70127-3 4/10/2007 1/12

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

April
~~March~~ 10, 2007

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Carrie Daniels
Representative of Novozymes
Biologicals, Inc.
1730 Rhode Island Ave. NW - Suite 100
Washington, DC 20036

Subject: Notification of Alternate Brand Name
EPA#70127-3
Letter dated February 28, 2007

Dear Ms. Daniels

The Biopesticides and Pollution Prevention Division is in receipt of the above dated application. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action requested falls within the scope of PR 98-10. Our records have been duly noted, and the label submitted with this application has been stamped Notification received, but not reviewed and will be placed accordingly in our records.

Questions concerning this action should be directed to me at 703-308-8269 or email at reilly.sheryl@epa.gov.

Sincerely,

Sheryl K. Reilly

Sheryl K. Reilly, PhD, Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division

CONCURRENCES								
SYMBOL ▶	7511P							
SURNAME ▶	Pollard							
DATE ▶	4/10/07							

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* **OFFICIAL FILE COPY**

☆ U.S. Government Printing Office: 2005 206-899 (mac)

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Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
70127-3	Susanne Cerrelli	[ ] None [ ] Restricted
4. Company/Product (Name) Novozymes Biologicals, Inc./ Novozymes Biofungicide 145F	PM#	

5. Name and Address of Applicant *(Include ZIP Code)*

Novozymes Biologicals, Inc.
5400 Corporate Circle
Salem, Virginia 24153

[ ] *Check if this is a new address*

6. **Expedited Reveiw.** 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

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

NOTIFICATION
Received But Not Reviewed
Date: 4/10/07
Initial: CP

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification for alternate brand name Roots EcoGuard-GN Biofungicide

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *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	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ]

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Carrie Daniels	Managing Regulatory Consultant	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 knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	5. Date
Carrie Daniels	Authorized Representative	2/28/07
4. Typed Name: Carrie Daniels		

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Exponent

Exponent
1730 Rhode Island Ave., NW
Suite 1100
Washington, DC 20036

telephone 202-772-4900
facsimile 202-772-4979
www.exponent.com

February 28, 2007

Susanne Cerrelli
Biopesticides and Pollution Prevention Division (7504C)
Office of Pesticide Programs
Document Processing Desk (NOTIF)
One Potomac Yard, Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

RE: Submission of Alternate Brand Name Notification Per PR Notice 98-10
Novozymes Biofungicide 145F, EPA Registration No. 70127-3

Dear Ms. Cerrelli:

On behalf of Novozymes Biologicals, Inc. (5400 Corporate Circle, Salem, Virginia 24153), Exponent is submitting a notification to add the alternate brand name Roots EcoGuard-GN BioFungicide per PR Notice 98-10 to Novozymes Biofungicide 145F (EPA Registration #70127-3). The following items are enclosed in support of this notification:

- Application for Pesticide Amendment, EPA 8570-1 Form; and
- Label reflecting the alternate brand name.

We have not submitted a new confidential statement(s) of formula for the alternate brand name product Roots EcoGuard-GN BioFungicide, because no changes have been made to the confidential statement(s) of formula on file with EPA.

This notification is consistent with provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If you have any questions, please contact me at (202) 772-4916.

Sincerely,

Carrie Daniels
Exponent
Authorized Representative of
Novozymes Biologicals, Inc.

Enclosures

cc: James Messina, Exponent
Anne Turnbough & Shawn Semones, Novozymes

NOTIFICATION
Received But Not Reviewed
Date: 4/10/07
Initial: CP

4/12

Master Label

Roots EcoGuard-GN BioFungicide

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 10^9 Colony Forming Units (CFU)/ml
** A non-fungicidal plant growth regulating ingredient shown to improve the overall growth and health of ornamental plants.

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

[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 Roots EcoGuard-GN BioFungicide 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 Roots EcoGuard-GN BioFungicide formulation is applied as a foliar spray or soil drench on ornamental plants at the following sites: greenhouses, nurseries, and ornamental gardens. Roots EcoGuard-GN BioFungicide 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
Rhizoctonia solani	Vinca, Zinnia, Geranium, Impatiens	64
Phytophthora drechsleri	Poinsettia, marigold, petunia, impatiens	64

INCLUSION IN PEST MANAGEMENT PROGRAM:

Roots EcoGuard-GN BioFungicide 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 Roots EcoGuard-GN BioFungicide with treatments of other fungicides. Another approach is to apply Roots EcoGuard-GN BioFungicide 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 Roots EcoGuard-GN BioFungicide.

TANK MIXING:

Due to the nature of this microbial product (contains live spores), tank mixing of Roots EcoGuard-GN BioFungicide with solutions containing strong acids, bases, oxidizing agents, or solvents should be avoided.

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IRRIGATION APPLICATION:

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

Roots EcoGuard-GN BioFungicide 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, Roots EcoGuard-GN BioFungicide should be applied after the recommended time for replanting.

Injector Ratio	**1:100**	**1:200**
Roots EcoGuard-GN BioFungicide / Gallon	64 oz	Direct Siphon

Direct Siphon:

When using Roots EcoGuard-GN BioFungicide with a high ratio (1:200), a siphon can be drawn directly out of the original container without dilution.

Soil Drench Application:

Roots EcoGuard-GN BioFungicide 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 Roots EcoGuard-GN BioFungicide may be applied using hand held, mechanical or motorized spray equipment. Direct spray applications may also use sprinkler irrigation systems. Roots EcoGuard-GN BioFungicide 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.

Roots EcoGuard-GN BioFungicide **Direct Drench**		
Crop	Roots EcoGuard-GN BioFungicide **concentration**	**Application interval**
Annual flowers	64 fluid ounces / 100 gallons water OR 0.5 ounces / Gallon water	7 – 14 days
Perennial flowers		14-28 days
Foliage		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 Roots EcoGuard-GN BioFungicide to the tank. If using direct siphon method, the container should be shaken well before beginning the siphon.

Roots EcoGuard-GN BioFungicide is to be applied continuously for the duration of the water application. Always shake Roots EcoGuard-GN BioFungicide 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 Roots EcoGuard-GN BioFungicide to the tank. If using direct siphon method, the container should be shaken well before beginning the siphon.

Roots EcoGuard-GN BioFungicide is to be applied continuously for the duration of the water application. Always shake Roots EcoGuard-GN BioFungicide 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 Roots EcoGuard-GN BioFungicide to the tank. If using direct siphon method, the container should be shaken well before beginning the siphon.

Roots EcoGuard-GN BioFungicide is to be applied continuously for the duration of the water application. Always shake Roots EcoGuard-GN BioFungicide 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 Roots EcoGuard-GN BioFungicide to the tank. If using direct siphon method, the container should be shaken well before beginning the siphon.

Roots EcoGuard-GN BioFungicide is to be applied continuously for the duration of the water application. Always shake Roots EcoGuard-GN BioFungicide 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:
Roots EcoGuard-GN BioFungicide 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 may be disposed of on site or at an approved waste disposal facility.

Container Disposal:
Triple-rinse (or equivalent) then offer for recycling or reconditioning, 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 should 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. 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.

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. 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.
ROOTS® Plant Care Group
www.novozymes.com/roots
5400 Corporate Circle, Salem, VA 24153
1-800-342-6173

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