



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

MAR 14 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Amy Plato Roberts
Technology Sciences Group Inc.
Regulatory Consultant for Advanced Microbiologics, LLC
712 Fifth Street, Suite A
Davis, CA 95616

Re: March 2010 Amendments to Remove the Expiration Date and Change the Active Ingredient Name to *Bacillus sphaericus* 2362, serotype H5a5b, strain AML614, Updated Labels and Confidential Statements of Formula Dated March 10, 2011 for AM61432 Primary Powder, AM61432 (50G), and AM61432 WP
EPA Registration No. 84268-1, 84268-2, and 84268-3

Dear Ms. Roberts:

The amendments referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable subject to the following comments.

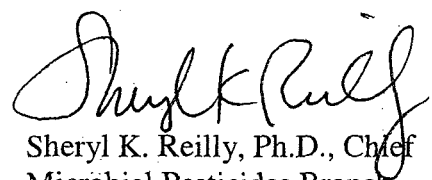
- 1) The expiration date for the subject products have been removed so that they no longer automatically expire.
- 2) Your revised basic Confidential Statement of Formulas for all products listed above dated March 10, 2011 and the (50G) Alternate Formulation A dated March 10, 2011 are acceptable and have been placed in your products' file.
- 3) The specific data listed in the conditions of registration for the three (3) subject products have been satisfied except for the acute dermal irritation study required for the WP product. You had submitted an acute dermal toxicity study, but this does not satisfy the dermal irritation requirement. You must submit a dermal irritation study for the WP product within six (6) months.

Mendenhall
754P
3/10/11

Ms. Amy Roberts
EPA Registration Nos. 84263-1,-2,-3

Submit five (5) copies of your final printed labeling before you release the amended product for shipment. A stamped copy of the label is enclosed for your records.

Sincerely,



Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures

3/10

AM61432 WP

(Alternate Brand Names: "Spheratax SPH WP")

ACTIVE INGREDIENT:

Bacillus sphaericus 2362, Serotype H5a5b, strain AML614*65.00%

OTHER INGREDIENTS:35.00%

TOTAL:100.00%

* Equivalent to 650 *Bacillus Sphaericus* International Toxic Units (BS ITU) per mg of product (0.299 billion BS ITU per lb of product). Potency units should not be used to adjust rates beyond those specified in the Directions for Use Section. Note: The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

KEEP OUT OF REACH OF CHILDREN WARNING / AVISO

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

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 – 20 minutes. • Call a poison control center or doctor for treatment advice.
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.	

EPA Reg. No.: 84268-3
EPA Establishment No.: XXXXX-XX-XX

Manufactured for:
ADVANCED MICROBIOLOGICS, LLC
1801 North Gale Road
Mitchell, SD 57301

**ACCEPTED
with COMMENTS
In EPA Letter Dated
MAR 14 2011**

Net Contents: XX
Batch Code: XXX

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
84268-3

(Precautionary Statements and Directions for Use for uses covered by the Worker Protection Standard)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - WARNING. Causes moderate eye irritation and skin irritation. Do not get in eyes, on skin or on clothing. Wear appropriate Personal Protective Equipment as specified below. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Harmful if inhaled. Avoid breathing dust or spray mist. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE): Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks
- Protective eyewear such as goggles, face shield or shielded safety goggles

Mixers / loaders and applicators not in enclosed cabs or aircraft must wear a dust / mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Follow the manufacturer's instructions for cleaning and maintaining PPE. If no instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters or rinsate. Do not apply to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human consumption.

DIRECTIONS FOR USE

It is a violation of Federal law to apply this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or thorough drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It

contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted-entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

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

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water), is:

- Coveralls
- Waterproof gloves
- Shoes plus socks
- Protective eyewear such as goggles, face shield, or shielded safety glasses

(AM61432 WP is a highly selective microbial insecticide effective against mosquitoes in a variety of habitats. Apply AM61432 WP to any water sites except treated, finished water reservoirs or drinking water receptacles when the water is intended for human consumption. AM61432 WP can be applied to areas that contain aquatic life, fish and plants. AM61432 WP can be applied to areas used by or in contact with humans, animals, horses, livestock, pets, birds or wildlife.)

APPLICATION DIRECTIONS

Mosquito species effectively controlled by AM61432 WP.

- Aedes vexans*
- Anopheles quadrimaculatus*
- Coquillettidia perturbans*
- Culex spp.*
- Ochlerotatus melanimon (Aedes melanimon)*
- Ochlerotatus nigromaculis (Aedes nigromaculis)*
- Ochlerotatus sollicitans (Aedes sollicitans)*
- Ochlerotatus stimulans (Aedes stimulans)*
- Ochlerotatus triseriatus (Aedes triseriatus)*
- Psorophora columbiae*
- Psorophora ferox*

For control of mosquito larvae from the list of affected species above in the following crop sites.

Habitats	Rate / Acre
Rice fields, pastures / hay fields, orchards, citrus groves, irrigated crops, agricultural irrigation waters	0.5 – 1.5 lbs

Use higher rates (1 – 1.5 lbs / acre) in areas where extended residual control is necessary, or in habitats having deep water or dense surface cover. Apply uniformly by aerial and conventional ground equipment. Reapply as needed after 1-4 weeks.

Do not apply this product through any type of irrigation system.

Specific Ground and Aerial Application Instructions:

Apply AM61432 WP using conventional ground or aerial application equipment with quantities of water sufficient to provide uniform coverage of the target area. For application, mix AM61432 WP with the desired amount of water to produce the final spray mixture.

The amount of water will depend on weather, spray equipment, and mosquito habitat characteristics. For application, fill the mix tank or plane hopper with the desired quantity of water. Start the mechanical agitation or manual agitation before adding AM61432 WP. Agitate backpack and compressed air sprayers by shaking after suspending AM61432 WP in the water before addition to the sprayer. AM61432 WP suspends readily in water and stays suspended for prolonged periods. Brief recirculation may be necessary if the spray mixture has sat for a prolonged period of time. Do not mix more AM61432 WP than can be used in a 48 hour period. Avoid continuous agitation of the spray mixture during application

For ground spraying, apply 0.5 – 1.5 pounds of AM61432 WP in 5 – 100 gallons of water per acre using a hand pump, air blast, mist blower, or other spray equipment. For aerial application, apply 0.5 – 1.5 pounds of AM61432 WP per acre through fixed or rotary winged aircraft equipped with either conventional boom and nozzle systems or rotary atomizers at an appropriate dilution rate. For aerial application, apply 0.5 – 10 gallons of final spray mixture per acre sufficient to provide uniform coverage.

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment and weather related factors determine the potential spray drift. The applicator and treatment coordinator are responsible for considering all these factors when making decisions.

Rinse and flush spray equipment thoroughly following each use.

Amount of AM61432 Needed to Treat Small Areas:

Rate of AM61432 WP / Acre

Area to Treat	8 oz	16 oz	24 oz
¼ acre	1/8 lb	¼ lb	3/8 lb
½ acre	¼ lb	½ lb	¾ lb
10 acres	5 lb	10 lb	15 lb
20 acres	10 lb	20 lb	30 lb

(Precautionary Statements and Directions for Use for uses not covered by the Worker Protection Standard)

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Ochlerotatus sollicitans (Aedes sollicitans)
Ochlerotatus stimulans (Aedes stimulans)
Ochlerotatus triseriatus (Aedes triseriatus)
Psorophora columbiae
Psorophora ferox

For control of mosquito larvae from the list of affected species above in agricultural / non-crop sites where mosquito breeding occurs:

Habitats	Rate / Acre
Wastewater: Sewage effluent, sewage lagoons, oxidation ponds, septic ditches, animal waste lagoons, impounded wastewater associated with fruit and vegetable processing.	0.5 – 1.5 lbs
Storm Water / Drainage Systems: Storm sewers, catch basins, drainage ditches, retention, detention, and seepage ponds.	0.5 – 1.5 lbs
Marine / Coastal Areas: Salt marshes, mangroves, estuaries.	0.5 – 1.5 lbs
Water Bodies: Natural and manmade aquatic sites such as lakes, ponds, rivers, canals, and streams.	0.5 – 1.5 lbs
Dormant Rice Fields: Impounded water in dormant rice fields. (For application only during the interval between harvest and preparation of the field for the next cropping cycle.)	0.5 – 1.5 lbs

Use higher rates (1 – 1.5 lbs / acre) in areas where extended residual control is necessary, or in habitats having deep water or dense surface cover. Apply uniformly by aerial and conventional ground equipment. Reapply as needed after 1-4 weeks.

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20 acres	10 lb	20 lb	30 lb

(Storage and Disposal instructions and Notice to User statements are for both uses covered by the WPS and not covered by the WPS)

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place.

Pesticide Disposal: To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration. Do not burn unless allowed by state and local ordinances. If outside container is contaminated, dispose of in the same manner as the bag.

NOTICE TO USER

To the extent consistent with applicable law, seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning the use of this product other than as indicated on the label. User assumes all risks of use, storage or handling not in strict accordance with label instructions.

OPTIONAL LABEL CLAIMS

- Biolarvicide.
- Biological Mosquito Control.
- Mosquito Biolarvicide Wettable Powder.
- Biological Larvicide Wettable Powder.
- Highly selective microbial larvicide.
- A (highly selective) microbial insecticide effective against mosquitoes in a variety of habitats.
- Easy to use.
- Effective year-round when mosquito larvae are present.
- Controls mosquito(es) (larvae).
- When ingested by mosquito larvae, (product name) prevents mosquitoes from becoming (developing into) breeding, biting adults.
- When ingested by mosquito larvae, (product name) prevents the development of adults.
- When ingested by mosquito larvae, (product name) prevents emergence of breeding, biting adults.
- Kills (mosquitoes) (developing mosquitoes) (mosquito larvae) (before they hatch) including those which may (can) transmit (carry) West Nile virus (and encephalitis) (and equine encephalitis).
- Kills (mosquitoes) (developing mosquitoes) (mosquito larvae) before they become breeding, biting adults, including those which may (can) transmit (carry) West Nile Virus (and encephalitis) (and equine encephalitis).
- Kills (mosquitoes) (developing mosquitoes) (mosquito larvae) (before they hatch) including those which may (can) transmit heartworm disease to dogs and cats.