



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 25, 2019

Matthew Feinberg
Authorized Agent to Novozymes Biologicals, Inc.
Exponent, Inc.
1150 Connecticut Avenue NW, Suite 1100
Washington, D.C. 20036

Subject: Pesticide Registration Improvement Act (PRIA) Labeling and Formulation
Amendment – Add an Alternate Supplier for the Active Ingredient and an Alternate
Producer for the Product to the Basic Confidential Statement of Formula (CSF) and
Make Other Changes to the Basic CSF and Labeling Requested by the EPA (e.g.,
Update the Description of Uses in the Directions for Use)
Product Name: TAE-001 Technical Bioinsecticide
EPA Registration Number: 70127-7
Application Date: 05/16/2018
OPP Decision Number: 541423

Dear Mr. Feinberg:

The amended labeling and Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable.

The alternate brand name Met52 Technical has been added to the registration, and our records have been updated accordingly. This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following acceptable CSF:

- Basic CSF dated 02/12/2019

Any CSFs other than that listed above are superseded/no longer valid.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling

or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company’s website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to the EPA’s Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Alex Boukedes by phone at (703) 347-0305 or via email at boukedes.alexandra@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jeannine Kausch', with a stylized flourish at the end.

Jeannine Kausch, Product Manager 92
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

[Note to Reviewer: This label will be printed as one continuous document and placed on the front of the container. Text in square brackets is explanatory or optional.]

TAE-001 TECHNICAL BIOINSECTICIDE FOR MANUFACTURING PURPOSES ONLY

FOR THE MANUFACTURE OF END-USE PRODUCTS USED FOR THE CONTROL OF CERTAIN
TICK, MITE, AND OTHER LABELLED INSECT PESTS

ABN: Met52 Technical

ACTIVE INGREDIENT – <i>Metarhizium anisopliae</i> Strain F52*	% w/w 99.6%
OTHER INGREDIENTS	0.4%
TOTAL	100.0%

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

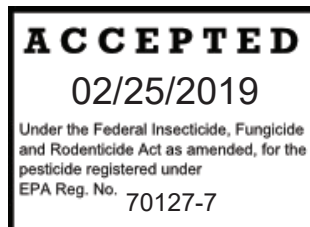
KEEP OUT OF REACH OF CHILDREN CAUTION

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 by mouth-to-mouth, if possible. Call a poison control center or doctor for 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 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.
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For non-emergency information concerning this product, call the National Pesticide Information Center (NPIC) at 1-800-858-7378, Monday through Friday, 8:00 AM to 12:00 PM Pacific Time (NPIC Web site: www.npic.orst.edu). For medical emergencies, call your poison control center at 1-800-222-1222.	

Net Weight: ____ Lbs.
Batch Code/Expiry Date: _____

Produced [for] [by]:
Novozymes Biologicals, Inc.
5400 Corporate Circle

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



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.

Individuals handling this product must wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any R or P filter; OR a NIOSH-approved powered air purifying respirator with an HE filter. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

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.

For formulating only into end-use products for the following uses:

- End-use products for food and non-food greenhouse and terrestrial, as well as residential outdoor, uses. For use in control of the following pests: thrips, whiteflies, mites, weevils, and ticks.
- End-use products for soil applications (including drenching), foliage and root dips, and foliar applications on the following crops:
- **Food crops** such as onion, celery, lettuce, spinach, pepper, tomato, grape, strawberry, cranberry, raspberry, and blackberry
- **Ornamental plants and grasses** such as shrubs, vines, trees, lawns, and bedding plants
- **Turf** such as institutional and residential lawns

This product may be used to formulate products for any additional use(s) not listed on this manufacturing-use product label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(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 below 73°F (23°C) in a dry, locked place out of the reach of children and out of direct sunlight. Do not use or store near heat or open flame. Use product within one year and by the expiry date noted on this label.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into formulating 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. If burned, stay out of smoke.

WARRANTY

Novozymes Biologicals, Inc. warrants that, at the time of the first sale, this product conforms to the compositional description on this label and, when used according to the label directions, 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, Inc.

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 GUARANTEE, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.