

70127-6

01-22-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

EPA Reg.
Number:

70127-6

Date of Issuance:

JAN 22 2010

Term of
Issuance:

Unconditional

Name of Pesticide Product:

Taegro Technical

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Novozymes Biologicals, Incorporated
5400 Corporate Circle
Salem, VA 24153

Note: Changes in labeling 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 under the Federal Insecticide, Fungicide, and Rodenticide Act.

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 her 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.

This registration does not eliminate the need for continual reassessment of the pesticide. If the EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.

This product is registered in accordance with FIFRA section 3(c)(5) and is subject to the following terms and conditions:

1. Submit a five-batch analysis from batches produced at the new manufacturing facility in Salem, Virginia by February 15, 2011 (in accordance with OPPTS Harmonized Guideline 885.1400).
2. Submit two (2) copies of the final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for further description of a final printed label.

A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

W. Michael McDavit, Associate Director
Biopesticides and Pollution Prevention Division

Date:

JAN 22 2010

EPA Form 8570-6

CONCURRENCES

SYMBOL	7511P	7511P					
SURNAME	KAUSCH	only					
DATE	01/22/2010	1/22/10					

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

Mr. Thomas Schreier
Regulatory Affairs Manager
Novozymes Biologicals, Incorporated
5400 Corporate Circle
Salem, VA 24153

JAN 22 2010

Re: Novozymes Biologicals, Incorporated; Taegro Technical
EPA Registration No. 70127-6
Registration Notice Correction Request / Minor Label ("Fast Track") Amendment
Submissions dated 01/29/2008 and 08/03/2009
Decisions #389764 and #418264

Dear Mr. Schreier:

The Agency has reviewed your request to amend the subject product registration, which included the following changes to the product label:

- 1) Correction of minor formatting and typographical errors.
- 2) Conversion of the product brand name from "TAE Technical" to "Taegro Technical."
- 3) Removal of the Spanish signal word ("AVISO") and Spanish statement ("Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle."), along with its associated English translation ("If you do not understand the label, find someone to explain it to you in detail."), as this product is not subject to the Worker Protection Standard.
- 4) Addition of a referral statement should the Precautionary Statements occur on the container in a location other than the front panel.
- 5) Adjustment of "Net Contents:" to "Net Weight:" given that the product is a dry formulation.
- 6) Modification of the EPA Establishment Number from "70127-VA-006" to "70127-VA-010."
- 7) Modification of the First Aid and Hazards to Humans and Domestic Animals statements so that they coincide with the toxicity categories obtained from the supporting data.
- 8) Addition of manufacturing-use product specific statements to the Directions for Use.
- 9) Revision of the Storage and Disposal statements, in accordance with Pesticide Registration (PR) Notices 2007-4 and 83-3, to match the product's specified container type.

CONCURRENCES								
SYMBOL	7511P	7511P						
SURNAME	Kausch	Only						
DATE	01/22/2010	1/22/10						

Mr. Thomas Schreier
EPA Registration Number 70127-6

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In addition to the label amendment, you also requested a revised registration notice (J. Messina to S. Reilly; letter dated January 29, 2008) due to a mistake made on the Agency's part, which resulted in the incorrect application of particular conditions to this product in the notice of pesticide registration dated February 12, 2007. This processing error has been acknowledged and, accordingly, the Agency has corrected and is reissuing the registration notice for Taegro Technical.

The changes referred to on the previous page, submitted in connection with registration under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable provided that you:

- 1) Submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of a final printed label.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of this condition. If you have any questions, contact Jeannine Kausch at 703-347-8920 or by email at kausch.jeannine@epa.gov.

The corrected registration notice and a stamped copy of the label are enclosed for your records.

Sincerely,



Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures (3):
- Unconditional Registration Notice
- A-79 Enclosure
- Acceptable Label

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TAEGRO Technical

For manufacturing purposes only

	% w/w
ACTIVE INGREDIENT: <i>Bacillus subtilis</i> var. <i>amyloliquefaciens</i> Strain FZB24*	73.3%
OTHER INGREDIENTS	26.7%
Total	100.0%

*Contains 5.0×10^{11} Colony Forming Units [(CFU)]/gram.

KEEP OUT OF REACH OF CHILDREN

WARNING

[See additional precautionary statements on the [side/back] panel]

[This statement will be inserted if the label is printed on more than one sheet]

Net weight: _____ [Actual value to be inserted, generally from 100 to 500 lb.]

Novozymes Biologicals, Inc.
5400 Corporate Circle, Salem, VA 24153
1-800-342-6173
www.novozymes.com

Made in U.S.A.
EPA Reg. No. 70127-6
EPA Est. No. 70127-VA-010

ACCEPTED

JAN 22 2010

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 70127-6

Not for sale or use after: [Date to be inserted]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING - Causes substantial but temporary eye injury. Causes skin irritation. Do not get in eyes, on skin, or on clothing. Wear coveralls worn over short-sleeved shirt and short pants, socks, chemical-resistant footwear, chemical-resistant gloves, protective eyewear, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95 when handling this product. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Harmful if absorbed through skin, inhaled, or swallowed. 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:	<ul style="list-style-type: none">• 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 ON SKIN OR CLOTHING:	<ul style="list-style-type: none">• 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 INHALED:	<ul style="list-style-type: none">• 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 SWALLOWED:	<ul style="list-style-type: none">• 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 the 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. You may also contact 1-800-222-1222 for emergency medical treatment information.	

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.

DIRECTIONS FOR USE

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

For formulation into fungicide products intended for use in/on crops and ornamental plants. 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.

WARRANTY: 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 is reasonably fit for the purposes referred to above. 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 and to the extent consistent with applicable law, customer's sole remedy for breach of warranty shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes Biologicals. SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

TAEGRO consists of living microbes. Do not freeze or expose to temperatures above 80° F. Close opened containers tightly. Store in a cool, dry place and use within one year.

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 container.

Completely empty bag into formulation equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

[Note to reviewer: The "Not for sale or use after (date)" is to serve as the batch code.]

[Note to reviewer: This product is sold in large plastic bags contained in cardboard frames.]