



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

January 13, 2009

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Amy Plato Roberts  
Regulatory Consulting for  
Advanced Microbiologics, LLC  
1150 18<sup>th</sup> Street, NW, Suite 1000  
Washington, DC 20036

RE: Product Name: AM61432 WP  
EPA Reg. No: 84268-3  
Application for Label Notification dated December 15, 2008 to Correct Typo in  
Active Ingredient Statement and Add Alternate Brand Name: Spheratax SPH WP

Dear Ms. Roberts:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration (PR) Notice 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PR Notice 98-10 and it has been determined that the action(s) requested falls within the scope of PR Notice 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification, received and reviewed" and will be placed accordingly in our records.

Questions concerning this action should be directed to Ms. Diana Hudson at (703) 308-8713 or email at [HUDSON.DIANA@EPA.GOV](mailto:HUDSON.DIANA@EPA.GOV).

Sincerely,

*Sheryl K. Reilly*

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

28420072



United States  
**Environmental Protection Agency**  
 Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 84268-3	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) AM61432 WP	PM# 90/Microbial Pesticides Br/BPPD	
5. Name and Address of Applicant (Include ZIP Code) Advanced Microbiologics, LLC 11146 NW 69th Place Parkland, FL 33076 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

**Section - II**

Amendment - Explain below.  Final printed labels in response to Agency letter dated \_\_\_\_\_

Resubmission in response to Agency letter dated \_\_\_\_\_  "Me Too" Application.

Notification - Explain below.  Other - Explain below.

**NOTIFICATION**  
 Date Reviewed: 1-13-09  
 Reviewed By: D. Hudson

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)  
 NOTIFICATION to add an alternate brand name. See attached cover letter dated December 15, 2008 for details.  
 This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

**Section - III**

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container

3. Location of Net Contents Information  
 Label  Container

4. Size(s) Retail Container

5. Location of Label Directions  
 on container label

6. Manner in Which Label is Affixed to Product  
 Lithograph Paper glued Stenciled  Other \_\_\_\_\_

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Amy Plato Roberts / aroberts@tsgusa.com	Title Regulatory Consultant	Telephone No. (Include Area Code) (202) 828-8954
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**Certification**  
 I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title Regulatory Consultant	6. Date Application Received (Stamped)
4. Typed Name Amy Plato Roberts	5. Date December 15, 2008	



December 15, 2008

**WASHINGTON**

1150 18th Street, N.W.  
Suite 1000  
Washington, D.C. 20036  
Telephone 202 223-4392  
Fax 202 872-0745

Sheryl Reilly  
Chief, Microbial Pesticides Branch  
Biopesticides and Pollution Prevention Division (7511P)  
Office of Pesticide Programs, EPA  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

**RE: AM61432 WP; EPA Reg. No. 84268-3**

**NOTIFICATION to add an alternate brand name and correct a typo**

**SACRAMENTO**

712 Fifth Street  
Suite A  
Davis, CA 95616  
Telephone 530 757-1298  
Fax 530 757-1299

Dear Dr. Reilly:

With this letter you will find a label notification to add an alternate brand name and to correct a typo for the above referenced product. Enclosed you will find the following in support of this notification:

- 1) NOTIFICATION form;
- 2) One (1) copy of the label with all changes highlighted.

The purpose of this notification is the following:

- a. Add the alternate brand name "**Spheratax SPH WP.**"
- b. Correct a typo in the active ingredient percent by weight listed. It was incorrectly listed as 66% active ingredient and 35% other ingredients. The correct listing is **65%** active ingredient and 35% other ingredients. Under separate cover, an updated Confidential Statement of Formula (CSF) has been submitted for this product with the correct active ingredient percent by weight.

**CANADA**

275 Slater Street  
Suite 900  
Ottawa, Ontario  
K1P 5H9  
Telephone 613 247-6285  
Fax 613 236-3754

There are no other changes made to the label at this time. If you have any questions or comments please let me know directly.

Sincerely,

Amy Plato Roberts  
Regulatory Consultant for Advanced Microbiologics, LLC  
Direct dial: (202) 828-8964; E-mail: [aroberts@tsgusa.com](mailto:aroberts@tsgusa.com)

**NOTIFICATION**

Date Reviewed: 1-13-09

Reviewed By: D. Hudson

# AM61432 WP

(Alternate Brand Names: "Spheratax SPH WP")

**ACTIVE INGREDIENT:**

*Bacillus sphaericus*, Serotype H5a5b, strain 2362\* ..... 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	
<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>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15 – 20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If inhaled</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>HOT LINE NUMBER</b>	
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

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 - WARNING.** Causes substantial but temporary eye injury 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 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.

**AM61432 WP; EPA Reg. No. 84268-3**

NOTIFICATION – To add an alternate brand name and correct typo in active ingredient statement

MASTER LABEL - Label version (3abn) dated December 15, 2008

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

8/11

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

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS – WARNING.** Causes substantial but temporary eye injury and skin irritation. Do not get in eyes, on skin or on clothing. Wear long-sleeved shirt, long pants, waterproof gloves, shoes plus socks, and protective eyewear such as goggles, face shield, or shielded safety glasses. 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.

Mixers / loaders and applicators 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 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 agricultural / non-crop sites where mosquito breeding occurs:**

<b>Habitats</b>	<b>Rate / Acre</b>
<b>Wastewater:</b> Sewage effluent, sewage lagoons, oxidation ponds, septic ditches, animal waste lagoons, impounded wastewater associated with fruit and vegetable processing.	<b>0.5 – 1.5 lbs</b>
<b>Storm Water / Drainage Systems:</b> Storm sewers, catch basins, drainage ditches, retention, detention, and seepage ponds.	<b>0.5 – 1.5 lbs</b>
<b>Marine / Coastal Areas:</b> Salt marshes, mangroves, estuaries.	<b>0.5 – 1.5 lbs</b>
<b>Water Bodies:</b> Natural and manmade aquatic sites such as lakes, ponds, rivers, canals, and streams.	<b>0.5 – 1.5 lbs</b>
<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.)	<b>0.5 – 1.5 lbs</b>

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

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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**

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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

(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.

**AM61432 WP**; EPA Reg. No. 84268-3

NOTIFICATION – To add an alternate brand name and correct typo in active ingredient statement  
MASTER LABEL - Label version (3abn) dated December 15, 2008

## 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.