

70127-3

9/6/2013

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

SEP 6 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Carrie Daniels, Agent for Novozymes Biologicals, Inc.
Exponent
1150 Connecticut Avenue, N.W.
Suite 1100
Washington DC 20036

EPA Registration No: 70127-2 ,and 70127-3
Product Names: Novozymes Biofungicide Green-Release, and Novozymes Biofungicide 145F
Decision Nos: D478531 and D478529
Subject: Application for Notifications Request Dated May 3, 2013 for Revision to Storage and Disposal
Label Statements on the Labels

Dear Ms. Daniels:

The Biopesticides and Pollution Prevention Division is in receipt of your applications for Notification under Pesticides Registration Notice (PRN) 2007-4 dated above. A preliminary screen of these requests has been conducted for its applicability under PRN 2007-4 and it has been determined that the action(s) requested falls within the scope of PRN 2007-4. Our records have been duly noted, and the letters and labels submitted with these applications have been stamped "Notification, received and accepted" and will be placed accordingly in our records.

Questions concerning this action should be directed to Susanne Cerrelli (703) 308-8077 or email at cerrelli.susanne@epa.gov.

Sincerely,

Kimberly Nesci, Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)

CONCURRENCES

SYMBOL	7511P	7511P					
SURNAME	S Cerrelli	Nesci					
DATE	9/6/13	9/6/13					

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- Registration
- Amendment
- Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70127-3	2. EPA Product Manager Kimberly Nesci	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Novozymes Biologicals, Inc./EcoGuard-GN	PM# BPPD	
5. Name and Address of Applicant (Include ZIP Code) Novozymes Biologicals, Inc. 5400 Corporate Circle, Salem, Virginia 24153 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156.

Section III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag
*Certification must be submitted		If "Yes" Unit Packaging wgt. No. per Container	If "Yes" Package wgt. No. per Container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 1 gal., 2.5 gal.	5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other Crack and peel <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Carrie Daniels	Title Authorized Representative	Telephone No. (Include Area Code) 202-772-4916

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature BY: <i>Carrie Daniels</i>	3. Title Senior Managing Regulatory Consultant, Exponent, Inc., Representative for Novozymes Biologicals, Inc.	6. Date Application Received (stamp) SEP 26 2013 <i>Send</i>
4. Typed Name: Carrie Daniels	5. Date: May 3, 2013	

Notification Accepted
Date: SEP 26 2013
Reviewer: *Send*

Kimberly Nesci
May 3, 2013
Page 2

Please note that the information in this letter is considered **Confidential Business Information** and must not be disclosed to any party outside of EPA. Should you have any questions regarding this notification, please contact me via telephone at 202-772-4916 or via email at cdaniels@exponent.com.

Sincerely,



Carrie Daniels
Authorized Representative of
Novozymes Biologicals, Inc.

Enclosures

cc: Dean Thome, Novozymes
Matthew Feinberg, Exponent

cc: Dean Thome, Novozymes
Matthew Feinberg, Exponent

Master Label

Notification Accepted

Novozymes Biofungicide 145F
[ABN: EcoGuard-GN]

Date: SEP - 6 2013
Reviewer: Scirelli

For Use on Ornamental Plants
Ornamental Plant Liquid Concentrate Fungicide

ACTIVE INGREDIENTS:

Bacillus licheniformis SB3086* 1.26% (w/w)
Indole-3-butyric Acid 0.002755% (w/w)

OTHER INGREDIENTS: 98.737245% (w/w)

TOTAL:.....100.00%

* Contains 9.0 x 10⁹ Colony Forming Units (CFU)/ml

EPA Registration No.: 70127-3
EPA Establishment No.: 70127-VA-001

Net Contents:
Batch Code:

[See side panel for additional Precautionary Statements.]

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

**PRECAUTIONARY STATEMENTS: Hazards To Humans and Domestic Animals
- CAUTION:**

Personal Protective Equipment (PPE):

Applicators and other handlers must wear:

- Long-sleeved shirt and long-pants
- Shoes plus socks
- For handling activities use a non-powered air purifying NIOSH approved respirator with any N, P, R, or HE filter.

Follow the 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:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Environmental Hazards: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of residual product or equipment washwaters. Do not use this product on plants intended for food or feed. Do not feed treated plants to livestock or domestic animals.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product when weather conditions, cultural practices, extreme moisture conditions or other environmental conditions are outside of the ranges that are generally recognized as being conducive to good growing practices. Do not apply with solutions containing strong acids, bases, oxidizing agents, or solvents.

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 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), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: coveralls and shoes plus socks and protective eyewear.

Product Description:

The Novozymes Biofungicide 145F is a concentrated suspension of the bacterial spores of the organism *Bacillus licheniformis* SB3086 (U.S. Patent No. 6,569,425), which has been found effective as an inhibitor of a variety of agronomically important fungal disease species

Product Use Sites:

The Novozymes Biofungicide 145F formulation is applied as a foliar spray or soil drench on ornamental plants at the following sites: greenhouses, nurseries, and ornamental gardens. Novozymes Biofungicide 145F is a preventative or curative treatment for the fungal diseases *Rhizoctonia solani* and *Phytophthora drechsleri*.

Ornamental Plants including Greenhouse Applications, and Nursery and Ornamental Garden Uses:

Apply as a drench or directed spray using hand held, mechanical or motorized spray equipment after seeding or sticking of cuttings or after transplanting to beds, containers, pots, or trays. Thoroughly soak the growing media. Apply every 7-14 days for adequate crop protection. Rotate with other approved fungicides if disease conditions last for several months.

Disease	Crops	Ounces / 100 gallons
<i>Rhizoctonia solani</i>	Vinca, Zinnia, Geranium, Impatiens	64
<i>Phytophthora drechsleri</i>	Poinsettia, marigold, petunia, impatiens	64

INCLUSION IN PEST MANAGEMENT PROGRAM:

Novozymes Biofungicide 145F also works well as part of an Integrated Pest Management (IPM) program, especially to help reduce the occurrence of disease resistance to other fungicide products. In addition, during times of high disease pressure, such combinations may provide optimal pest management while reducing overall yearly pesticide application amounts. Such an integrated program may be achieved by regular rotation of the treatments using Novozymes Biofungicide 145F with treatments of other fungicides. Another approach is to apply Novozymes Biofungicide 145F until the onset of high disease pressure, then to substitute another fungicide (at standard application rates) for a brief period (1-4 treatments) followed by a return to standard applications of Novozymes Biofungicide 145F.

TANK MIXING:

Due to the nature of this microbial product (contains live spores), tank mixing of Novozymes Biofungicide 145F with solutions containing strong acids, bases, oxidizing agents, or solvents should be avoided.

IRRIGATION APPLICATION:

Novozymes Biofungicide 145F is a liquid concentrate that can be used through various irrigation systems such as drip (trickle), flood (basin) or sprinkler systems. Novozymes Biofungicide 145F can be used on annual and perennial flowers, bedding and foliage plants, ground cover crops and trees and shrubs for indoor and outdoor landscaping.

Novozymes Biofungicide 145F is compatible with fertilizers and pesticides. It is recommended that a jar test should be done if there is any question about compatibility. If a soil sterilant or strong oxidizer is used, Novozymes Biofungicide 145F should be applied after the recommended time for replanting.

Injector Ratio	1:100	1:200
Novozymes Biofungicide 145F / Gallon	64 oz	Direct Siphon

Direct Siphon:

When using Novozymes Biofungicide 145F with a high ratio (1:200), a siphon can be drawn directly out of the original container without dilution.

Soil Drench Application:

Novozymes Biofungicide 145F can be used on annual and perennial flowers, foliage crops, and ground cover crops as a drench or directed spray by various mechanical or automated equipment. For drench or directed spray Novozymes Biofungicide 145F may be applied using hand held, mechanical or motorized spray equipment. Direct spray applications may also use sprinkler irrigation systems. Novozymes Biofungicide 145F applications should begin before or shortly after initial seeding, planting of cutting, or after transplanting to propagation beds, containers, pots or trays. Drench the planting media thoroughly. Apply every 7-28 days through the growing season or the part of the season where the plant is most susceptible to disease pressure.

Novozymes Biofungicide 145F Direct Drench		
Crop	Novozymes Biofungicide 145F concentration	Application interval
Annual flowers	64 fluid ounces / 100 gallons water	7 - 14 days
Perennial flowers	OR	14-28 days
Foliage	0.5 ounces / Gallon water	14-28 days
Ground cover		14-28 days

Apply this product only through sprinkler including solid set, or hand move; flood (basin); furrow; border or drip (trickle) irrigation system(s). Do not apply this product through any other type of irrigation system.

Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from non-uniform distribution of treated water.

If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Chemigation Systems Connected to Public Water Systems:

1. Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

2. Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, back flow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the flow outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

3. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.

4. The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

5. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.

6. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

7. Do not apply when wind speed favors drift beyond the area intended for treatment.

Light agitation is recommended in the pesticide supply tank directly after adding Novozymes Biofungicide 145F to the tank. If using direct siphon method, the container should be shaken well before beginning the siphon.

Novozymes Biofungicide 145F is to be applied continuously for the duration of the water application. Always shake Novozymes Biofungicide 145F container well before metering out to the pesticide supply tank.

Sprinkler Chemigation:

1. The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from back flow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.
3. The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Do not apply when wind speed favors drift beyond the area intended for treatment.

Light agitation is recommended in the pesticide supply tank directly after adding Novozymes Biofungicide 145F to the tank. If using direct siphon method, the container should be shaken well before beginning the siphon.

Novozymes Biofungicide 145F is to be applied continuously for the duration of the water application. Always shake Novozymes Biofungicide 145F container well before metering out to the pesticide supply tank.

Floor (Basin), Furrow and Border Chemigation:

1. Systems using a gravity flow pesticide dispensing system must meter the pesticide into the water at the head of the field and downstream of a hydraulic discontinuity such as a drop structure or weir box to decrease potential for water source contamination from back flow if water flow stops.

2. Systems utilizing a pressurized water and pesticide injection system must meet the following requirements:

- a. The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from back flow.
- b. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- c. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- d. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- e. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
- f. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Light agitation is recommended in the pesticide supply tank directly after adding Novozymes Biofungicide 145F to the tank. If using direct siphon method, the container should be shaken well before beginning the siphon.

Novozymes Biofungicide 145F is to be applied continuously for the duration of the water application. Always shake Novozymes Biofungicide 145F container well before metering out to the pesticide supply tank.

Drip (Trickle) Chemigation:

- 1. The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from back flow.
- 2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- 3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

4. The system must contain functional inter-locking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Light agitation is recommended in the pesticide supply tank directly after adding Novozymes Biofungicide 145F to the tank. If using direct siphon method, the container should be shaken well before beginning the siphon.

Novozymes Biofungicide 145F is to be applied continuously for the duration of the water application. Always shake Novozymes Biofungicide 145F container well before metering out to the pesticide supply tank.

STORAGE AND DISPOSAL:

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

Pesticide Storage:

Novozymes Biofungicide 145F is a stable suspension of microbial spores. For best results, store within the recommended storage temperature range of 40° F to 95° F (4° C to 35° C). Avoid longer-term storage at warmer temperatures or in direct sunlight. This product can also be stored at lower temperatures (<40° F) for up to 2 weeks as freezing will not affect its usefulness. Store product in original container in a secure location.

Pesticide Disposal:

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

Container Disposal:

Nonrefillable container. Do not reuse or refill this container.

Triple-rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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.

Prompt Notice of Claim:

To the extent consistent with applicable law, Novozymes Biologicals must have prompt notice as soon as Buyer or User has reason to believe they may have a claim (not to exceed twenty-one days from date of application) so that an inspection of the affected property and growing crops may be made. To the extent consistent with applicable law, unless Buyer and User(s) shall promptly notify Novozymes Biologicals of any claims, the manufacturer does not intend to pay any damages.

[See side panel for Storage & Disposal directions.]

[For information on product use, availability or MSDS requests, please contact]

Manufactured By:

Novozymes Biologicals, Inc.
5400 Corporate Circle, Salem, VA 24153
1-888-744-5662

U.S. Patent No. 6,569,425