

84268-1

1/13/2009

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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 Primary Powder  
EPA Reg. No: 84268-1  
Application for Label Notification dated December 15, 2008 for Alternate  
Brand Name: Spheratax Primary Powder

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)

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Please read instructions on reverse before completing form.

Form Approved, MB No. 2070-0060, Approval expires 2-28-95



United States  
Environmental Protection Agency  
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 84268-1	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) AM61432 Primary Powder	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

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application. <b>NOTIFICATION</b>
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below. <b>Date Reviewed: 1-13-09</b>

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

**Reviewed By:** D. Hudson

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:				2. Type of Container	
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		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
<b>* Certification must be submitted</b>	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					<input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> on container label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> 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) 828-8964
<b>Certification</b> 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 both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Consultant	
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 Primary Powder; EPA Reg. No. 84268-1**  
**NOTIFICATION to add an alternate brand name**

**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 to 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 add the following alternate brand name:

**"Spheratax Primary Powder"**

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

**CANADA**

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

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  
NOT TO BE USED DIRECTLY FOR TREATMENT OF PESTS  
FOR MANUFACTURING USE ONLY Date Reviewed: 1-13-09

Reviewed By: D. Hudson

# AM61432 Primary Powder

(Alternate Brand Names: "Spheratax Primary Powder")

**ACTIVE INGREDIENT:**

*Bacillus sphaericus*, Serotype H5a5b, strain 2362\* ..... 100.0%  
**TOTAL:**..... 100.0%

\* Equivalent to 1,000 *Bacillus Sphaericus* International Toxic Units (BS ITU) per mg of product (0.46 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.: 84268-1  
EPA Establishment No.: XXXXX-XX-XX

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

**Net Contents:** \_\_\_\_\_  
**Batch/Lot Number:** \_\_\_\_\_

**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.

**ENVIRONMENTAL HAZARDS:** Do not discharge effluent containing the product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of the National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**FOR MANUFACTURING USE ONLY.** For formulating only into end-use products for terrestrial and aquatic use sites. End-use products formulated from this product must be registered by the US EPA. This product may be used to formulate products for additional uses not listed on the Manufacturing-use Product (MP) label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding the support of such uses.

**STORAGE AND DISPOSAL**

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

**Pesticide Storage:** Store in a cool, dry place until used.

**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. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.