

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Avenue NW
Washington, DC 20460

### NOTICE OF PESTICIDE REGISTRATION

X Registration

\_ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:

Date of Issuance

70127-7

2/2/09

Term of Issuance:

Conditional

Name of Pesticide Product:

TAE-001 Technical Bioinsecticide

Name and Address of Registrant (include ZIP Code):

Mr. Tom Schreier Regulatory Affairs Manager Novozymes Biologicals, Inc. 5400 Corporate Circle Salem, VA 24153

Note: Changes in Jabeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number:

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registration amendment application, referred to above, is acceptable under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, provided that you do the following:.

- 1. Submit/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 three (3) copies of the revised final printed labeling before you release the product for shipment. Refer to attached Type Size Requirements for final printed labeling.
- 3. Provide confirmatory data to demonstrate that potential unintentional ingredients, including fungal and microbiological

Signature of Approving Official:

Dat

WALL

2/2/09

(See second page for signature)

EPA Form 8570-6

contaminants, of the technical active ingredient, *Metarrhizium anisopliae* strain F52, will not harm human health and the environment. These data must meet the microbial pesticide data requirements of 40 CFR §158.2100 (OPPTS guidelines 885.1200 and 885.1300). They are required to proceed to FIFRA Section 3(c)(5) registration of the source material TAE-001 Technical (EPA Reg. No. 70127-7)and must be provided within one year of the registration date of this product. This registration notice supersedes all previous registration notices issued for this pesticide product. Except for the condition of registration described in this registration notice, all other conditions previously imposed for the technical for the currently registered uses have been satisfied.

This registration will automatically expire on midnight January 30, 2010, if you do not comply with these conditions. Any requests for time extensions to provide the data must be submitted in writing prior to the expiration date. If approved, extension requests will result in other appropriate expiration dates as determined by the Agency. When you submit the data required, the registration will continue until the data are evaluated and found to be acceptable to the Agency and in accordance with new projections regarding appropriate expiration dates.

If at any time, EPA determines that additional data are required to maintain an existing conditional registration, the Agency will require such data under Section 3(c)(2)(B) of FIFRA. If you do not comply with these conditions, this registration is subject to cancelation under FIFRA section 6(e). Your release of this product for shipment constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. If you need further assistance on this matter, please email Shanaz Bacchus at <u>bacchus.shanaz@epa.gov</u> or call her on 703-308-8097.

Sincerely,
W. Michael McL

W. Michael McDavit, Associate Director

Biopesticides and Pollution Prevention Division.

Enclosure: - stamped label

Cc: 70127-7

3015

[Front Panel. Reviewer Notes: This label will be printed as one continuous document and placed on the front of the container.]

### **TAE-001 TECHNICAL BIOINSECTICIDE**

### FOR MANUFACTURING PURPOSES ONLY

FOR THE MANUFACTURE OF BIOINSECTICIDE END USE PRODUCTS USED FOR THE CONTROL OF CERTAIN TICKS AND OTHER LABELED INSECT PESTS

	70 VV/VV
ACTIVE INGREDIENT – Metarhizium anisopliae Strain F52*	97.6%
OTHER INGREDIENTS	<u>2.4%</u>
Total	100.0%
* Contains 1.0 x 10 <sup>10</sup> Colony Forming Units (CFU)/gram.	

## **ACCEPTED**

# CAUTION

Under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, for the posticide registered under

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Causes moderate eye irritation. Harmful if inhaled, absorbed through skin, or swallowed. Avoid contact with skin, eyes, or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID		
IF IN EYES:	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.	
IF INHALED:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.	
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes. Call a poison control center or doctor for treatment advice.	
IF SWALLOWED:	Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.	

#### **HOT LINE NUMBER**

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

For emergency information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents) call the National Pesticide Information Center at 1-800-858-7378 6:30 a.m. – 4:30 p.m. Pacific Time (PT), seven days a week. During other times call the poison control center at 1-800-222-1222.

[Reviewer Notes: The mot for sale of	date is to serve as the batch code.			
	et Contents: Lbs.			
Not for Sale or Use after (insert date)				
Novozymes Biologicals, Inc.	EPA Establishment Number: 70127-VA-001			
5400 Corporate Circle	EPA Registration Number: 70127-7			
Salem, VA 24153 USA	Made in USA			

#### PERSONAL PROTECTIVE EQUIPMENT

Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Applicators and other handlers must wear: long-sleeved shirt and long pants, waterproof gloves, (neoprene gloves for EP with petroleum distillates) protective eyewear, shoes and socks and dust/mist filtering respirator with NIOSH prefix N-95, P-95 or R-95. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### **ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a 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.

#### PHYSICAL OR CHEMICAL HAZARDS

For spill, leak, fire, exposure, or accident call CHEMTREC at 1-800-424-9300, day or night.

### **DIRECTIONS FOR USE**

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

Only for formulation into products for the following use:

1-800-342-6173

- Bioinsecticide end-use products for urban and suburban greenhouse and outdoor terrestrial non-food uses for the control of certain ticks and other labeled insect pests. Do not use near endangered insect habitat.non-food greenhouse and residential outdoor terrestrial uses
- This product may be used to formulate products for any additional use(s) not listed on the TAE-001 Technical Bioinsecticide label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such uses(s).

File: 70127-00007.20090107b.Final Draft

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#### STORAGE AND DISPOSAL

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

#### **PESTICIDE STORAGE**

Store TAE-001 Technical Bioinsecticide in its original container in a cool, dry locked place out of reach of children and out of direct sunlight. Do not use or store near heat or open flame.

#### 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 HANDLING

Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. 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.

#### WARRANTY

The Directions for Use of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and must be followed carefully.

Novozymes Biologicals warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions under normal growing conditions is reasonably fit for the purposes referred to above. To the extent consistent with applicable law, buyers/users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above, customer's sole remedy for breach of warranty, to the extent consistent with applicable law, shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes Biologicals.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, EXCEPT AS PROVIDED ELSEWHERE IN WRITING CONTAINING AN EXPRESS REFERENCE TO THIS WARRANTY AND LIMITATION OF DAMAGES, SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.