

84268-2

4/8/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION
AGENCY

Washington, D.C. 20460

APR - 8 2010

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES**CERTIFIED MAIL**

Amy Plato Roberts
Regulatory Consultant for Advanced Microbiologics, LLC
Technology Science Group, Inc.
1150 18th Street, N.W.
Suite 1000
Washington, DC 20036

Subject: Fast Track Amendment to Add Water Soluble Packaging, Update
Labeling, and Basic Formulation for AM61432 (50 G)
EPA Reg. No.: 84268-2
Decision # 412697

Dear Ms. Plato Roberts,

The Agency has reviewed your request to amend the subject product registration,
which included the following changes to the product label:

- 1) Addition of Alternate Brand Name "Spheratax SPH (50 G) WSP."
- 2) Addition of Direction for Use and container handling statements for water soluble packaging.
- 3) Additional use sites were added to include the following: storm drains, roadside ditches, irrigation ditches, floodwater, standing water, unused and abandoned swimming pools or spas, water gardens, flooded basements, urns, birdbaths, gutters and drains, hollow trees, tree holes, pool covers, rain barrels, fountains, wheelbarrows, livestock watering ponds, troughs and tanks, flower pots and planters, garbage cans and covers, snowmelt pools, and discarded tires.
- 4) Addition of "Water Soluble Pouches" optional label claim.

In addition to the label amendment described above, the confidential statement of formula (CSF) was updated. The new basic CSF dated August 18, 2009 supersedes the previous basic CSF dated June 5, 2007 and will be filed in the Agency's records as the official basic CSF.

CONCURRENCES

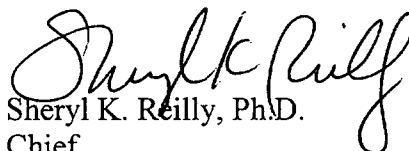
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DATE	04/07/2010	4/8/10					

The amendment referred to on the previous page, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit two (2) copies of the final printed labeling prior to releasing the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA § 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. If you have any questions, contact Susanne Cerrelli at 703-308-8077 or by email at cerrelli.susanne@epa.gov. A stamped copy of the label is enclosed for your records.

Sincerely,



Sheryl K. Reilly, Ph.D.
Chief

Biopesticides and Pollution Prevention Division
Microbial Pesticides Branch (7511P)

Enclosure

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Optional Label Claims

TOTAL:100.00%

Mitchell, SD 57301

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 84268-2

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Sublabel A: AM61432 (50 G) loose granules

AM61432 (50 G)

(Alternate Brand Name: "Spheratax SPH (50 G)")

ACTIVE INGREDIENT:

Bacillus sphaericus, Serotype H5a5b, strain 2362*5.00%

OTHER INGREDIENTS:95.00%

TOTAL:100.00%

* Equivalent to 50 *Bacillus sphaericus* International Toxic Units (BS ITU) per mg of product (0.023 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 CAUTION

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.
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.: 84268-2

EPA Establishment No.: XXXXX-XX-XX

Net Contents: XX

Batch Code: XXX

Manufactured for:

ADVANCED MICROBIOLOGICS, LLC
1801 North Gale Road
Mitchell, SD 57301

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION. Causes moderate eye irritation. Avoid contact with eyes or clothing. 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.

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

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

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 through 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.

AM61432 (50 G); EPA Reg. No. 84268-2

Label and CSF Amendment (FAST TRACK) to add WSP and updated container disposal per PRN 2007-4

MASTER LABEL - Label version (7) dated May 9, 2009

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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 4 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

(AM61432 (50 G) is a highly selective microbial insecticide effective against mosquitoes in a variety of habitats. Apply AM61432 (50 G) to any water sites except treated, finished water reservoirs or drinking water receptacles when the water is intended for human consumption. AM61432 (50 G) can be applied to areas that contain aquatic life, fish and plants. AM61432 (50 G) 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 (50 G).

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	5 – 20 lbs

Use higher rates (10 – 20 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.

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.

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION. Causes moderate eye irritation. Avoid contact with eyes or clothing. 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. 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.

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.

(AM61432 (50 G) is a highly selective microbial insecticide effective against mosquitoes in a variety of habitats. Apply AM61432 (50 G) to any water sites except treated, finished water reservoirs or drinking water receptacles when the water is intended for human consumption. AM61432 (50 G) can be applied to areas that contain aquatic life, fish and plants. AM61432 (50 G) 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 (50 G).

Aedes vexans
Anopheles quadrimaculatus
Coquilleltidia 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 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.	5.0 – 20 lbs
Storm Water / Drainage Systems: Storm sewers, catch basins, drainage ditches, retention, detention, and seepage ponds.	5.0 - 20 lbs
Marine / Coastal Areas: Salt marshes, mangroves, estuaries.	5.0 – 20 lbs
Water Bodies: Natural and manmade aquatic sites such as lakes, ponds, rivers, canals, and streams.	5.0 – 20 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.)	5.0 – 20 lbs

Use higher rates (10 – 20 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.

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.

(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.

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Sublabel B: AM61432 (50 G) in water soluble pouches

AM61432 (50 G)

(Alternate Brand Name: "Spheratax SPH (50 G) WSP")

ACTIVE INGREDIENT:

Bacillus sphaericus, Serotype H5a5b, strain 2362 *.....5.00%

OTHER INGREDIENTS:95.00%

TOTAL:100.00%

* Equivalent to 50 *Bacillus sphaericus* International Toxic Units (BS ITU) per mg of product (0.023 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 CAUTION

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.
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.	

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

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. Once the foil bag containing the Water Soluble Pouches is opened, use pouches within one day.

(AM61432 (50 G) is a highly selective microbial insecticide effective against mosquitoes in a variety of habitats. Apply AM61432 (50 G) to any water sites except treated, finished water reservoirs or drinking water receptacles when the water is intended for human consumption. AM61432 (50 G) can be applied to areas that contain aquatic life, fish and plants. AM61432 (50 G) 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 (50 G).

Aedes vexans
Anopheles quadrimaculatus
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Culex spp.
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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 non-crop sites where mosquito breeding occurs.

Habitats	Rate
Storm Water / Drainage Systems: Storm sewers, storm drains, catch basins, drainage ditches, retention, detention, seepage ponds, roadside ditches, irrigation ditches, floodwater, ponds, standing water, unused and abandoned swimming pools or spas, water gardens, flooded basements, urns, birdbaths, gutters and drains, hollow trees, tree holes, pool covers, rain barrels, fountains, wheelbarrows, livestock	1 pouch per 50 sq. ft. ⁽¹⁾

watering ponds, troughs and tanks, flower pots and planters, garbage cans and covers, snowmelt pools, discarded tires.

(Apply AM61432 (50 G) to) any (water sites) (location where water accumulates and remains standing for periods of time) except treated, finished water reservoirs or drinking water receptacles when the water is intended for human consumption.

⁽¹⁾ Treat on the basis of surface area of the potential mosquito breeding sites by placing one AM61432 (50 G) water soluble pouch for up to 50 square feet of treatment area. Reapply as needed after 1 – 4 weeks.

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. Offer for recycling, if available, or dispose of the empty outer foil pouch in the trash as long as WSP is unbroken.

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 Granule.
- Biological Larvicide Granule.
- Highly selective microbial larvicide.
- A (highly selective) microbial insecticide effective against mosquitoes in a variety of habitats.
- Easy to use.
- Water Soluble Pouches.
- 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.