected, you will dress again in your street clothes and may take the shoes you wore on study, if you wish.

15. Dr. Selim will check your hands before you leave for redness or other signs of irritation. You will be paid for you time and trouble in cash, and will be free to go.

Risks

Potential risks to you in this study are of several different kinds:

- Risk of a reaction to the test material. EPA requires that the label for the concentrated SANI-CARE LEMON QUAT product bear the signal word "Danger." Direct contact with the concentrated product could damage your eyes permanently, could irritate your skin, and could harm you if you breathe it in. But in this research you will never handle the concentrated product, since it will already be mixed with water in the buckets that are provided to you. You will also be wearing safety glasses to keep the mopping water out of your eyes, and long sleeves, pants, and socks to keep it off your skin. It isn't expected, but you might possibly have an allergic reaction to the mopping water, or it might interact with medicines you are taking. If you have had an allergic reaction to a cleaning product before, or if you are taking medicine, be sure to tell the researchers before you sign this form. The risk of a reaction to the test material is low, but if you do notice any redness or itching or other discomfort, or if you think you may have gotten some of the mopping water in your eye, stop mopping immediately and tell a researcher. A copy of the product label and the Material Safety Data Sheet (MSDS) for SANI-CARE LEMON QUAT will be given to you for reference. A person will be available to help explain these documents to you (in either English or Spanish) and to answer any questions you may have.

- Risk of over-exertion and stroke or heart attack. Mopping continually for 30 minutes is hard physical labor. If you are not in good physical condition, this much work may be dangerous to your health.

- Risk of discomfort. The air pump you will be wearing on your belt and the air hose used to sample the air you breathe may be awkward or uncomfortable for you. Wearing two layers of clothing may also be uncomfortable.

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- 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.

- Because you'll be wearing two complete layers of clothing there is a small possibility that you might experience heat stress. The researchers will monitor the temperature and humidity at the test location, and will stop the study if it gets too hot to be safe. If you feel at all faint or overheated, or are sweating heavily, stop mopping and tell a member of the research team immediately.

- Risk of embarrassment. You may find it embarrassing to have a researcher present with you while you change clothes. This is necessary to make sure the special underwear fits properly, and that it and the outer clothing do not 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 be wearing your own underwear all the time.

- If you are a female, you might be surprised to learn the results of the required pregnancy test on the day of the research. No-one but you and one female researcher will know those results, and they will not be recorded.

Pregnancy Risks
We don't know the risks to the unborn from exposure to SANI-CARE LEMON QUAT **and may be hazardous**, so it is important that you do NOT participate in this study if you are pregnant. That's why on the day of the test all female volunteers under 50 will be given a pregnancy test kit like 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 continue in the study or withdraw; if you decide to withdraw, you won't be asked why. You'll be paid for the inconvenience of coming to the test location, and then you'll be free to go. If you want to continue in the study, a female researcher trained to understand the results of this pregnancy test will check the results with you privately. No-one but you and she will see the results, and they will not be recorded.

Unknown/Unforeseeable Risks
In addition to the risks listed above, there may be some other unknown or unforeseen risks associated with the use of this pesticide, including the possibility of an allergic reaction or interaction with a medication. You will be told in a timely manner both verbally and in writing of any new information that may influence your decision to participate.

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Research-Related Injuries
If you are injured as a result of being in this study, medical treatment will be available from a near-by health care facility that knows about this study. The people who are paying for this study will pay any costs of your medical treatment that are not covered by your own insurance or by a third party. If necessary, Golden Pacific Laboratories will transport you to receive medical attention and pay costs associated with reasonable and appropriate treatment for any injuries you get as a result of participating in this study. For more information, or if you think you may have been injured during the research, call Dr. Selim at Golden Pacific Laboratories (559 275-9091).

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

Alternatives to Participation
If you decide to participate 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. Your alternative is to not participate.

Benefits
There are no direct benefits to you from your participation. Because what we learn from this study will be used to make sure cleaning products like SANI-CARE LEMON QUAT can be used safely, you and other people who do janitorial work may benefit indirectly from the research. You may benefit if you request results from this study that let you know how your exposure compared to other workers doing your job. The people who are paying for the study will also benefit, since they need to do this study to be able 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. If you have any questions or problems during the study, ask Dr. Selim or any other member of the research team.

As a research volunteer, you have rights. They are spelled out in the attached "Research Subject's Bill of Rights." If you have any questions about your rights as a research volunteer, call Kim Lerner, Chairman of the Independent Investigational Review Board, Inc. toll free at (877-888-4472) during regular working hours. The Independent Investigational Review Board is a committee established to protect the rights of research volunteers. The Independent Investigational Review Board has reviewed and approved the plans for this study and this informed consent document.

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Costs and Reimbursement
There will be no cost to you to participate in this study. If you are selected to participate in the study, you will receive $100 in cash at the end of the day of the study, or whenever you withdraw. If you are designated as an alternate subject, you will receive a payment of $50 in cash for your inconvenience in coming to the study location.

Confidentiality
Each volunteer will be assigned an identification number, and all research data will be recorded under that number. All analysis and reporting will be done using data identified only by the identification number. Your name will appear only in the field raw data, and there only once. The document linking your name to the identification number will be stored separately, in a locked cabinet, away from all other study data. You will not be identified by name or any other personal identifier in any reports of this study.

Golden Pacific Laboratories will retain the records of this study indefinitely. You may obtain a copy of your own records by asking Dr. Selim for it but you may have to wait until the study has been completed. Representatives from the Sponsor (AEATF II), the U.S. Environmental Protection Agency (EPA), the California Department of Pesticide Regulation, and the Independent Investigational Review Board, Inc., may have access to all non-personal information collected in this study. Because information from this study may be released to these parties, absolute confidentiality cannot be guaranteed.

Right to Withdraw
You are free to withdraw from this study at any time, for any reason. Simply tell Dr. Selim or another member of the research team if you wish to withdraw. Your decision not to participate in this study or to withdraw from this study will not affect your future medical care and will involve no penalty or loss of benefits to which you are otherwise entitled.

Removal from Study
Dr. Selim, the Principal Investigator in charge of this study, can remove you from this study without your consent. He might do this if, for example:

- He thinks staying in the study could put you at risk,
- You fail to follow the instructions of the researchers,
- The temperature and humidity at the test site get so high it would be dangerous to continue the test, or
- The study is stopped for other reasons.

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If you are removed from the study, or if the entire study is stopped, you are still entitled to compensation for your time and inconvenience.

Consent and Signature

I have read this Informed Consent Form and have received satisfactory answers to all of my questions 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 Informed Consent Form. I shall receive a 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 my presence. I have faithfully translated all questions from the volunteer and all the answers provided by the researchers. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____
Translator's Signature

_____
Translator'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 on (date) _____ by (initials) _____
Independent Investigational Review Board, Inc.
Approved: 1/22/08

Version: 1/22/08
Protocol: 070265

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Signature 1/22/08 Date

Initials: _____
Date: _____

FORMULARIO DE CONSENTIMIENTO INFORMADO

Título: (Protocolo № 070265) Un Estudio para la Medición de la Exposición Potencial Dérmica y de Inhalación, Durante la Aplicación de un Producto Líquido Pesticida Anti-microbiano, mediante el Uso de Equipo de Balde y Estropajo [*Mop*] para la Limpieza de Superficies Interiores.

Investigador Principal:
Sami Selim, PhD
Golden Pacific Laboratories, LLC
4720 W. Jennifer, Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Coordinador de Campo:
Tami I. Belcher
Grayson Research, LLC
1040 Grayson Farm Road
Creedmoor, NC 27522
Teléfono: 919-528-5508

Lugares de Campo: 3 Sitios en el Condado de Fresno, CA

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

Número Telefónico las 24 Horas: 559-447-5364 (Sami Selim)

Queda invitado a participar en un estudio de investigación científica. 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 participar. Si tiene cualquier pregunta(s), o si no entiende algo que contenga este formulario, por favor pídale al Dr. Selim, el Investigador Principal, que se lo explique. Si usted prefiere hablar acerca de la participación, o bien en inglés o en castellano [español], por favor dígalo. Este formulario se encuentra disponible tanto en inglés como en español y nosotros podemos explicarle el estudio a usted en cualquiera de los dos idiomas. También tenemos a disposición un traductor que lo puede ayudar a usted a entender la investigación científica.

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El Propósito de este Estudio
Golden Pacific Laboratories está llevando a cabo esta investigación científica para averiguar cuánta agua del estropajo [*mop*] pueda llegar a su piel cuando usted le pasa un estropajo al piso. Nosotros mediremos qué cantidad del agua del estropajo [*mop*] se mete sobre las ropas que usted usa durante el estudio, sobre sus manos, cara y cuello, y qué cantidad hay en el aire que usted respira mientras que usted le pasa un estropajo al piso.

El estudio lo está pagando Antimicrobial Exposure Assessment Task Force II (AEATF II), un grupo de compañías que fabrican productos de limpieza anti-microbianos. Estos productos matan a los gérmenes que están sobre las superficies interiores, y actualmente se encuentran aprobados 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. Tami I. Belcher de Grayson Research es el Coordinador de Campo.

El Producto a Prueba
El material que se está probando es un pesticida llamado SANI-CARE LEMON QUAT, un producto de limpieza comercial que se usa para limpiar las superficies duras tal como los pisos, paredes y el acero inoxidable. Se recomienda este producto para el uso en oficinas y en edificios comerciales e institucionales, tal como hospitales, escuelas y hoteles.

SANI-CARE LEMON QUAT contiene dos substancias químicas activas: cloruros amónicos [de amoníaco] didecil, dimetil y n-álcali dimetil benzil, los cuales matan a los gérmenes. SANI-CARE LEMON QUAT es un concentrado fuerte y, en este estudio, se mezclará con agua para hacer la solución para usar con el estropajo.

La Selección de los Sujetos
Las personas quienes participen en esta investigación científica deben ser adultos sanos, entre las edades de 18 y 65, quienes lean y hablen inglés o español. Ellos deben tener experiencia en el trabajo de limpieza; y deben estar interesados en participar en este estudio y dispuestos a firmar un formulario de consentimiento, un formulario que contiene su información personal y deben 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 ó de Grayson Research; si usted está embarazada o amamantando [dando el pecho]; si usted no puede pasarle el estropajo a pisos durante 30 minutos en un momento entre los descansos [*breaks*]; 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

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tomando medicamentos que puedan reaccionar con el producto a prueba; o si usted tiene problemas del corazón o respiratorios.

Aproximadamente 24 personas participarán en este estudio. Se inscribirá a unas pocas personas más de las que se necesiten, en el caso de que alguien, inesperadamente, no pueda participar en el día de la prueba.

La investigación científica se llevará a cabo en tres diferentes edificios comerciales desocupados, en días diferentes. Se les pedirá a seis personas y a dos alternos que participen en cada edificio. Usted puede participar solamente una vez, pero si usted es el alterno y no es seleccionado, usted pudiera participar completamente en otro día.

La Inscripción en el Estudio
Antes de que se pueda inscribir en este estudio, usted vendrá a las oficinas de Golden Pacific Laboratories en 4720 W. Jennifer Ave., Suite 105, Fresno, para reunirse con el Investigador Principal, el Dr. Selim. Él contestará a todas sus preguntas en lo concerniente al estudio, y le contará más, a usted, acerca de qué esperar mientras que esté participando y qué se espera de usted. Esta primera visita llevará alrededor de una hora.

Si usted cumple con todos los requisitos de elegibilidad y decide que desea participar en el estudio, nosotros le pediremos a usted que firme este Formulario de Consentimiento Informado y que proporcione algo de información acerca de su experiencia laboral [de trabajo] y acerca de su salud general. Le preguntaremos su nombre y edad, le preguntaremos acerca de su experiencia como en pasar estropajos a pisos y acerca de su uso anterior de productos anti-microbianos o pesticidas. Nosotros le mediremos su estatura y peso, y le preguntaremos sus tamaños [tallas] de ropas y de zapatos.

Si usted es aceptado en calidad de participante, le pediremos que se presente en uno de los tres lugares del estudio de campo, en cierto día y a cierta hora, y le daremos un mapa con instrucciones hacia el lugar del estudio.

Lo llamaremos el día anterior al día de prueba programado, para confirmar su disponibilidad. También le pediremos que no se olvide de darse una ducha o un baño antes de venir al lugar del estudio.

Los Procedimientos del Estudio
El estudio en sí llevará alrededor de 4 a 6 horas en un día. Durante ese tiempo, usted se cambiará de ropa, se pondrá una ropa especial para la prueba y zapatos, y le pondrán un dispositivo para hacer el muestreo del aire que respira usted, luego le pedirán que limpie un piso, con una solución diluida de SANI-CARE LEMON QUAT durante 30 a 90 minutos y, finalmente, usted le dará las ropas especiales al equipo de

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la investigación científica y se volverá a poner sus propias ropas. A continuación se describe exactamente lo que sucederá en el día del estudio.

1. En el día del estudio, usted irá al lugar del estudio a la hora que le hayan dicho y se reunirá con los investigadores.

2. Si usted es una mujer que tiene menos de 50 años, la llevarán a un área privada y le pedirán que se haga una prueba de embarazo por medio del análisis de orina, mediante el uso de un equipo de pruebas de embarazo de venta libre. Después de que usted se haya hecho la prueba de embarazo, le preguntarán si usted aún desea participar en la prueba. Si usted dice que no, le pagarán por su inconveniente y podrá irse libremente. Si usted dice que sí, un miembro del sexo femenino del equipo de investigaciones científicas, volverá a verificar los resultados de la prueba de embarazo. Todos los resultados de la prueba de embarazo se mantendrán de manera confidencial, ellos no serán registrados, y solamente se hablará de ellos con usted.

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 una oportunidad de hacer preguntas adicionales. Nosotros le haremos recordar que usted puede cambiar de parecer acerca de la participación, en cualquier momento – antes o después de que empiece el estudio. Todo lo que usted tiene que hacer es decirnos que usted desea retirarse del estudio. No habrá multa de ninguna clase, para usted, si es que usted decide retirarse del estudio.

4. Un miembro del mismo sexo del equipo de investigaciones científicas le mostrará a usted 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, y luego que se ponga ropa interior larga (calzoncillos largos), de algodón, y una camisa de algodón de manga larga y pantalones largos de algodón. Todas estas ropas se las proporcionarán a usted. El técnico pudiera tener que recortar las mangas y los pantalones de la ropa interior larga, de modo que no sobresalga nada hacia afuera. También le darán calcetines y zapatos especiales. Sus ropas de calle y sus objetos de valor los pondrán en un área de almacenamiento bajo llave, y le darán la llave para que se la guarde con usted.

5. Le darán anteojos de seguridad, y usted debe usarlos mientras que esté limpiando el piso.

6. Antes de que empiece la prueba, usted se lavará las manos y la cara con jabón Ivory y agua, y se las secará bien mediante el uso de toallas de papel.

7. Nosotros le adjuntaremos una bomba pequeña de muestreo de aire, en un cinturón alrededor de su cintura, y le adjuntaremos un tubo pequeño conectado a la bomba

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de aire, en el cuello de su camisa. Esto hará un muestreo del aire que usted respira mientras que esté limpiando el piso. La bomba es pequeña y liviana – alrededor del tamaño de un receptor portátil de radio.

8. Nosotros encenderemos la bomba de aire, y usted se pondrá los anteojos de seguridad. Le daremos un estropajo de tiras y un balde que contenga la solución ya diluida SANI-CARE LEMON QUAT, y le pediremos que empiece a pasarle el estropajo al piso de la manera en la cual usted lo hace normalmente en su trabajo. Un investigador lo observará a usted mientras que usted esté trabajando, registrando cuánto tiempo trabaja usted y a cuánto piso le pasa el estropajo usted, y pidiera sacar fotos o grabar un vídeo. **Si usted no quiere que lo fotografíen ni que lo graben, no participe en este estudio.**

9. Nosotros le daremos, un balde con solución nueva de limpieza cada quince minutos, ó más a menudo si usted lo pide.

10. Después de que usted haya estado pasando el estropajo durante 30 minutos, el investigador le enjuagará las manos a usted, con una solución de alcohol de frotar y agua, y guardará la solución del enjuague para el análisis. Luego le darán un período de descanso de 10 minutos. No le permitirán que fume durante el período de descanso, pero usted puede comer (si se lava las manos con jabón Ivory y agua, seguido a la comida) y le aconsejamos que beba mucho líquido. Usted puede descansar más a menudo si lo necesita, pero antes de cada período de descanso el investigador enjuagará sus manos y guardará la solución del enjuague. Dependiendo de cuál grupo a usted lo hayan asignado, pudieran pedirle que continúe pasando el estropajo durante 2 períodos más de pasar el estropajo, de 30 minutos, por un total de 90 minutos, cada uno seguido por un descanso de 10 minutos.

11. Cuando usted termine de pasar el estropajo, un investigador del mismo sexo lo llevará a usted de vuelta al área para cambiarse, para recoger muestras adicionales y para remover la ropa interior especial y otras ropas. Las muestras se recogerán en este orden:

    a. La bomba del muestreo de aire y el tubo de muestreo serán removidos y guardados para ser analizados.

    b. El investigador le enjuagará las manos a usted con una solución de alcohol de frotar y agua, por última vez, y guardará la solución del enjuague.

    c. El investigador le limpiará la cara y el cuello a usted, con alcohol de frotar con almohadillas humedecidas con agua, para recoger cualquier solución del estropajo que pudiera haber en su piel, y guardará las almohadillas para ser analizadas.

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d. El investigador lo ayudará a usted a quitarse la camisa de uso exterior y los pantalones, y guardará cada ropa para analizarla.

e. El investigador lo ayudará a usted a quitarse la ropa interior larga, y la guardará para ser analizada.

f. Los investigadores lo ayudarán a usted a quitarse los zapatos y se guardarán los calcetines para mandarlos a analizar.

12. Luego le pedirán que se ponga un juego de ropa interior larga de algodón (calzoncillos largos), una camisa de algodón de manga larga, pantalones largos de algodón y calcetines de algodón, según se ha descripto en los Puntos 4 al 7. Nosotros encenderemos la bomba de aire y usted se pondrá sus anteojos de seguridad. Le pedirán que vacíe los baldes que contengan la solución diluida SANI-CARE LEMON QUAT. Si usted pasó el estropajo durante 30 minutos, usted tendrá que vaciar por lo menos 2 baldes. Si usted pasó el estropajo durante 90 minutos, usted tendrá que vaciar por lo menos 6 baldes.

13. Cuando usted termine de vaciar los baldes, un investigador de su propio sexo lo llevará de vuelta al área para cambiarse, para que se quite la ropa interior especial y otras ropas y para recoger las muestras, según se ha descripto en el Punto 11.

14. Cuando se hayan juntado todas las muestras, usted volverá a vestirse en sus ropas de calle y podrá quitarse los zapatos que usó en el estudio, si usted lo desea.

15. El Dr. Selim le revisará las manos antes de que usted se vaya, para ver si hay enrojecimiento u otras señales de irritación. Le pagarán por su tiempo y molestia, en efectivo, y se podrá ir libremente.

Riesgos

Los riesgos potenciales para usted, en este estudio, son de varias clases diferentes:

- Riesgo de una reacción al material de prueba. EPA requiere que la etiqueta para el producto concentrado SANI-CARE LEMON QUAT contenga la palabra de señal «Peligro» ["Danger" en inglés]. El contacto directo con el producto concentrado podría dañar a sus ojos permanentemente, podría irritarle la piel, y podría dañarlo a usted si usted lo respira. Pero en esta investigación científica, usted nunca manipuleará el producto concentrado, debido a que ya estará mezclado con agua en el balde que le den a usted. Usted también estará usando anteojos de seguridad para evitar que el agua para pasar el estropajo entre en contacto con sus ojos y, mangas, pantalones y calcetines largos para mantenerlo alejado de su piel. No se espera, pero usted podría posiblemente tener una reacción alérgica al agua para pasar el estropajo, o ella podría interactuar con medicamentos que usted esté tomando. Si usted ha tenido una reacción alérgica a un producto de limpieza anteriormente, o si usted está

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tomando algún medicamento, asegúrese de decírselo a los investigadores antes de que usted firme este formulario. El riesgo de una reacción al material de prueba, es bajo, pero si usted notase cualquier enrojecimiento o picazón o cualquier otra molestia, o si usted piensa que pudo habérsele metido algo del agua del estropajo en sus ojos, deje de pasar el estropajo inmediatamente y dígaselo a un investigador. Le darán a usted una copia de la etiqueta del producto y de la Hoja de Datos de Seguridad de los Materiales (MSDN) (*Material Safety Data Sheet*) para SANI-CARE LEMON QUAT, para referencia. Habrá una persona a disposición para ayudar a explicarle a usted estos documentos (ya sea en inglés o en español) y para responder a cualquier pregunta(s) que usted pueda tener.

- Riesgo de sobre-esfuerzo y golpe de calor o ataque al corazón. El hecho de pasar el estropajo continuamente durante 30 minutos es trabajo físico pesado. Si usted no se encuentra en buena condición física, esta cantidad de trabajo pudiera ser peligrosa para su salud.

- Riesgo de molestia. La bomba de aire que usted va a estar usando en su cinturón y la manguera de aire que se usa para hacer el muestreo del aire que respira usted, pueden resultarles difícil de manejar o incómodos. El hecho de usar dos capas de ropas también pudiera ser incómodo.

- 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.

- Debido a que usted estará usando dos capas completas de ropas, existe una pequeña posibilidad de que usted pudiera experimentar estrés debido al calor. Los investigadores monitorearán la temperatura y humedad en el lugar donde se lleve a cabo la prueba, y detendrán 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 pasar el estropajo y dígaselo inmediatamente a un miembro del equipo de investigaciones científicas.

- Riesgo de vergüenza [turbación]. Usted pudiera sentirse avergonzado de que un investigador esté presente 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 estará usando su propia ropa interior todo el tiempo.

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- Si usted es mujer, usted podría sorprenderse al conocer los resultados de la prueba de embarazo requerida, en el día de la investigación científica. Nadie, sino usted y una investigadora del sexo femenino, conocerá esos resultados, y ellos no quedarán registrados.

Riesgos del Embarazo
Nosotros no conocemos los riesgos para el nonato, provenientes de la exposición a SANI-CARE LEMON QUAT **y pueden ser peligrosos**, de modo que es importante que usted NO participe en este estudio si está embarazada. Es por eso que en el día de la prueba a todas las voluntarias menores de 50 años de edad, se les dará un equipo para la prueba de embarazo, como los que usted puede comprar en la farmacia. Una investigadora podrá explicarle cómo usarlo y contestará a sus preguntas. Después de que usted se haya hecho la prueba, nosotros le preguntaremos si desea continuar en el estudio o retirarse; si usted decide retirarse, no le preguntarán el porqué. Le pagarán por el inconveniente de venir al lugar de la prueba, y luego podrá irse libremente. Si usted desea continuar en el estudio, una investigadora que está capacitada para entender los resultados de esta prueba de embarazo, verificará los resultados con usted, en privado. Nadie, sino usted y ella, verá los resultados, y ellos no quedarán registrados.

Riesgos Desconocidos/Imprevisibles
Además de los riesgos mencionados anteriormente, podría haber algunos otros riesgos desconocidos o imprevisibles, que estén relacionados con el uso de este pesticida, incluyendo la posibilidad de una reacción alérgica o la interacción con un medicamento. Se le informará de manera puntual, tanto verbalmente como por escrito, acerca de cualquier información nueva, hallazgos o cambios a la manera en que la investigación científica será llevada a cabo, lo cual podría influir sobre su decisión de participar en este estudio.

Lesiones Relacionadas con la Investigación Científica
Si usted se lesionase como resultado de estar en este estudio, habrá disposición tratamiento médico de una instalación cercana del cuidado de la salud que sepa acerca de este estudio. Las personas quienes están pagando por este estudio pagarán por cualquier costo(s) de su tratamiento médico que no esté cubierto por su propio seguro o por un tercero. Si fuese necesario, Golden Pacific Laboratories lo transportará a usted para que reciba atención médica y pagará los costos asociados con el tratamiento razonable y apropiado por cualquier lesión(es) que usted reciba como resultado de la participación en este estudio. Para más información, o si usted piensa que puede haberse lesionado durante la investigación científica, llame al Dr. Selim en Golden Pacific Laboratories (559-9091).

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

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Alternativas a la Participación
Si usted decide participar 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. Su alternativa es la de no participar.

Beneficios
No hay beneficios directos para usted provenientes de su participación. Debido a que lo que nosotros aprendamos de este estudio se usará para asegurarse que los productos de limpieza como el SANI-CARE LEMON QUAT puedan usarse de manera segura, usted y otras personas quienes hacen trabajos de limpieza pudieran beneficiarse indirectamente de la investigación científica. Usted pudiera beneficiarse si usted pide los resultados de este estudio que le hagan saber cómo se comparó su exposición, comparada con la de otros trabajadores que hacen su trabajo. Las personas quienes están pagando por el estudio también se beneficiarán, dado que ellos necesitan hacer este estudio para poder 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. Si tiene alguna pregunta(s) o problema(s) durante el estudio, pregúntele al Dr. Selim o a cualquier otro miembro del equipo de investigaciones científicas.

En calidad de voluntario de una investigación científica, usted tiene derechos. Ellos aparecen en la «Carta de los Derechos del Sujeto de una Investigación Científica». Si usted tiene cualquier pregunta(s) acerca de sus derechos en calidad de voluntario de una investigación científica, llame a la señora Kim Lerner, Presidenta del Independent Investigational Review Board, Inc. al teléfono gratuito (877) 888-4472 durante horas regulares de oficina. El Independent Investigational Review Board es un comité que se ha establecido para proteger los derechos de los voluntarios en investigaciones científicas. El Independent Investigational Review Board ha revisado y aprobado los planes para este estudio y este documento de consentimiento informado.

Costos y Reembolso
No habrá costo para usted por participar en este estudio. Si usted fuese seleccionado para participar en el estudio, recibirá $100 en efectivo al final del día del estudio, o cuando usted se retire. Si usted fuese designado como un sujeto alterno, usted recibirá un pago de $50 en efectivo por su inconveniente de haber venido al lugar del estudio.

Confidencialidad
A cada voluntario se le asignará un número de identificación, y todos los datos de la investigación científica se registrarán bajo ese número. Todos los análisis e informes se harán mediante el uso de datos identificados solamente por medio del número de

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identificación. Su nombre solamente aparecerá en los datos iniciales del campo, y allí solamente una vez. El documento que vincula su nombre con el número de identificación, será almacenado separadamente, en un gabinete bajo llave, alejado de todos los otros datos del estudio. Usted no será identificado por nombre ni por medio de ningún otro identificador personal, en ningún informe(s) sobre este estudio.

Golden Pacific Laboratories retendrá los expedientes de este estudio, indefinidamente. Usted puede obtener una copia de sus propios expedientes pidiéndosela al Dr. Selim, pero usted pudiera tener que esperar hasta que el estudio haya sido completado. Representantes del Patrocinador (AEATF II), la Agencia Estadounidense de Protección Medioambiental (la EPA), el Departamento Californiano de Reglamentación de Pesticidas, y el Independent Investigational Review Board, Inc., pueden tener acceso a toda la información no-personal que se haya recopilado en este estudio. Debido a que la información proveniente de este estudio puede divulgárseles a estas partes, no puede garantizarse una confidencialidad absoluta.

El Derecho a Retirarse
Usted tiene la libertad de retirarse de este estudio en cualquier momento, por cualquier razón. Simplemente dígaselo al Dr. Selim o a otro miembro del equipo de la investigación científica, si es que usted desea retirarse. Su decisión de no participar en este estudio o de retirarse de este estudio, no afectará a su atención médica en el futuro y no implicará ninguna multa ni pérdida de beneficios a los cuales usted, de otro modo, tiene derecho.

La Remoción del Estudio
El Dr. Selim, el Investigador Principal a cargo de este estudio, puede removerlo a usted de este estudio sin su consentimiento. Él podría hacer esto 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,
- La temperatura y la humedad en el sitio de la prueba se pusiesen tan altas que sería peligroso continuar con la prueba, ó
- El estudio fuese detenido por otras razones.

Si a usted lo removiesen del estudio, o si el estudio entero fuese detenido, usted aún tiene derecho a compensación por su tiempo e inconveniente.

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Consentimiento y Firma

Yo he leído este Formulario de Consentimiento Informado y he recibido respuestas satisfactorias a todas mis preguntas 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 de Consentimiento Informado. Yo recibirá una 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 my presence. I have faithfully translated all questions from the volunteer and all the answers provided by the researchers. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____
Translator's Signature

_____
Translator'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 el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 22/enero/08

Versión: 22/enero/08
Protocolo: 070265

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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

January 24, 2008

To Whom It May Concern:
A Quién Corresponda:

This is to certify that the attached document from English into Spanish is an accurate representation of the informed consent form received by this office, before being approved by the IIRB. This document is designated as:

(Protocol # 070265) A Study For Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using Bucket and Mop Equipment for Cleaning Indoor Surfaces.
(Protocol: 070265) (1/22/08) (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, antes de ser aprobado por el IIRB. Dicho documento es:

(Protocolo № 070265) Un Estudio para la Medición de la Exposición Potencial Dérmica y de Inhalación, Durante la Aplicación de un Producto Líquido Pesticida Anti-microbiano, mediante el Uso de Equipo de Balde y Estropajo [*Mop*] para la Limpieza de Superficies Interiores.
(Protocolo: 070265) (22/enero/08) (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*