

# 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 PrimaryPowder, 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.

mender 75WP 3/19/11 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

## NOT TO BE USED DIRECTLY FOR TREATMENT OF PESTS FOR MANUFACTURING USE ONLY

## AM61432 Primary Powder

(Alternate Brand Names: "Spheratax Primary Powder")

ACTIVE INGREDIENT:	
Bacillus sphaericus 2362, Serotype H5a5b, strain AML614*	100.0%
TOTAL:	100.0%

# KEEP OUT OF REACH OF CHILDREN CAUTION

• 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.
<ul> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
HOT LINE NUMBER
ct container or label with you when calling a poison control center or doctor, or ent. You may also contact 1-800-222-1222 for emergency medical treatment

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:	

ACCEPTED
with COMMENTS
In EPA Letter Dated
MAR 1 4 2011

Under the Federal Insections: Fungicide, and Rodenticks Act an amended, for the pesticide registered under EPA Reg. No

<sup>\*</sup> 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.

#### 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.