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

> OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

DEC 1 5 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: CSFdated 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 EXTM 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 cancelation 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

[Front Panel]

10127-8

TAENURE GRANULAR BIOINSECTICIDE [ABN: Met52[™] GRANULAR BIOINSECTICIDE]

ACTIVE INGREDIENT – Metarhizium anisopliae Strain F52*	% w/w 2.0%
OTHER INGREDIENTS	<u>98.0%</u>
Total	100.0%

* Contains 9.0 x 10⁸ Colony Forming Units (CFU)/gram.

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.			

ACCEPTED 115, 121

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. -70/27-8

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

Not for Sale or Use after (insert date) _________ Net Contents: [3 Lbs.][5 Lbs.][25 Lbs.][bag]

Produced for: Novozymes Biologicals Inc. 5400 Corporate Circle Salem, VA 24153, USA 1-800-342-6173 EPA Establishment Number: [070127-VA-001] [085238-CAN-001] EPA Registration Number: 70127-8 Made in [USA] [Canada]

PERSONAL PROTECTIVE EQUIPMENT

Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Mixer/loaders, applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes and socks
- Protective eyewear
- Dust-mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N-95, R-95, P-95 or HE filter. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

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.

USER SAFETY RECOMMENDATIONS

- □ Users should remove clothing immediately if pesticide gets inside, then wash thoroughly and put on clean clothing.
- □ Remove personal protection equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

For terrestrial uses, Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. This product is approved for residential (urban and suburban) outdoor terrestrial non-food uses. Do not use near endangered insect habitat. Do not contaminate water when disposing of equipment washwater or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

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

DIRECTIONS FOR USE READ THE LABEL BEFORE USING

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

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the state or tribal agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

For uses that are <u>soil incorporated mechanically</u>, there is a <u>0 hour</u> Restricted Entry Interval (REI) - the Worker Protection Standard allows workers to enter the treated area if there will be no contact with anything that has been treated. For <u>all other uses</u>, do not enter or allow worker entry into treated areas during the REI of <u>four hours</u>.

PPE required for early entry to treated areas requiring a REI that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water are:

- Coveralls
- Waterproof gloves
- Shoes plus socks
- Protective eyewear
- Dust-mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N-95, R-95, P-95 or HE filter.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treated areas until sprays have dried.

GENERAL

Taenure Granular Bioinsecticide is composed of spores of the insect pathogenic fungus *Metarhizium anisopliae* Strain F52 on a grain matrix. Once the product is incorporated into the growing medium, insects that come into contact with the fungus will become infected. The spores of *Metarhizium anisopliae* attach to the surface of the insect, germinate and begin to grow. It will penetrate the exoskeleton of the insect and grow very rapidly inside the insect, causing the insect to die. It usually takes 3 to 5 days, once the insect is exposed for death to occur. As insects are infected, other insects that come into contact with them may also become infected. Depending on cultural practices, it is not uncommon for control to last up to nine months.

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APPLICATION INSTRUCTIONS

Apply Taenure Granular Bioinsecticide prior to or during planting by thoroughly mixing the product into the growing medium, ensuring even distribution. Agitate the product during application to shake some fungal growth free from grains and into the surrounding growing medium. Apply at a rate of 1.5 to 3.0 lbs. of product per cubic yard of growing medium (or 25 to 50 grams per cubic foot of growing medium). Use higher label rates when larval pressure is expected to be high.

This product is not for use on agricultural crops which bear fruit or can be used as a food or feed commodity.

Do not mix fungicides in growth medium containing Taenure Granular Bioinsecticide. Keep the plants above 60°F and maintain good drainage. Taenure Granular Bioinsecticide is grown on cereal grains that will decompose in the growing media. Pests likely to be attracted by grains, such as rodents, must be controlled prior to use of this product.

INSECTS CONTROLLED

Root weevils

Thrip pupae

Ticks

SITES FOR USE

This product is approved for greenhouse and residential (urban and suburban) outdoor terrestrial non-food uses. Do not use near endangered insect habitat.

ORNAMENTALS

Do not use treated plants for food or animal feed.

Do not use treated plan	is for food or animal feed		
Abutilon	Buddleia	Crocus	Ficus
Achillea	Bulbs	Crossandra	Fittonia
Actinopteris	Buttercup	Croton	Foliage Plants
African Violet	Butterfly Bush	Crown of Thorns	Foxglove
Ageratum	Cactus	Cultivated Greens	Freesia
Aglaonema	Caladium	Cut Florist Greens	Fuchsia
Ajuga	Calathea	Cut Flowers	Gaillardia
Allamanda	Calceolaria	Cuttings	Gardenia
Allium (ornamental)	Calendula	Cyclamen	Gaultherium
Alocasia	Calla Lily	Daffodils	Gazania
Alyssum	Calliandra	Dahlia	Geranium
Amaryllis	Calluna	Daisy	Gerbera
Anemone	Campanula	Daylily	Geum
Annuals, Ornamental	Candy-Tuft	Delphinium	Gladiolus
Anthurium	Carnation	Dianthus	Gloxinia
Aphelandra	Celosia	Dieffenbachia	Grape (non-bearing)
Aralia	Centaurea	Dizygotheca	Grass, Ornamental
Artemisia	Cerastium	Dracena	Ground Covers
Aster	Chinese Evergreen	Dusty Miller	Gynura
Azalea	Chrysanthemum	Easter Lily	Gypsophila
Baby's Breath	Cineraria	Echeveria	Hedera
Bachelors Button	Cissus	Episcia	Hibiscus (ornamental)
Bedding Plants	Clematis	Erica	Hollyhock
Beefsteak Plant	Cockscomb	Euonymus	Honeysuckle
Begonia	Coleus	Euphorbia	Hosta (Plantain Lily)
Bird of Paradise	Columbine	Exacum	Hoya (Wax Plant)
Bleeding Heart	Coral Bells	False Dragonhead	Hyacinth
Bougainvillea	Coreopsis	Fatsia	Hydrangea
Bromeliad	Cosmos	Ferns	Ice Plant

Impatiens Iris Ivy, Algerian Ivy, English Jasmine (ornamental) Jessamine Kalanchoe Lantana Liatris Lilv Lily of the Nile Liriope Lobelia Loosestrile Lupine Manvilla Maple, Flowering Marigold Monarda Mondo Grass Morea, Yellow **Mvrtle** Narcissus Nasturtium

Nigella Nursery Crops (nonbearing) Ophiopogon Orchid Ornithogalum Osmanthus Oxalis Pachysandra Pansv Pelargonium Peonv Peperomia Perwinkle Petunia Philodendron Phlox Photinia Pilea Pinks Pittosporum Podocarpus Poinsettia Poppy

Portulaca Potentilla Pothos **Potted Flowering Plants Prayer** Plant Primrose Pyracantha Ranunculus Rhododendron Rose **Rubber Plant** Rudbeckia Saintpaulia Salvia Sansevieria Saxifraga Schefflera Scilla Sedum Seed Beds Seedling Plants Sempervivum Senecio Shrubs

Sinningia Snapdragon Spathiphyllum Stachvs Statice Stock Stokesia Strawflower Sweet Pea Sweet William Syngonium Tulip Verbena Veronica Vinca Violet Virginia Creeper Wall Flower Wandering Jew Wisteria Yarrow Yucca Zinnia

SHRUBS

Do not use treated plants for food or animal feed.

Abelia Andromeda Arborvitae Aucuba Azalea Bamboo Barberry Beauty Bush Bedding Plants Blueberry, Ornamental Bog Rosemary Bottlebrush Boxwood Bridal Wreath Broom Buckthorn Camelllia Caranaga Carob	Cordyline Crape Myrtle Cotoneaster Cuttings Daphne Deutzia Elderberry Escallonia Eugenia Euonymus Fig (non-bearing) Firethorn Forsythia Fuchsia Guava (non-bearing) Hawthorn Heath Heather	Hydrangea Indian Hawthorn Juniper Laurel Leucothoe Ligustrum Lilac Lippia Manzanita Mock Orange Nandina Nursery Crops (non- bearing) Oleander Oregon Grape (non- bearing) Osmanthus Pachistima	Podocarpus Poinciana Privet Pyracantha Quince, (<i>non-bearing</i> Ornamental) Rhamnus Rhododendron Rockrose Rose Santolina Snowberry Spicebrush Spirae Viburnum Wax Myrtle Weigla Yew
Buckthorn	Hawthorn	bearing)	Wax Myrtle
Caranaga Carob Carex Ceanothus Cleyera		Pachistima Pachysandra Photinia Pittosporum	Ŷ.

SHADE AND FOREST TREE SEEDLINGS

This product is approved for residential (urban and suburban) outdoor uses on seedlings. Do not use near endangered insect habitat.

Acacia	Beech	Cedar	Conifers
Alder	Birch	Chamaecyparis	Cottonwood
Ash	Bougainvillea	Cherry, Wild (non-	Crabapple
Aspen	Buckeye	bearing)	Cuttings
Basswood	Butternut	Chestnut (non-bearing	Cypress
Bedding Plants	Catalpa	ornamental)	Dogwood

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Douglas Fir Elder Elm Fir Forest Seedlings Forest Trees Gingko Gum Hackberry Hawthorn Hemlock Hickory Holly Hornbeam Horse Chestnut Ironwood Juneberry Juniper Larch Linden Locust Magnolia Maple Mimosa Mulberry Myrtle Nursery Crops Oak Palm PawPaw (*non-bearing ornamental*) Pine Poplar Privet Quince (*non-bearing ornamental*)

Redbud Redwood Sassafras Sourwood Spruce Sumac Sycamore Tamarack Tulip Tree Willow Yellowwood

Applicators other than homeowners:

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store Taenure Granular 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.

Homeowners:

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store Taenure Granular 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 AND CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill container.

If empty:

Place container in trash or offer for recycling, if available.

If partly filled:

Call your local solid waste agency or 1-800-CLEANUP for disposal intructions. Never place unused product down any indoor or outdoor drain.

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.