



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.

Mendel  
7540  
3/10/11

2013

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

# AM61432 (50 G)

<b>Sublabel A:</b> AM61432 (50 G) loose granules
<b>Sublabel B:</b> AM61432 (50 G) in water soluble pouches
<b>Optional Label Claims</b>

**ACTIVE INGREDIENT:**

*Bacillus sphaericus* 2362, Serotype H5a5b, strain AML614\* .....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.

**EPA Reg. No.:** 84268-2

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

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

Updated ingredient statement

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40413

**Sublabel A: AM61432 (50 G) loose granules**

**AM61432 (50 G)**

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

**ACTIVE INGREDIENT:**

*Bacillus sphaericus* 2362, Serotype H5a5b, strain AML614\* .....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"><li>• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
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 about personal protective equipment (PPE), and restricted-entry intervals. The requirements in

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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*

*Coquillettidia perturbans*

*Culex* spp.

*Ochlerotatus melanimon* (*Aedes melanimon*)

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*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
<b>Wastewater:</b> Sewage effluent, sewage lagoons, oxidation ponds, septic ditches, animal waste lagoons, impounded wastewater associated with fruit and vegetable processing.	5.0 – 20 lbs
<b>Storm Water / Drainage Systems:</b> Storm sewers, catch basins, drainage ditches, retention, detention, and seepage ponds.	5.0 - 20 lbs
<b>Marine / Coastal Areas:</b> Salt marshes, mangroves, estuaries.	5.0 – 20 lbs
<b>Water Bodies:</b> Natural and manmade aquatic sites such as lakes, ponds, rivers, canals, and streams.	5.0 – 20 lbs
<b>Dormant Rice Fields:</b> 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.



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

**AM61432 (50 G)**

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

**ACTIVE INGREDIENT:**

*Bacillus sphaericus* 2362, Serotype H5a5b, strain AML614\* .....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	
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
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

**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*  
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*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
<b>Storm Water / Drainage Systems:</b> 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. <sup>(1)</sup>

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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.

<sup>(1)</sup> 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.