Agricultural Handlers Exposure Task Force (AHETF)

VOLUME II

AHE55 – Protocol and Supporting Documents

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Volume II, Part A: AHE55 Protocol

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

AGRICULTURAL HANDLERS EXPOSURE TASK FORCE (AHETF)

STUDY No. AHE55

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

PROTOCOL AUTHORIZATION

Read and Approved by:

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

Signature _____

Date _____

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

Signature _____

Date _____

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1.0 GENERAL INFORMATION

1.1 Study Title

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

1.2 Study No. AHE55

1.3 Objective

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

1.4 Timeline

Proposed Experimental Start Date: August, 2008

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

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

Proposed Final Report Issue Date: December, 2009

1.5 Good Laboratory Practice

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

1.6 Pesticide Assessment Guideline

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

1.7 Institutional Review Board

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

1.8 Testing Facility, Sponsor's Representative and Sponsor

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1.9 Study Director

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1.10 Principal Field Investigators

Principal Field Investigators may include:

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4720 W. Jennifer Ave., Suite 106
Fresno, CA 93722
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Aaron Rotondaro
Paragon Research Services, Inc.
6773 Woodcliff Circle

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

1.11 Field Facilities

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

1.12 Principal Analytical Investigator and Analytical Facility

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

1.15 Quality Assurance Unit

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

2.0 ETHICAL CONSIDERATIONS

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

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

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

2.1 Inclusion and Exclusion Criteria

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

Participants in this study must meet the following inclusion criteria;

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

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

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

2.2 Remuneration of Subjects

During recruitment, workers will be offered an opportunity to take part in a group meeting with the Study Director or other designated member of the study team (but without the workers’ supervisors) to learn about participating

in this study (Section 6.2). No remuneration is offered for this introductory meeting. Workers who are still interested will attend a private meeting with a researcher who will obtain the informed consent of the worker (Section 2.7). Workers will be paid $20 for their attendance right after the consent meeting, whether or not they decide to participate in the study. Workers who decide to participate in the study will be paid an additional $80 each time they suit up (i.e., put on the long underwear) to participate in the study. Usually, workers will participate in the study on only one day unless their participation is terminated due to weather or other unexpected occurrences. The additional $80 is provided in cash at the end of the monitoring period or at the time the volunteer withdraws from the study. All workers who participate will receive the payment, even if they withdraw or their participation is terminated by the study team.

2.3 Risks to Subjects

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

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

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

2.3.1 Risk of Heat-Related Illness

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

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

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

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

- Ensure plenty of water and sports drinks are available for the workers.
- During worker orientation immediately before participation in the study, remind the workers of the risk of heat stress, suggest they drink some water before they start work, and let them know how/where they can get water during the monitoring period.
- Urge workers to drink water during the monitoring period and remind them that thirst does not give a good indication of how much water a person needs to drink.
- Observe workers during the monitoring period and be aware of the signs and symptoms of heat-related illness.
- Require workers to take rest breaks when early signs or symptoms of heat illness are present.
- Monitor the heat index (based on air temperature and relative humidity) at least hourly whenever ambient temperature is at or above 70 ºF.
- In cases where the worker has exited the air conditioned cab for a period exceeding 30 minutes, stop the worker activity when the heat index (adjusted for direct sunlight, if applicable) reaches 120^0F and/or move the worker to a cooler environment until monitoring can be resumed
- Have a medical professional on site to observe for signs of heat-related illness
- Know the location of the nearest medical facility

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

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

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

2.3.2 Risk of Exposure to Surrogate Chemicals

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

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

Margins of Exposure for Closed-cab Airblast Application:

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

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

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

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

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

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

For this application study, participants will only be exposed to product that has been diluted in water. The closed cab will likely provide significant protection from both dermal and inhalation exposure. In

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

2.3.3 Risk Associated with Scripting of Field Activities

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

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

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

2.3.4 Psychological Risks

Participating in AHETF exposure monitoring studies involves activities that are unusual and might cause subjects psychological

distress. These include:

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

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

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

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

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

2.3.5 Background Risk of Injury Associated with Agricultural Work

Agriculture remains one of the country's most dangerous occupations (i.e., farm occupations, see Bureau of Labor Statistics). It perennially ranks in the top ten occupations measured by fatality rate (on-the-job deaths divided by total number of workers) or injury/illness rate. The most common risks for serious injury to farmers are vehicular accidents (especially tractor rollovers, but also accidents while driving machinery on roads) and entanglement with moving parts of farm machinery. Farm workers are also commonly exposed to a variety of chemical products that present increased risks compared to the general public. These include pesticides, fertilizers, solvents, lubricants, fuels,

etc.

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

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

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

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

- Selecting only experienced pesticide handlers
- Requiring experience operating the equipment to be used
- Reminding workers of safe chemical handling practices
- Identifying nearby hospitalization facilities in case of emergency
- Monitoring the heat index and stopping the study if conditions warrant
- Providing transportation to medical treatment and covering the costs of treatment
- Having a medical professional on site to observe the workers and provide urgent care
- Observing study participants throughout the monitoring period
- Ensuring that all tank mix products are used according to approved label (s) and do not require any additional PPE.

2.4 Benefits

The risks and likely benefits of the study described in this protocol will be reviewed with potential participants during the consenting process. There are no personal benefits to the study participants. Growers who allow the study to be conducted using their equipment, crops and facilities will be reimbursed for the pesticides used for the study. While this is beneficial to the grower, it is considered a minor benefit when compared to the costs of running their businesses. The AHETF member companies will likely realize a benefit by addressing regulatory data requirements generically, at lower cost (and using fewer human subjects), than if they conducted similar studies for individual pesticide ingredients.

Data from the AHETF exposure monitoring program has the potential to improve the ability of EPA and other regulatory agencies to accurately assess occupational risks associated with spraying pesticides using airblast equipment and closed-cab tractors. The knowledge likely to be obtained from this study is generalizable and will contribute to assessments of the risks of both new and existing pesticides.

Since there are no existing data suitable for use in a generic database describing the exposure of closed-cab airblast application workers, society will likely benefit from data generated by this study through the improved risk assessments by EPA and other regulatory agencies.

2.5 Risk/Benefit Balance

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

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

The likely benefit to agricultural workers as a whole and to society in general, in the form of more accurate measurements of potential exposure to pesticides, must be weighed against the risks to participants. Airblast applications are common in both orchard and trellis crops across the country, and a wide variety of experts consulted by AHETF reported that closed cabs are most common now, and are becoming even more common. Exposure data for this scenario meeting contemporary standards of reliability and quality will likely provide a significant benefit to society. Because the margins of exposure (MOEs) calculated for the exposures in this research indicate that subjects are very unlikely to experience acute toxic effects, and because extensive procedures will be in place to minimize these and other risks to participants, the likelihood of serious adverse effects is very small. In sum, AHETF believes the risks to study participants from participating in this study are reasonable in light of the likely benefit to society of the knowledge to be gained.

2.6 Respect for Subjects

2.6.1 Subject Privacy

The AHETF employs many procedures, summarized below, to protect subject privacy during recruitment, consent, study conduct, and maintenance of study records. The consent form also summarizes important confidentiality issues for subjects.

Initial contact with workers during recruitment will be made without the presence of their employer as described in detail in Sections 2.7

and 6.2 of this protocol. If workers are interested in participating, a private meeting with the Study Director or his/her designee will be used to explain the study further, address any questions, and seek the candidate's consent to participate.

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

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

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

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

2.6.2 Freedom to Withdraw

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

Any volunteer expressing a need or desire to withdraw from the

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

2.7 Informed Consent

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

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

During the private consent meeting the worker will be provided with a full explanation of the study, its requirements, any potential risks, and its likely benefits. Workers will be informed that the grower or their employer will be reimbursed for the product used in the conduct of the study on their farms. Workers will be advised of their right to withdraw from the study at any time and for any reason without jeopardizing their normal position with their employers. Each volunteer will be provided a copy of the supervisor's signed Employer's Cooperation Statement (in the worker's preferred language) that states they will not suffer any consequence if they decide to participate or not and they will receive their usual pay for the day when the study is conducted.

The volunteer will be informed that he/she will receive the $20 remuneration payment even if he/she decides not to participate.

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

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

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

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

When the pool of available worker volunteers at a site, or a particular citrus grove, exceeds the number of MUs required, a simple random selection of equivalent participants will be made. The names of the volunteers will be written on slips of paper of equal size and placed into a container and mixed thoroughly. The required number of slips will be drawn from the container to fill the MUs. All potential participants will be informed of the possibility of not being selected for this reason. Volunteer workers who decide against participation or who are not selected will be paid $20 for meeting with the study team member and released to resume their normal activities.

In all situations, if the AHETF interviewer is not comfortable that the worker fully understands the discussions and the contents of the consent form, the worker will be excluded from consideration to participate in the study. This

will be ascertained by providing repeated opportunities to ask questions and by asking questions of the potential volunteers that would require a response that indicates understanding of key issues for all sections of the consent form. These responses will be documented and if necessary the person conducting the consent meeting will re-explain topics until the volunteer demonstrates an appropriate understanding.

2.8 Study Procedures

During the consenting process the Study Director or designated researcher will inform each volunteer of the procedures used during the study. Volunteers will be informed if they participate in this study, they will do the following:

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

Volunteers will also be informed about the procedures to expect on the day of their participation in the study. The Study Director or designated researcher will explain the following procedures to each volunteer during the consenting process. Participants must do the following on the day of the study:

1. Arrive at the study site approximately 1 hour before starting their work.
2. Wash their long-sleeved shirt and long pants before participating in the study to remove any residues of the product we are studying.
3. Bathe or shower the evening or morning before participating in the study to remove any residues of the product we are studying.
4. Wear all personal protection equipment required by the product label (see Product Risk Statement).
5. Work about 4 to 8 hours applying a commercial pesticide according to their normal practices and spray at least 3 loads. Participants will apply the pesticide according to the product label.
6. Wear new long underwear underneath their long-sleeved shirt and long pants. Participants may wear their choice of personal undergarments under the long underwear. The long underwear will be supplied by AHETF and collected at the end of the day. Participants will be asked to dress and undress with the assistance of a researcher of the same sex. A changing area will be provided for privacy. When participants complete their work in the study, they will put on their own clothes and return to their normal work. Participants will be informed there is a risk of becoming overheated and suffering heat illness.

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

2.9 Post-Exposure Follow-Up

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

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

3.0 SITE OF THE FIELD PHASE OF THE STUDY

The site for the field phase of the study will be commercial citrus groves in Polk and Hillsborough counties in Florida. These counties were selected because Polk is highest in orange production and Hillsborough is an adjacent county accessible to major transportation routes. In addition, AEHTF has already expended resources to

discuss airblast applications with the handler community in Florida citrus (Bruce, et. al. 2007) and identified a suitable Local Site Coordinator. These counties are typical of citrus producing areas of Florida that utilize conventional closed cab airblast equipment to maintain the groves. The counties are also adjacent to other citrus producing counties that can be contacted if suitable test conditions cannot be found in these two.

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

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

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

4.0 ELIGIBLE GROWER POOL SELECTION

4.1 Use of Local Resources to Identify Potential Eligible Local Growers

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

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

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

4.2 Random Selection of Eligible Growers

The compiled list of growers from local resources shall be placed in random order for further consideration. The randomization process will be

documented and maintained in the study file.

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

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

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

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

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

Screening of the growers (in the order of the random list) continues until the

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

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

5.0 EFFICIENT MU DESIGN

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

6.0 PARTICIPANT SELECTION

6.1 Site Inspection

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

6.2 Initial Potential Participants Recruitment

AHETF will follow standard procedures (see SOP AHETF-11.B) to recruit

potential participants for this closed cab airblast application study. Individual workers will be recruited during an initial site inspection or subsequent visit(s) to an eligible grower facility.

The Study Director or designated researcher will seek permission from the eligible grower to approach his/her employees to recruit volunteers for the study. Depending on the number of employees and size of the grower facility the Study Director or researcher may contact employees through the use of an informational recruitment flyer posted in a common work area. Such a flyer will briefly describe the research study and provide contact information for employees who may have an interest in participation in the study. The flyer shall have been previously reviewed and approved by an IRB.

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

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

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

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

6.3 Participant Selection and Consenting

The Study Director or designated researcher will establish a pool of eligible growers and workers (potential participants) from those in the efficient configuration who shall be contacted prior to initiating the field phase of the study to confirm their availability and interest in being in the study. Individual volunteers will be informed of study provisions to accommodate their language preference, the need for readers, witnesses, and their desire to have a confidant or counselor present during an informed consent meeting.

The Study Director or designated researcher will arrange a place and schedule to conduct consent meetings with individual volunteers from the eligible pool. Prior to such meetings, accommodations will have been made for interpreters, witnesses, and ancillary personnel who must be present for the meeting. Consent meetings shall be conducted as described above in Section 2.7.

7.0 FIELD MATERIALS AND METHODS

7.1 Test System Identification - Workers

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

7.2 Justification of the Test System and Test Substances

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

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

7.3 Mixing/Loading Stations and Application Area

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

7.4 Study Personnel – Field

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

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

7.5 Test Substances

7.5.1 Approved Test Substances

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

Selection of the exact test substance is determined as the product selected by an eligible grower for his crop on the day of the study. As previously described, eligible growers are selected from an efficient configuration of MUs who plan to use or are willing to use one of the products approved by the AHETF. As the time approaches to conduct the field phase of the study, the grower will confirm the actual product

he will be using on the day of the study. The researchers will insure a sufficient amount of the test substance product will be available at the grower site. The AHETF will reimburse the grower for the product used in the study at the completion of the study on his farm.

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

Table 1. Approved Test Substances for AHE55

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

7.5.2 Active Ingredient Stability

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

7.5.3 Purity Analysis

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

7.5.4 Retention Samples

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

7.6 Application Parameters

Carrier:	Water
Target application rate:	Products will be applied at a rate specified on the label for the particular crop. Rates depend on target crop and field needs. Actual application rates will be documented in study raw data.
Target application volume:	Application volume will comply with the product label. Volumes depend on target crop and field needs. Actual application volumes will be documented in study raw data.
Route of application:	Applications will be made using available common airblast application equipment.

7.7 Equipment Accuracy Verification

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

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

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

7.8 Amount of Material Handled

The amount of test substance that is mixed and loaded for each applicator

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

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

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

Each MU shall consist of a period of at least 4 hours of spraying and at least 3 tank loads of the spray mixture. The application volume, gallons per acre, may be adjusted by ground speed and output volume to achieve a stratum-assigned range of pounds ai handled. The application volume applied shall be in accordance with the product label. The volume of spray mixture applied will be determined and recorded in the field raw data, along with other critical measurements including application area and duration. Upon completion of spraying each load of diluted product, the amount of spray volume remaining in the tank(s) will be determined and recorded in the raw data. Disposal of excess spray mixture will occur in accordance with applicable regulations.

7.9 Rationale for the Route of Administration

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

8.0 DERMAL EXPOSURE SAMPLING

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

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

workers may wear a hat or cap.

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

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

At the end of the monitoring period (and after the inhalation exposure equipment is removed as described below), the worker will first remove his/her PPE (e.g. waterproof gloves) and shoes, then enter a clean, private area for collecting the remaining samples. Once inside the private area, the worker will remove his/her outer clothing and socks. The outer layer of clothing and socks will not be collected or analyzed. To reduce the potential for cross contamination, each set of outer work garments will be used only once. Dermal exposure samples will be collected in the following order: final hand wash sample, final face/neck wipe sample, and the inner dosimeter.

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

Face/neck exposure will be measured by wiping the entire face and neck areas (front and back of neck) with two gauze sponges, sequentially, that have been wetted with 0.01% Aerosol OT as described in the most recent version of SOP AHETF-8.C. Interim face/neck wipe samples (consisting of two gauze sponges) will be collected prior to eating. After each MU is completed, a final face/neck wipe sample will be collected from each worker after the hand wash sample is collected and before

removal of the whole body dosimeters. Face/neck wipe samples will be wrapped in aluminum foil prior to placement in pre-labeled re-sealable plastic bags. All wipes collected during the study for a worker will be combined in the same container, resulting in a single sample for analysis. If more than two samples (4 sponges) are in a sample container, the laboratory must be notified as to the number in the container. All face/neck wipe samples will be placed in pre-labeled containers and placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will be maintained in frozen storage until analysis.

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

9.0 INHALATION EXPOSURE SAMPLING

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

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

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

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

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

operate or the tubing becomes kinked.

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

10.0 CONTROL OF BIAS

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

11.0 FIELD RECOVERY EVALUATION

11.1 Fortification Procedures

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

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

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

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

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

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

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

11.2 Field Fortification Levels

Matrices will be fortified in triplicate at the following levels:

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

12.0 OBSERVATIONS

Observations will be recorded according to SOP AHETF-10.C throughout the monitoring period while the workers perform their tasks. Any specific occurrences that could affect exposure will be noted on the observation forms. Measurements will be made of the amount of test substance handled. A detailed time log will be

maintained for all activities. A photographic record will be taken of representative study-related activities during exposure monitoring.

13.0 ENVIRONMENTAL MONITORING

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

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

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

14.0 SAMPLE IDENTIFICATION, SHIPPING AND STORAGE

14.1 Sample Identification

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

14.2 Shipping

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

14.3 Storage

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

15.0 ANALYTICAL PROCEDURES

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

15.1 Reference Substance(s)

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

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

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

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

15.2 Analytical Methods

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

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

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

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

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

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

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

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

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

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

15.3 Analytical Design

All analytical procedures, techniques and matrices will be provided by the AHETF. Procedures and techniques will be followed as rigidly as possible. No changes are permitted without the prior approval of the AHETF Analytical Monitor and the Study Director.

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

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

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

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

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

field samples. The LOQ is defined in each analytical method.

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

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

15.4 Analytical Statistical Methods

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

16.0 STUDY RECORDS

16.1 Field Records

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

1. Test and reference substance lot numbers, receipt and storage location(s) use records
2. Crop description and growth stage, if applicable
3. Mixing/loading equipment details, if applicable
4. Application equipment details, if applicable
5. If available, application equipment maintenance records (retained in the study file)
6. Environmental conditions for the entire monitoring period, including data used for making determinations of potential heat stress indices
7. Approvals from the Institutional Review Board covering the protocol and the Informed Consent document, and all amendments to either document
8. All correspondence with the Institutional Review Board
9. Personal details of workers, including consent forms and documentation of consent process (which will be maintained under confidential conditions as per SOP AHETF-6.D)
10. Trial location maps, including description, dimensions, and exact locations of plots and mixing/loading stations

11. Pounds active ingredient handled, monitoring time, acres treated, and volume of liquid applied
12. Dermal exposure sampling information
13. Inhalation exposure sampling information, including pump identification, calibration, flow rates and times of sampling
14. Field recovery procedure information for all sampling media
15. Test and reference substance, and sample storage temperature records
16. Observations on work practices, including photographs
17. Sample information (including inventory and chain of custody)

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

16.2 Analytical Records

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

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

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

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

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

17.0 DATA HANDLING

17.1 Communication of Results

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

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

18.0 QUALITY ASSURANCE

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

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

19.0 WORKER SAMPLE RETENTION

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

20.0 PHASE REPORTS

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

20.1 Field Report

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

1. Identification of the locations of the study, and the general environmental conditions during the exposure monitoring periods
2. A field laboratory QAU statement giving dates of inspections and dates that findings were reported to the Study Director and AHETF Management
3. A summary of the worker recruitment and consent process
4. A description of the workers and handling activities
5. A summary of worker observations identifying any specific occurrences that may contribute to unusual worker exposure
6. A detailed summary of the amount of test substance handled by each worker
7. A detailed summary of the length of time each worker was monitored
8. A complete description of the field recovery procedure with a summary of specific handling and weathering of all field samples
9. A complete description of collection, handling, storage, and shipping of field samples

20.2 Analytical Report

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

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

21.0 FINAL STUDY SUMMARY REPORT

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

22.0 PROTOCOL CHANGES

22.1 Amendments

Amendments to this protocol during the course of the study are permissible and subject to review and approval by the Study Director, the Sponsor representative and the IRB prior to implementation, except where necessary to eliminate apparent immediate hazards to the human subjects (40 CFR 26.1108(a)(4)). Protocol amendments shall to be documented in accordance with SOP AHETF-2.C and reported in the Field Report, Analytical Report and Summary Reports.

22.2 Deviations

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

23.0 REFERENCES

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

Volume II, Part B: AHE55 Informed Consent Form

(English / Spanish Versions)

RESEARCH INFORMATION AND INFORMED CONSENT FORM

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

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

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

FIELD LOCATIONS: 3 to 5 Orange Orchards in Florida

_____
_____
_____

INTRODUCTION and PURPOSE

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

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

APPROVED BY
Independent IRB
_____ 3/25/08
Signature Date

Initials: _____
Date: _____

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

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

STUDY DURATION
The duration of your participation in this study is approximately 4-8 hours of one of your normal workdays.

PROCEDURES BEFORE THE DAY OF THE STUDY
If you participate in this study, you will do the following:

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

APPROVED BY
Independent IRB
Signature 3/25/08 Date

Initials: _____
Date: _____

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

PROCEDURES ON THE DAY OF THE STUDY

1. Bathe or shower the evening or morning before you come to work.
2. Wear a freshly laundered long-sleeved shirt and long pants.
3. Put on new long underwear (which we will provide) under your long-sleeved shirt and long pants. Wear your choice of personal undergarments under the long underwear. The long underwear will be collected at the end of the day. You will be asked to dress and undress with the assistance of a researcher of the same sex. A changing area will be provided for privacy. When you complete your participation, you will put on your own clothes and return to your normal work.
4. Wear a tube attached to your shirt collar and connected to a portable air-sampling pump on a belt worn around your waist. The pump is small and light about the size of a portable radio. This may be uncomfortable or annoying.
5. Wear all personal protection equipment required by the product label (see Product Risk Statement).
6. Work about 4 to 8 hours applying a commercial pesticide according to your normal practices and spray at least 3 loads.
7. Have your face and neck wiped with gauze pads moistened with a mild detergent and water mixture. This will be done before you eat anything, any time you would normally wash your face, and at the end of the day.
8. Have your hands washed in a mild detergent and water mixture. This will be done before you eat anything, any time you would normally wash your hands (such as when you use the toilet), and at the end of the day.
9. Allow researchers to watch all of your work activities and take notes on what you do.
10. Allow photographs and video recordings to be taken. You will not be photographed or video recorded while dressing or undressing. AHETF will own all rights to the photos and videos and may use them for any purpose. **If you do not want to be photographed or recorded you should not participate in this study.**

PRODUCTS HANDLED

You will be asked to apply a pesticide product that is registered by the US Environmental Protection Agency (EPA) and approved for spraying citrus with airblast equipment. The active ingredient will be carbaryl or malathion and farm management will select the product. However, you will know which product you will handle before you are asked to sign this consent form.

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Independent IRB

Signature 3/25/08 Date

Initials: _____
Date: _____

In addition to the pesticide you will spray, farm management may require tank-mixes with other registered or approved products according to label directions. You will be told before your participation which materials will be in the tank mix.

RISKS AND DISCOMFORTS

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

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

You will review the product label with the research staff to identify the airblast use directions and precautions. From the label, and Product Risk Statement, you will learn of any possible side-effects (such as skin irritation) and the signs and symptoms of overexposure. If you feel any of the signs or symptoms during or after the workday, or do not feel well for any reason, notify a researcher immediately. A copy of the product Material Safety Data Sheet (MSDS), is available for your review and discussion any time you desire.

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

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

You may have other risks or discomforts, including:

- Eye or skin irritation from the detergent and water mixture used to rinse your hands, face and neck
- Discomfort from wearing a portable air sampling pump around your waist
- Being embarrassed during dressing and undressing
- Being concerned about taking an over-the-counter pregnancy test
- Working longer than normal because of the extra time it takes to collect samples for analysis

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Independent IRB

Signature 3/25/08 Date

Initials: _____
Date: _____

There may be other risks that are unknown at this time. You will be told in a timely manner both verbally and in writing of any new information that might change your decision to be in the study.

INJURY TO PARTICIPANTS

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

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

CONFIDENTIALITY

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

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

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

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

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

APPROVED BY
Independent IRB

Signature 3/25/08 Date

Initials: _____
Date: _____

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

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

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

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

You will also receive your normal pay from your employer.

If more people volunteer than we need, we will decide which volunteers participate by drawing names from a container. You may or may not be selected to participate; if not selected, you will not receive the $80.

VOLUNTARY PARTICIPATION / WITHDRAWAL
Your employer has agreed to let us do the research and has confirmed that he/she does not care whether you to participate in this study. Your decision to be in this study is voluntary and entirely up to you. If you decide to participate, you may change your mind later and drop out of the study at any time and for any reason. A decision not to participate, or to withdraw from the study after it begins, will have no effect on your job or pay or include any penalty or any loss of benefits to which you may be entitled.

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

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

APPROVED BY
Independent IRB
Signature 3/25/08
Date

Initials: _____
Date: _____

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

ALTERNATIVES

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

QUESTIONS

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

Larry D. Smith (Study Director) at 440-255-1954 (collect)
Or 440-554-2812 (24 hours)
Or
David Johnson, Ph.D. (sponsor contact) at 660-349-4601 ext #1.

If you have any questions regarding your rights as a research volunteer, please contact Kim Lerner, Chairman of the Independent Investigational Review Board, Inc. at toll free (877) 888-iirb (4472) during regular working hours. The Independent Investigational Review Board is a committee established for the purpose of protecting the rights of volunteers in a research study.

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

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

APPROVED BY
Independent IRB

Signature 3/25/08 Date

Initials: _____
Date: _____

CONSENT

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

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

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

_____ _____
Date Subject's Name (print)

_____
Subject's Signature

_____
Subject's Unique Worker Code

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

_____ _____
Date Name of Person Conducting Informed Consent Discussion (print)

_____
Signature of Person Conducting Informed Consent Discussion

_____
Title and Affiliation of Person Conducting Informed Consent Discussion

APPROVED BY
Independent IRB
Signature 3/25/08 Date

Initials: _____
Date: _____

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

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

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

_____ _____
Date Impartial Witness' Name (print)

_____
Impartial Witness' Signature

_____
Title and Affiliation of Impartial Witness

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

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08, Revised: 3/25/08

APPROVED BY
Independent IRB
_____ 3/25/08
Signature Date

Initials: _____
Date: _____

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 26, 2008

To Whom It May Concern:
A Quién Corresponda:

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

(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/25/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 25/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Américo Gómez, who translated this document, is fluent in Spanish and standard North American English and qualified to translate. He attests to the following:

Américo Gómez, quien tradujo dicho documento, tiene dominio de los idiomas inglés norteamericano y español, y está capacitado para traducir. Él declara lo siguiente:

"To the best of my knowledge, the accompanying text is a true, full and accurate translation of the specified document".
«Según mi leal saber y entender, el texto que sigue a continuación es una traducción fiel y correcta del documento que se adjunta».

Signature of Américo Gómez/*Firma de Américo Gómez*

FORMULARIO DE INFORMACIÓN SOBRE LA INVESTIGACIÓN Y CONSENTIMIENTO INFORMADO

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, PhD
P.O. Box 509
Macon, Missouri 63552

DIRECTOR DEL ESTUDIO: Larry D. Smith, PhD
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Teléfono: 440-255-1954
Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIONES DE CAMPO: De 3 a 5 huertos de naranjas en la Florida.

_____
_____
_____

INTRODUCCIÓN y PROPÓSITO

La Agricultural Handlers Exposure Task Force (AHETF) fue formada por un grupo de compañías de pesticidas. El propósito de este estudio es medir cuánto pesticida podría recibir usted en su piel y respirar, mientras que usted esté usando equipo de pulverización neumática de cabina cerrada. Se hará esto mediante la medición de residuos de pesticida en las muestras que nosotros recojamos de usted. Se monitoreará a unas 5 personas en este estudio. Los resultados del estudio se usarán para estimar la exposición y los riesgos a los trabajadores que estén fumigando pesticidas con equipo de pulverización neumática [*airblast*] de cabina cerrada.

Para que usted pueda participar en este estudio, usted debe entender y firmar este formulario de consentimiento y una Declaración de Riesgo del Producto que describe los riesgos provenientes del pesticida. Si hemos usado palabras o presentado información que usted no entienda con claridad, por favor pídame que le explique. Usted puede llevarse a su casa una copia, sin firmar, de este formulario de consentimiento, para pensarlo o para hablar sobre esto con sus familiares o amigos, o investigadores, antes de tomar su decisión. Si usted se pone de acuerdo para estar en

APROBADO POR
Independent IRB
Firma — 25/marzo/08 Fecha

Iniciales: _____
Fecha: _____

este estudio, le darán una copia firmada y fechada de este formulario de consentimiento y de la Declaración de Riesgo del Producto.

ELEGIBILIDAD

Para poder participar en el estudio, usted debe:

1. Haber hecho aplicaciones de pulverización neumática [*airblast*] usando un tractor de cabina cerrada dentro del lapso de tiempo del último año.
2. Proporcionar prueba de que tiene por lo menos 18 años de edad (identificación con foto, emitida por un ente gubernamental).
3. Confirmar que no trabaja para una compañía de pesticidas ni para un contratista de AHETF exceptuando un empleado del Coordinador local del Sitio para este estudio.
4. Considera que su estado general de salud es «lo suficientemente bueno como para hacer el trabajo». Díganos si tiene alguna afección [dolencia] médica que afecte a su capacidad para participar en el estudio.
5. No estar embarazada ni lactando [dándole el pecho a un niño]. Si usted es mujer, usted debe hacerse una prueba de embarazo, de las de venta libre, antes del estudio. Esta prueba será supervisada por una investigadora. Usted no tiene que decirle a nadie si es que tiene una prueba positiva. Los resultados de una prueba negativa deben ser confirmados por la investigadora o usted no puede participar.
6. Confirmar que usted no usa, normalmente, equipo de protección personal que exceda los requisitos de la etiqueta para las aplicaciones de pulverización neumática [*airblast*] de cabina cerrada. Confirmar que usted seguirá las instrucciones de la etiqueta.
7. Tener una reunión privada con un investigador para repasar este formulario de consentimiento. El propósito es cerciorarse de que usted entienda con qué se está poniendo de acuerdo y que le respondan a todas sus preguntas. Usted puede tener a un amigo, a un miembro de su familia o a un asesor, con usted, durante la reunión. Si usted es un empleado, esta persona no puede ser de la gerencia de operaciones.
8. Entender inglés ó castellano [español].
9. Entender y firmar este formulario de consentimiento y Declaración de Riesgo del Producto.

LA DURACIÓN DEL ESTUDIO

La duración de su participación en este estudio es de aproximadamente 4-8 horas de uno de sus días normales de trabajo.

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LOS PROCEDIMIENTOS ANTERIORES AL DÍA DEL ESTUDIO

Si participa en este estudio, usted hará lo siguiente:

1. Díganos su nombre y cuántos años ha estado haciendo aplicaciones de pulverización neumática [*airblast*] de cabina cerrada.
2. Permitirles a los investigadores que midan y registren su estatura [altura] y peso.
3. Permitirles a los investigadores que midan y registren su género, edad, e idioma preferido.
4. Confirmar si usted ha recibido entrenamiento de seguridad en pesticidas o si está exento del entrenamiento de seguridad en pesticidas.
5. Permitirnos tomar notas sobre los debates, durante la sesión(es) del consentimiento informado.

Si usted lee solamente español, le proporcionarán una versión de los documentos en español, junto con un intérprete [traductor] durante nuestra reunión. Si usted tuviese problemas para leer estos documentos en el idioma que usted haya elegido (inglés ó español), entonces se los leerán a usted.

LOS PROCEDIMIENTOS EN EL DÍA DEL ESTUDIO

1. Báñese o dúchese en la noche o en la mañana, antes de venir al trabajo.
2. Use una camisa de manga larga y pantalones largos, recién lavados.
3. Póngase ropa interior larga nueva (la cual se la proporcionaremos) debajo de su camisa de manga larga y pantalones largos. Use la ropa interior que usted desee, debajo de la ropa interior larga. La ropa interior larga se recogerá al final del día. Le pedirán que se vista y se desvista con la asistencia de un investigador del mismo sexo. Le proporcionarán un área para cambiarse, por razones de privacidad. Cuando usted complete su participación, usted se pondrá sus propias ropas y regresará a su trabajo normal.
4. Usted usará un tubo adherido al cuello de su camisa y éste estará conectado a una bomba portátil de muestreo de aire, en un cinturón que usted usará alrededor de la cintura. La bomba es pequeña y liviana, alrededor del tamaño de una radio portátil. Esto puede ser incómodo y molesto.
5. Use todo el equipo de protección personal requerido por la etiqueta del producto (vea la Declaración de Riesgo del Producto).
6. Trabaje alrededor de 4 u 8 horas aplicando un pesticida comercial, de acuerdo con sus prácticas normales y fumigue por lo menos 3 cargas.
7. Limpiarse la cara y cuello con almohadillas de gasa humedecidas con una mezcla de detergente suave y agua. Esto se llevará a cabo antes de que usted coma nada, en cualquier momento en el que usted normalmente se lavaría la cara y, al final del día.
8. Lavarse las manos con una mezcla de detergente suave y agua. Esto se llevará a cabo antes de que usted coma nada, en cualquier momento en el que usted normalmente se lavaría las manos (tal como cuando usa el cuarto de baño) y, al final del día.

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9. Permitirles a los investigadores que observen todas sus actividades laborales [de trabajo] y que tomen notas acerca de lo que hace usted.
10. Permitirles que saquen fotografías y grabaciones en vídeo. No lo fotografiarán ni lo grabarán en vídeo, mientras que se esté vistiendo o desvistiendo. AHETF será la propietaria exclusiva [con todos los derechos] de las fotografías y vídeos y puede usarlos con cualquier propósito. **Si usted no desea que lo fotografíen ni que lo graben en vídeo, usted no debería participar en este estudio**.

PRODUCTOS MANIPULADOS

Le pedirán que aplique un producto pesticida que está registrado por la Agencia Estadounidense de Protección Medioambiental (EPA) y aprobado para fumigar cítricos con equipo de pulverización neumática [*airblast*]. El ingrediente activo será carbarilo [carbaryl] ó malatión [malathion] y la gerencia de la granja seleccionará el producto. No obstante, usted sabrá cuál producto va a manipular, antes de que le pidan que firme este formulario de consentimiento.

Además del pesticida que usted fumigará, la administración de la granja pudiera requerir las mezclas de tanques con otros productos registrados o aprobados, de acuerdo con las instrucciones de la etiqueta. Antes de su participación, le dirán cuáles materiales habrá en la mezcla del tanque.

RIESGOS Y MOLESTIAS

En este estudio, usted correrá los riesgos usuales del uso de equipos de fumigación. Usted usará solamente equipos en los que tenga experiencia en operarlos.

Le pedirán que firme otro documento, Declaración de Riesgo del Producto, que identifica al producto que usted fumigará, que indica cuánto de ese producto usted podría manipular y, que especifica los riesgos del manipuleo de ese producto. También describe qué equipo de protección personal debe usar usted.

Usted revisará la etiqueta del producto junto con el personal de la investigación científica, para identificar las instrucciones y precauciones del uso de la pulverización neumática [*airblast*]. De la etiqueta y de la Declaración de Riesgo del Producto, usted se informará acerca de cualquier efecto(s) secundario(s) posible (tal como irritación en la piel) y las señales y síntomas de la sobre-exposición. Si usted sintiese cualquiera de las señales ó síntomas durante ó después del día de trabajo, ó si no se sintiese bien por cualquier razón, notifíqueselo inmediatamente a un investigador. Hay a su disposición, en cualquier momento en el que usted lo desee, una copia de la Hoja de Datos de Seguridad del Material (MSDN) del producto.

Debido a que usted usará ropa interior larga debajo de sus ropas normales de trabajo, usted corre un riesgo de enfermarse debido a que sienta mucho calor. A esto se le conoce como golpe de calor [*heat stress* ó *heat illness* en inglés] y puede ser grave o puede constituir una amenaza a la vida. Las señales y los síntomas tempranos

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incluyen la sensación de exceso de calor, cansancio, mareos, estar irritable y, la disminución de concentración. Si usted sintiese cualquiera de estas señales ó síntomas, durante ó después de un día de trabajo, notifíqueselo inmediatamente a un investigador. Si usted no se sintiese bien por cualquier razón, notifíqueselo inmediatamente a un investigador. Un investigador que esté tratando de detectar estos síntomas, va a estar observándolo a usted. AHETF detendrá su trabajo si el tiempo se pusiese muy cálido.

Como medida de precaución, AHETF tendrá un paramédico, asistente de médico, enfermera, ó un técnico en emergencias médicas, en el sitio durante el estudio. Si fuere necesario, este profesional también lo observará a usted para detectar señales de enfermedad y le proporcionará atención médica.

Usted pudiera tener otros riesgos o molestias, incluyendo:

- Irritación en los ojos o en la piel, proveniente de la mezcla de detergente y agua que use para enjuagarse las manos, cara y cuello.
- Molestia debida al uso de una bomba portátil de muestreo de aire, alrededor de su cintura.
- Sentirse con vergüenza mientras que se esté vistiendo o desvistiendo.
- Estar preocupada acerca de tener que hacerse una prueba de embarazo de venta libre.
- El trabajar más tiempo de lo normal, debido al tiempo extra que lleva recolectar muestras para los análisis.

Pudiera haber otros riesgos que se desconozcan en estos momentos. Le dirán de manera puntual, tanto verbalmente como por escrito, acerca de cualquier información nueva que podría cambiar su decisión de estar en el estudio.

LESIÓN AL PARTICIPANTE

Si usted se lesionase o se enfermase durante o después del día del estudio, habrá a su disposición tratamiento médico en su lugar de trabajo y en una instalación cercana de atención médica. Si fuere necesario, AHETF arreglará para que lo transporten para que reciba atención médica. Usted puede rehusar el tratamiento médico, al menos que usted se enferme debido a la demasiada exposición al pesticida o debido al excesivo calor, o si nosotros creyésemos que usted está demasiado enfermo como para tomar una decisión racional acerca de recibir tratamiento médico. AHETF cubrirá el costo de la atención médica razonable y apropiada, que no esté cubierta por su propio seguro o por el seguro que le proporcione su empleador. Los expedientes del tratamiento no se convertirán en parte de los expedientes de la investigación científica para este estudio. No obstante, AHETF tomará nota del evento y esto estará reportado en el informe del estudio. Para más información acerca de esto, usted puede llamar al Administrador de AHETF (David Jonson) al 660-349-4601.

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

CONFIDENCIALIDAD

Su nombre aparecerá en el formulario de consentimiento, en la Declaración de Riesgo del Producto y, en un formulario optativo para que usted solicite sus resultados personales del estudio. Toda la otra información proveniente del estudio, lo identificará a usted solamente por medio de un código único. Los expedientes que contengan su nombre se almacenarán en un archivo seguro, de acceso limitado.

La información acerca de su participación en este estudio no se le dará a su empleador.

AHETF escribirá un informe del estudio y estará a disposición de compañías miembro. Se le enviará a la Agencia Estadounidense de Protección Medioambiental (EPA). También pudiera ser enviada a agencias gubernamentales estatales y a gobiernos de otros países. Su nombre no estará incluido en ningún informe del estudio.

Nosotros no podemos prometerle a usted una confidencialidad absoluta debido a la necesidad de darles información a algunas organizaciones o a partes [a terceros] en acciones legales, según lo requiera la ley. Toda la información proveniente del estudio, incluyendo los expedientes que lo identifiquen a usted, pueden ser mirados o copiados por el patrocinador y por cualquier consultor(es) que esté trabajando con el patrocinador, por la EPA o por otras agencias gubernamentales y, por el Independent Investigational Review Board, Inc. (IIRB). El IIRB es un grupo de personas quienes revisan y monitorean la investigación científica para cerciorarse de que las personas quienes participen en ella, estén protegidas.

Usted puede pedirle, al Director del Estudio, una copia de sus resultados personales provenientes de este estudio. Usted va a necesitar proporcionar su nombre y una dirección postal o de correo electrónico [*e-mail*].

COSTOS

No habrá costos para usted por la participación en este estudio.

BENEFICIOS

Usted no se beneficiará, directamente, de la participación en el estudio. El propietario de la granja pudiera beneficiarse del producto usado en el estudio, dado que AHETF lo reembolsará al propietario por ese producto. La información proveniente de este estudio se usará para mejorar la calidad de las evaluaciones de seguridad en los pesticidas, para los trabajadores que estén usando equipo de pulverización neumática [*airblast*] de cabina cerrada.

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EL PAGO POR LA PARTICIPACIÓN

Le pagarán $20 si usted se reúne en privado con un investigador para repasar este consentimiento informado. Usted recibirá el dinero si usted decide participar o no. Usted recibirá el dinero en efectivo enseguida de la reunión.

Le pagarán $80 adicionales por el día que usted participe en el muestreo. Le pagarán $80 por completar el día de muestreo y por permitirnos recoger sus muestras. Si usted decide retirarse durante el muestreo, aún le pagarán los $80. Si nosotros lo hiciésemos retirarse del estudio, usted aún recibirá los $80. El pago se efectuará en efectivo al final del día de muestreo.

Usted también recibirá su pago normal de su empleador.

Si hubiese más voluntarios de los que necesitamos, nosotros decidiremos cuáles voluntarios participarán, sacando nombres de un recipiente. Usted pudiera, o no, ser seleccionado para participar, si no fuese seleccionado, usted no recibirá los $80.

LA PARTICIPACIÓN / EL RETIRO VOLUNTARIOS

Su empleador se ha puesto de acuerdo en permitirnos llevar a cabo la investigación científica y ha confirmado que él/ella no le importa si usted participa en este estudio. Su decisión de estar en este estudio es voluntaria y queda librada enteramente a usted. Si usted decide participar, usted pudiera, más adelante, cambiar de manera de pensar y abandonar el estudio en cualquier momento y por cualquier razón. Una decisión de no participar, o de retirarse del estudio después de que éste haya empezado, no tendrá efecto sobre su trabajo ni sobre su pago, ni incluirá ninguna multa ni pérdida de beneficios a los cuales usted pueda tener derecho.

Si usted se retirase, la ropa interior larga y la bomba de muestreo de aire se los removerán, y las muestras de las manos y cara/cuello pudieran recogerse con su consentimiento.

Su participación en este estudio pudiera ser detenida en cualquier momento por los investigadores o por el patrocinador. La ropa interior larga y la bomba de muestreo de aire se los removerán, y las muestras de las manos y cara/cuello pudieran recogerse con su consentimiento.

Si usted se retirase del estudio, o si lo quitasen del estudio, o si el estudio no durase un día entero de trabajo, a usted lo dejarán que reanude sus actividades usuales.

ALTERNATIVAS

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

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PREGUNTAS

Si tiene preguntas acerca de este estudio o si en cualquier momento usted tuviese una lesión o enfermedad relacionada con el estudio, póngase en contacto con un investigador o llame a:

Larry D. Smith (Director del Estudio) al 440-255-1954 (llamada a cobrar; *collect*)
Ó 440-554-2812 (las 24 horas)
Ó
David Johnson, PhD (contacto del patrocinador) al 660-349-4601 ext. № 1.

Si usted tiene cualquier pregunta(s) en lo concerniente a sus derechos en calidad de voluntario de una investigación científica, por favor póngase en contacto con la señora Kim Lerner, Presidenta del Independent Investigational Review Board, Inc. llamando al número gratuito (877) 888-iirb (4472) durante horas regulares de trabajo. El Independent Investigational Review Board es un comité que se ha establecido con el propósito de proteger los derechos de los voluntarios en un estudio de investigación científica.

El IIRB es un grupo de personas quienes desempeñan la revisión independiente de la investigación científica.

No firme este formulario al menos que usted haya podido hacer preguntas y que haya recibido respuestas satisfactorias.

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CONSENTIMIENTO

Yo he leído la información existente en este formulario de consentimiento y en la Declaración de Riesgo del Producto (ó me la han leído) en un idioma que entiendo bien. Todas mis preguntas acerca del estudio y acerca del hecho de estar en él, me las han respondido. Yo consiento libremente a estar en este estudio.

Yo autorizo la divulgación de mis expedientes de la investigación científica, incluyendo fotografías y grabaciones de vídeo, al patrocinador, a los investigadores, a agencias gubernamentales en otros estados y/ó países, a la EPA, al IIRB, y a otras partes, según lo requiera la ley.

Al firmar este formulario de consentimiento, yo no he renunciado a ninguno de mis derechos legales.

Fecha _____ Nombre del Sujeto (en letra de molde; de imprenta)

_____
Firma del Sujeto

_____
Código Único de Trabajador, del Sujeto

Yo dirigí la reunión privada del consentimiento, con el trabajador mencionado anteriormente y confirmo que el consentimiento fue dado voluntariamente después de haber sido informado acerca de los beneficios, riesgos y procedimientos. Además, este trabajador ha revisado y firmado la Declaración de Riesgo del Producto, la cual yo almaceno junto con este formulario de consentimiento firmado, en un lugar seguro:

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

_____
Firma de la Persona que está Dirigiendo la Discusión del Consentimiento Informado

_____
Título y Afiliación de la Persona que está Dirigiendo la Discusión del Consentimiento Informado.

APROBADO POR
Independent IRB

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---------- Use lo siguiente solamente si fuere pertinente ----------

Si este formulario de consentimiento se le lee al trabajador debido a que el trabajador no puede leer el formulario, debe estar presente un testigo imparcial (quien no esté asociado con los investigadores ó quien no forme parte de la administración del cultivador donde el estudio se esté llevando a cabo) para atestiguar el consentimiento de este trabajador y firmar la siguiente declaración:

Yo confirmo que la información existente en este formulario de consentimiento y cualquier otra información escrita, le fue explicada con precisión a este trabajador y éste la entendió. Este trabajador consintió libremente a participar en el estudio de investigación científica.

_____ _____

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

_____

Firma del Testigo Imparcial

_____

Título y Afiliación del Testigo Imparcial

Nota: Este bloque de firmas no puede usarse para las traducciones a otro idioma. Se necesita un formulario de consentimiento, traducido, para inscribir a sujetos quienes no lean inglés.

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08; Revisado: 25/marzo/08

APROBADO POR
Independent IRB

_____ 25/marzo/08
Firma Fecha

Iniciales: _____
Fecha: _____

Volume II, Part C: AHE55 Product-Specific Risk Statements

(English / Spanish Versions)

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

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

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

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

LOCATION: _____
_____
_____

Introduction
You have agreed to participate in the above noted research study. The informed consent form that you signed stated that you would be informed verbally and in writing of any risks that might influence your willingness to participate in the study.

This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Sevin® Brand XLR Plus Carbaryl Insecticide (EPA Registration No. 264-333)

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

Formulation and Packaging: 4 lb AI/gallon Flowable liquid in 2.5 gallon plastic jugs

You may handle up to: 25 gallons of product

APPROVED BY
Independent IRB
Signature
3/25/08
Date

Initials: _____
Date: _____

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

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

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

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

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

Label date: 9/21/04
MSDS date: 1/17/08 (Bayer MSDS 102000001927, Version 2.1)

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08; Revised: 3/25/08

APPROVED BY
Independent IRB
Signature 3/25/08
Date

Initials: _____
Date: _____

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

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

SPONSOR AND SOURCE OF FUNDING:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, Ph.D.
P.O. Box 509
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Larry D. Smith, Ph.D.
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Phone: 440-255-1954
E-mail: lsconsulting@oh.rr.com

LOCATION: _____
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Introduction
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This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

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

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

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

You may handle up to: 100 water soluble packs

APPROVED BY
Independent IRB
Signature
3/25/08
Date

Initials: _____
Date: _____

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

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

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

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

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

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

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08; Revised: 3/25/08

APPROVED BY
Independent IRB
_____ 3/25/08
Signature Date

Initials: _____
Date: _____

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

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

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

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
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7919 Champaign Dr.
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LOCATION: _____
_____
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Introduction
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This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

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

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

Formulation and Packaging: 4 lb AI/gallon Flowable liquid in 2.5 gallon plastic jugs

You may handle up to: 25 gallons of product

APPROVED BY
Independent IRB
Signature
3/25/08
Date

Initials: _____
Date: _____

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

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

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

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

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

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

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08; Revised: 3/25/08

APPROVED BY
Independent IRB
Signature 3/25/08 Date

Initials: _____
Date: _____

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

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

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

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
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LOCATION: _____
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Introduction
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This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Gowan Malathion 8 (EPA Registration No. 10163-21)

Active Ingredient: Malathion (insecticide, CAS No. 121-75-5)

Formulation and Packaging: 8 lbs AI/gallon Emulsifiable Concentrate

You may handle up to: 12.5 gallons of product

APPROVED BY
Independent IRB
Signature
3/25/08
Date

Initials: _____
Date: _____

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

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

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

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

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

Label ID: 04-R0699
MSDS date: 2/1/07 (Gowan Malathion 8 Flowable)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08; Revised: 3/25/08

APPROVED BY
Independent IRB

Signature 3/25/08
Date

Initials: _____
Date: _____

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

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

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

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

LOCATION: _____
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Introduction
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This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Malathion 8-E Insecticide (EPA Registration No. 34704-452)

Active Ingredient (AI): Malathion (insecticide, CAS No. 121-75-5)

Formulation and Packaging: 8 lbs AI/gallon Emulsifiable Concentrate in 1 gallon plastic jugs

APPROVED BY
Independent IRB
Signature 3/25/08 Date

Initials: _____
Date: _____

You may handle up to: 12.5 gallons of product

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

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

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

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

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

Label date: None found
MSDS date: 6/8/06 (Loveland MSDS #000452-06-LPI)

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08; Revised: 3/25/08

Version: 3/25/08
Protocol: AHE55
Malathion 8-E

APPROVED BY
Independent IRB
Signature 3/25/08 Date

Initials: _____
Date: _____

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

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

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

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

LOCATION: _____
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Introduction
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This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Fyfanon® (EPA Registration No. 5905-196)

Active Ingredient (AI): Malathion (insecticide, CAS No. 00121-75-5)

Formulation and Packaging: 5 lbs AI/gallon Emulsifiable Concentrate

You may handle up to: 20 gallons of product

APPROVED BY
Independent IRB
Signature 3/25/08 Date

Initials: _____
Date: _____

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

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

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

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

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

Label date: 2005 MSDS date: 10-5-05

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08; Revised: 3/25/08

APPROVED BY
Independent IRB
Signature 3/25/08 Date

Initials: _____
Date: _____

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

TITLE: (PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus

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

STUDY DIRECTOR:
Larry D. Smith, Ph.D.
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LOCATION: _____
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This Product Risk Statement is in addition to the Informed Consent Form that you have already signed.

The product you will handle is identified as follows:

Name: Fyfanon® 8 lb. Emulsion (EPA Registration No. 5905-250-ZA)

Active Ingredient (AI): Malathion (insecticide, CAS No. 00121-75-5)

Formulation and Packaging: 8 lbs AI/gallon Emulsifiable Concentrate in 1 or 2.5 gallon plastic jugs

APPROVED BY
Independent IRB
Signature
3/25/08
Date

Initials: _____
Date: _____

You may handle up to: 12.5 gallons of product

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

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

Potential Health Effects From Too Much Exposure: The following signs and symptoms of toxicity from short-term exposure might occur. These effects are not anticipated with normal use, but might occur following a spill or other accidental exposure.

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

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

Label date: 2005
MSDS date: 1-5-05

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

Copy of consent form given to subject on (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 3/4/08; Revised: 3/25/08

APPROVED BY
Independent IRB
Signature 3/25/08
Date

Initials: _____
Date: _____

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 26, 2008

To Whom It May Concern:
A Quién Corresponda:

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

Fyfanon®
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/25/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

Fyfanon®
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 25/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Américo Gómez, who translated this document, is fluent in Spanish and standard North American English and qualified to translate. He attests to the following:

Américo Gómez, quien tradujo dicho documento, tiene dominio de los idiomas inglés norteamericano y español, y está capacitado para traducir. Él declara lo siguiente:

"To the best of my knowledge, the accompanying text is a true, full and accurate translation of the specified document".
«Según mi leal saber y entender, el texto que sigue a continuación es una traducción fiel y correcta del documento que se adjunta».

Signature of Américo Gómez/*Firma de Américo Gómez*

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

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, PhD
P.O. Box 509
Macon, Missouri 63552

DIRECTOR DEL ESTUDIO: Larry D. Smith, PhD
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Teléfono: 440-255-1954
Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIÓN: _____
_____
_____

Introducción
Usted se ha puesto de acuerdo para participar en el estudio de referencia. El formulario de consentimiento informado que usted firmó, enunciaba que se le informaría verbalmente y por escrito, acerca de cualquier riesgo(s) que podría influir sobre su disposición para participar en el estudio.

Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Fyfanon® (Registro de EPA № 5905-196)

Ingrediente Activo (AI): Malathion (insecticida, CAS № 00121-75-5)

Formulación y Embalaje: 5 lbs. AI/galón Concentrado Emulsionante.

Usted puede manipular hasta: 20 galones del producto

APROBADO POR
Independent IRB
Firma
25/marzo/08
Fecha

Iniciales: _____
Fecha: _____

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes a las substancias químicas y anteojos protectores para los ojos. Debe quitarse los guantes y los anteojos protectores para los ojos, antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto malatión [malathion] está clasificado como de toxicidad moderada para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación moderada de los ojos, irritación ligera de la piel, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Fecha de la etiqueta: 2005 Fecha de la MSDS: octubre-5-05

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma del Testigo Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08; Revisado: 25/marzo/08

APROBADO POR
Independent IRB
Firma 25/marzo/08 Fecha

Iniciales: _____
Fecha: _____

Américo Gómez
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435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 26, 2008

To Whom It May Concern:
A Quién Corresponda:

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

Fyfanon® 8 lb. Emulsion
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/25/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

Fyfanon® Emulsión de 8 libras
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 25/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Américo Gómez, who translated this document, is fluent in Spanish and standard North American English and qualified to translate. He attests to the following:

Américo Gómez, quien tradujo dicho documento, tiene dominio de los idiomas inglés norteamericano y español, y está capacitado para traducir. Él declara lo siguiente:

"To the best of my knowledge, the accompanying text is a true, full and accurate translation of the specified document".
«Según mi leal saber y entender, el texto que sigue a continuación es una traducción fiel y correcta del documento que se adjunta».

Signature of Américo Gómez/*Firma de Américo Gómez*

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

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, PhD
P.O. Box 509
Macon, Missouri 63552

DIRECTOR DEL ESTUDIO: Larry D. Smith, PhD
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Teléfono: 440-255-1954
Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIÓN: _____
_____
_____

Introducción
Usted se ha puesto de acuerdo para participar en el estudio de referencia. El formulario de consentimiento informado que usted firmó, enunciaba que se le informaría verbalmente y por escrito, acerca de cualquier riesgo(s) que podría influir sobre su disposición para participar en el estudio.

Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Fyfanon® 8 lb. Emulsión (Registro de EPA № 5905-250-ZA)

Ingrediente Activo (AI): Malathion (insecticida, CAS № 00121-75-5)

Formulación y Embalaje: 8 lbs. AI/galón Concentrado Emulsionante en jarras de plástico de 1 ó 2,5 galones.

APROBADO POR
Independent IRB
Firma
25/marzo/08
Fecha

Iniciales: _____
Fecha: _____

Usted puede manipular hasta: 12,5 galones del producto

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes a las substancias químicas. Debe quitarse los guantes antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto malatión [malathion] está clasificado como de baja toxicidad para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación moderada de los ojos, irritación ligera de la piel, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Fecha de la etiqueta: **2005**
Fecha de la MSDS: **enero-5-05**

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma del Testigo Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08; Revisado: 25/marzo/08

Versión: 25/marzo/08
Protocolo: AHE55
Fyfanon® 8 lb. Emulsión

APROBADO POR
Independent IRB
Firma 25/marzo/08
Fecha

Iniciales: _____
Fecha: _____

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 26, 2008

To Whom It May Concern:
A Quién Corresponda:

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

SevinBrand® 80 WSP
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/25/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

SevinBrand® 80 WSP
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 25/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

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«Según mi leal saber y entender, el texto que sigue a continuación es una traducción fiel y correcta del documento que se adjunta».

Signature of Américo Gómez/*Firma de Américo Gómez*

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

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
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c/o David R. Johnson, PhD
P.O. Box 509
Macon, Missouri 63552

DIRECTOR DEL ESTUDIO: Larry D. Smith, PhD
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UBICACIÓN: _____
_____
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Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Insecticida Servin® Brand 80 WSP Carbaryl (Registro de EPA № 264-526)

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

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

Usted puede manipular hasta: 100 paquetes solubles en agua

APROBADO POR
Independent IRB
Firma
25/marzo/08
Fecha

Iniciales: _____
Fecha: _____

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes al agua. Debe quitarse los guantes antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto carbarilo [carbaryl] está clasificado como de toxicidad moderada para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación ligera de los ojos, irritación mínima de la piel, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Fecha de la etiqueta: septiembre-23-04
Fecha de la MSDS: diciembre-26-02 (Número 000000001825; Versión 1.1)

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma de la Persona que está dirigiendo la discusión del Formulario de Consentimiento Informado Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08; Revisado: 25/marzo/08

APROBADO POR
Independent IRB
_____ 25/marzo/08
Firma Fecha

Iniciales: _____
Fecha: _____

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 26, 2008

To Whom It May Concern:
A Quién Corresponda:

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

SevinBrand® 4 F
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/25/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

SevinBrand® 4 F
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 25/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

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Signature of Américo Gómez/*Firma de Américo Gómez*

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

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, PhD
P.O. Box 509
Macon, Missouri 63552

DIRECTOR DEL ESTUDIO: Larry D. Smith, PhD
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Mentor, Ohio 44060
Teléfono: 440-255-1954
Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIÓN: _____
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_____

Introducción
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Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Insecticida Servin® Brand 4F Carbaryl (Registro de EPA № 264-349)

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

Formulación y Embalaje: 4 lbs. AI/galón líquido fluyente en jarras de plástico de 2,5 galones.

Usted puede manipular hasta: 25 galones del producto

APROBADO POR
Independent IRB
Firma
25/marzo/08
Fecha

Iniciales: _____
Fecha: _____

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes a las substancias químicas. Debe quitarse los guantes antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto carbarilo [carbaryl] está clasificado como de baja toxicidad para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación ligera de los ojos, irritación mínima de la piel, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Fecha de la etiqueta: septiembre-27-04
Fecha de la MSDS: diciembre-18-02 (№ 000000000194, Versión 2.1)

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma del Testigo Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08; Revisado: 25/marzo/08

APROBADO POR
Independent IRB
Firma 25/marzo/08 Fecha

Iniciales: _____
Fecha: _____

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 26, 2008

To Whom It May Concern:
A Quién Corresponda:

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

Malathion® 8
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/25/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

Malathion® 8
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 25/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
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Signature of Américo Gómez/*Firma de Américo Gómez*

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

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
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Introducción
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Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Gowan Malathion 8 (Registro de EPA № 10163-21)

Ingrediente Activo: Malathion (insecticida, CAS № 121-75-5)

Formulación y Embalaje: 8 lbs. AI/galón Concentrado Emulsionante.

Usted puede manipular hasta: 12,5 galones del producto

APROBADO POR
Independent IRB
Firma
25/marzo/08
Fecha

Iniciales: _____
Fecha: _____

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes a las substancias químicas. Debe quitarse los guantes antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto malatión [malathion] está clasificado como de baja toxicidad para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación ligera de los ojos y/ó piel, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

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Identificación de la etiqueta: 04-R0699
Fecha de la MSDS: febrero-1-07 (Gowan Malathion 8 que fluye)

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma del Testigo Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08; Revisado: 25/marzo/08

Versión: 25/marzo/08
Protocolo: AHE55
Gowan Malathion 8

APROBADO POR
Independent IRB
_____ 25/marzo/08
Firma Fecha

Iniciales: _____
Fecha: _____

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March 26, 2008

To Whom It May Concern:
A Quién Corresponda:

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Malathion® 8 E
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/25/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

Malathion® 8 E
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 25/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Américo Gómez, who translated this document, is fluent in Spanish and standard North American English and qualified to translate. He attests to the following:

Américo Gómez, quien tradujo dicho documento, tiene dominio de los idiomas inglés norteamericano y español, y está capacitado para traducir. Él declara lo siguiente:

"To the best of my knowledge, the accompanying text is a true, full and accurate translation of the specified document".
«Según mi leal saber y entender, el texto que sigue a continuación es una traducción fiel y correcta del documento que se adjunta».

Signature of Américo Gómez/*Firma de Américo Gómez*

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

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, PhD
P.O. Box 509
Macon, Missouri 63552

DIRECTOR DEL ESTUDIO: Larry D. Smith, PhD
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Teléfono: 440-255-1954
Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIÓN: _____
_____
_____

Introducción
Usted se ha puesto de acuerdo para participar en el estudio de referencia. El formulario de consentimiento informado que usted firmó, enunciaba que se le informaría verbalmente y por escrito, acerca de cualquier riesgo(s) que podría influir sobre su disposición para participar en el estudio.

Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Insecticida Malathion 8-E (Registro de EPA № 34704-452)

Ingrediente Activo (AI): Malathion (insecticida, CAS № 121-75-5)

Formulación y Embalaje: 8 lbs. AI/galón Concentrado Emulsionante en jarras de plástico de 1 galón.

Usted puede manipular hasta: 12,5 galones del producto

APROBADO POR
Independent IRB
Firma
25/marzo/08
Fecha

Iniciales: _____
Fecha: _____

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes a las substancias químicas. Debe quitarse los guantes antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto malatión [malathion] está clasificado como de baja toxicidad para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación moderada de los ojos, irritación ligera de la piel, posible reacción alérgica en la piel, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Fecha de la etiqueta: no se ha encontrado
Fecha de la MSDS: junio-8-06 (Loveland MSDS № 000452-06-LPI)

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma del Testigo Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08; Revisado: 25/marzo/08

APROBADO POR
Independent IRB
_____ 25/marzo/08
Firma Fecha

Iniciales: _____
Fecha: _____

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 26, 2008

To Whom It May Concern:
A Quién Corresponda:

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

SevinBrand® XLR Plus
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: 3/25/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

SevinBrand® XLR Plus
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: 25/marzo/08) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Américo Gómez, who translated this document, is fluent in Spanish and standard North American English and qualified to translate. He attests to the following:

Américo Gómez, quien tradujo dicho documento, tiene dominio de los idiomas inglés norteamericano y español, y está capacitado para traducir. Él declara lo siguiente:

"To the best of my knowledge, the accompanying text is a true, full and accurate translation of the specified document".
«Según mi leal saber y entender, el texto que sigue a continuación es una traducción fiel y correcta del documento que se adjunta».

Signature of Américo Gómez/*Firma de Américo Gómez*

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

TÍTULO: (PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverizaciones Neumáticas [*Airblast*] de Rociadores Líquidos, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.

PATROCINADOR Y FUENTE DE FINANCIAMIENTO:
Agricultural Handlers Exposure Task Force (AHETF)
c/o David R. Johnson, PhD
P.O. Box 509
Macon, Missouri 63552

DIRECTOR DEL ESTUDIO: Larry D. Smith, PhD
LS Consulting Service, LLC
7919 Champaign Dr.
Mentor, Ohio 44060
Teléfono: 440-255-1954
Correo electrónico [E-mail]: lsconsulting@oh.rr.com

UBICACIÓN: _____
_____
_____

Introducción
Usted se ha puesto de acuerdo para participar en el estudio de referencia. El formulario de consentimiento informado que usted firmó, enunciaba que se le informaría verbalmente y por escrito, acerca de cualquier riesgo(s) que podría influir sobre su disposición para participar en el estudio.

Esta Declaración de Riesgo del Producto es un agregado al Formulario de Consentimiento Informado que usted ya ha firmado.

El producto que usted manipulará se identifica de la siguiente manera:

Nombre: Insecticida Servin® Brand XLR Plus Carbaryl (Registro de EPA № 264-333)

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

Formulación y Embalaje: 4 lbs. AI/galón de líquido fluyente en jarras plásticas de 2,5 galones.

Usted puede manipular hasta: 25 galones del producto

APROBADO POR
Independent IRB
_____ Firma
25/marzo/08 Fecha

Iniciales: _____
Fecha: _____

Equipo Protector Personal (PPE) Requerido para el Manipuleo: Los aplicadores deben usar camisas de manga larga y pantalones largos y, zapatos más calcetines. Si usted sale de la cabina cerrada y llegase a tocar las superficies contaminadas, usted también debe usar guantes resistentes a substancias químicas. Debe quitarse los guantes antes de volver a entrar a la cabina y almacenarlos en un envase resistente a substancias químicas.

Recomendaciones de Seguridad para el Usuario: Los usuarios deberían lavarse las manos antes de comer, beber, masticar chicle, usar tabaco, o usar el cuarto de baño.

Efectos Potenciales a la Salud provenientes de Demasiada Exposición: Podrían ocurrir las siguientes señales y síntomas de toxicidad, provenientes de la exposición a corto plazo. Estos efectos no se anticipan con el uso normal, pero podrían ocurrir seguido a un derrame u otra exposición accidental.

Este producto carbarilo [carbaryl] está clasificado como de baja toxicidad para la exposición por boca, por piel y, por la respiración. Las señales y los síntomas de demasiada exposición a corto plazo, incluyen la irritación ligera de los ojos, e inhibición de la colinesterasa (la colinesterasa es una substancia química existente en nuestro sistema nervioso, la cual les permite a los nervios funcionar correctamente; cuando las substancias químicas los previenen de funcionar correctamente, hay una estimulación del sistema nervioso).

La inhibición de la colinesterasa puede resultar en dolor de cabeza, mareos, náuseas, vómitos, calambres, diarrea, visión nublada, puntitos en las pupilas, apretujamiento del pecho, dificultad para respirar, nerviosismo, sudores, los ojos acuosos, babeo, espasmos musculares y, coma.

Fecha de la etiqueta: septiembre-21-04
Fecha de la MSDS: enero-17-08 (Bayer MSDS 102000001927; Versión 2.1)

_____ _____
Firma del Sujeto Fecha

_____ _____
Firma de la Persona que está dirigiendo la discusión del Formulario de Consentimiento Informado Fecha

Copia del formulario de consentimiento dado al sujeto el (fecha) _____ por (iniciales) _____

Independent Investigational Review Board, Inc.
Aprobado: 4/marzo/08; Revisado: 25/marzo/08

APROBADO POR
Independent IRB
_____ 25/marzo/08
Firma Fecha

Iniciales: _____
Fecha: _____

Volume II, Part D: Recruitment Flyer

(English / Spanish Versions)

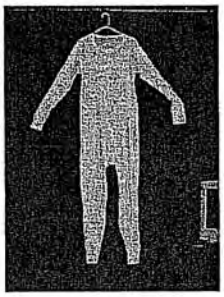
Research Study Volunteers

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

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

You will be asked to do the following:

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



You should also know that:

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

If you are interested, please contact the Study Director:

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

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

APPROVED 3/4/08
Independent Investigational Review Board

"ver. Research Study Volunteers"

Américo Gómez
Independent Translator
435 NE 23rd Street
Suite 204
Miami, Florida 33137-4902
Telephone: (305) 571-5070 • Fax: (305) 573-4683 • E-mail: AGomez5634@aol.com

March 12, 2008

To Whom It May Concern:
A Quién Corresponda:

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

Print Ad: (Research Study Volunteers) Approved 3/4/08
(PROTOCOL AHE55) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays to Crops Using Closed Cab Equipment in Florida Citrus.
(Protocol: AHE55) (Version: Research Study Volunteers) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

Por la presente se certifica que el documento adjunto, traducido del inglés al español, es una representación fiel del formulario de consentimiento informado recibido por esta oficina. Dicho documento es:

Aviso Impreso: (Voluntarios para Estudio de Investigación Científica) Approvado 3/4/08
(PROTOCOLO AHE55) La Determinación de la Exposición Dérmica e Inhalación de los Trabajadores Durante las Aplicaciones de Pulverización Neumática [*Airblast*] a las Cosechas, Usando Equipo de Cabina Cerrada en los Cítricos de la Florida.
(Protocolo: AHE55) (Versión: Voluntarios para Estudio de Investigación Científica) (Larry D. Smith, PhD; LS Consulting Service, LLC)
(Agricultural Handlers Exposure Task Force [AHETF])

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Signature of Américo Gómez/*Firma de Américo Gómez*

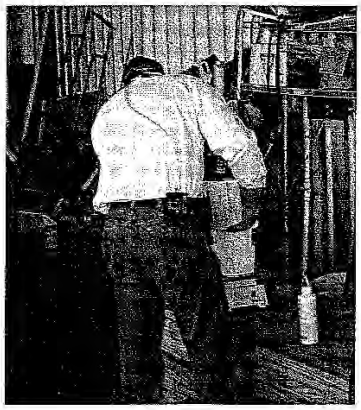
Voluntarios para un Estudio de Investigación Científica

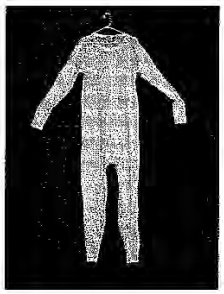
La Agricultural Handlers Exposure Task Force (AHETF) es un grupo de compañías de pesticidas que están llevando a cabo investigación científica para medir cuánta substancia química se agarran los trabajadores cuando ellos manipulan pesticidas. Están buscando aplicadores experimentados de pulverización neumática [*airblast*] para que desempeñen su trabajo usual y dejar que se les recoja datos de la exposición.

Para ofrecerse como voluntario usted debe:	Usted no cumple con los requisitos si:
• Tener por lo menos 18 años y una identificación, con foto, emitida por el gobierno • Dominar el idioma inglés o el español • Gozar de buena salud • No trabajar para un fabricante de pesticidas • Ser hombre, o mujer (que no esté embarazada ni lactando) • Ser experimentado y estar entrenado en el manipuleo de pesticidas	• Es menor de 18 años de edad • Si no tiene una identificación con foto que sea emitida por el gobierno • Si no habla ni inglés ni español • Si no goza de un buen estado de salud • Si trabaja para un fabricante de pesticidas • Si es una mujer que está embarazada o lactando • Si tiene insuficiencia cognitiva

Le pedirán que haga lo siguiente:

- **Que nos permita monitorearlo mientras que usted hace su trabajo, durante un día**
- **Que firme un formulario de consentimiento antes de participar (en inglés ó en español)**
- **Que use ropa interior larga debajo de sus ropas regulares**
- **Que nos deje tener la ropa interior larga al final del día**
- **Que nos deje lavarle las manos y frotarle la cara, periódicamente, con una solución de jabón suave**





Usted debería saber que:

- **La participación es completamente voluntaria**
- **Usted puede retirarse cuando quiera**
- **Se usan solamente técnicas no invasoras, de modo que usted no tiene que dar ni muestras de orina ni de sangre**
- **La información proveniente del estudio será usada por la EPA al evaluar los riesgos que corren los trabajadores agrícolas.**

Si está interesado, por favor póngase en contacto con el Director del Estudio:

Larry Smith
teléfono de la oficina 440-255-1954
teléfono celular 440-554-2812

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

ver. "Research Study Volunteers"

APPROVED 3/4/08
Independent Investigational Review Board