

70127-7

12/15/2010

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

DEC 15 2010

Ms. Carrie Daniels (Agent for Novozymes Biologicals, Inc.)
Exponent
1150 Connecticut Ave., N.W.
Suite 1100
Washington D.C. 20036

Re: Novozymes Biologicals, Inc.
Metarhizium anisopliae Strain F52 Pesticide Products
EPA Registration Numbers 70127-7, 70127-8, 70127-9, 70127-10.
Confidential Statements of Formula (CSF) and Labels
Amendment Requests Dated June 23, 2010 and July 6, 2010

Dear Ms. Daniels:

The Agency has reviewed your above-referenced requests, on behalf of Novozymes Biologicals, Inc., for amendments of Confidential Statements of Formula (CSFs) and labels under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 3(c)(7). These requests that include manufacture of pesticides containing the active ingredient, *Metarhizium anisopliae* Strain F52, at both US (Salem VA) and Canadian Establishments (Saskatoon) with EPA Establishment numbers are granted as follows:

The Confidential Statements of Formula (CSFs) for each of the products as specified below are acceptable for the non-food sites listed on the attached labels:
CSF dated 06/23/10: TAE-001 Technical BioInsecticide (EPA Reg. No. 70127-7)
CSF dated 06/23/10: Taenure Granular Bioinsecticide (EPA Reg. No. 70127-8)
CSF dated 06/23/10: Tick-EX G (EPA Reg. No. 701279)
CSF dated 11/02/10: Tick EX™ EC (EPA Reg. No. 70127-10)

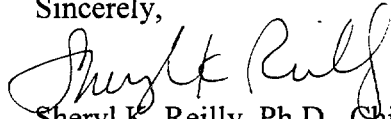
The enclosed stamped draft labels are approved for non-food use in urban and suburban residential areas until May 2, 2011, in accordance with the extensions granted August 08, 2010, with terms and conditions stated in the registration notices dated February 02, 2009.

You must submit final printed labels before releasing these products for shipment. 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 cancellation under FIFRA section 6(e). Your release of this product for shipment constitutes acceptance of these conditions.

The Agency is reviewing the requests and submissions from Novozymes Biologicals, Inc. for food use and for amending the conditional registrations for the referenced pesticide products to an unconditional status under FIFRA Section 3(c)(5).

If you have any questions regarding these pesticides, please email Shanaz Bacchus at bacchus.shanaz@epa.gov or call her at 703-308- 8097.

Sincerely,



Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch

Biopesticides and Pollution Prevention Division (7511P)

Enclosures: stamped draft labels

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[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**

| | |
|--|--------|
| | % w/w |
| ACTIVE INGREDIENT – <i>Metarhizium anisopliae</i> Strain F52* | 97.6% |
| OTHER INGREDIENTS | 2.4% |
| Total | 100.0% |

* Contains 1.0 x 10¹⁰ Colony Forming Units (CFU)/gram.

ACCEPTED

12/15/2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 70127-7

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

**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. | |

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[Reviewer Notes: The "not for sale" date is to serve as the batch code.]

Net Contents: ___ Lbs.
Not for Sale or Use after (insert date) _____

Produced for:
Novozymes Biologicals, Inc.

EPA Establishment Number: [070127-VA-001]
[085238-CAN-001]

5400 Corporate Circle
Salem, VA 24153 USA
1-800-342-6173

EPA Registration Number: 70127-7
Made in [USA] [Canada]

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:

- 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.
- 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).

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.