



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

September 12, 2008

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Jeanette A. Covert
Authorized Representative for
Northwest Agricultural Products
Product & Regulatory Associates, L.L.C.
P.O. Box 1683
Voorhees, NJ 08043-9998

Subject: Product Name: Bloomtime Biological FD Biopesticide
EPA Reg. No: 71975-1
Your Application for Label Notification Dated August 21, 2008, Update
Container Disposal Language per PR Notice 2007-4

Dear Ms. Covert:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification, received and reviewed" and will be placed accordingly in our records.

Questions concerning this action should be directed to Ms. Diana Hudson at (703) 308-8713 or email at hudson.diana@epa.gov.

Sincerely,

Linda Hollis

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Northwest Agricultural Products / 71975-1	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Bloomtime Biological FD Biopesticide	PM# 92 B PPD	
5. Name and Address of Applicant (Include ZIP Code) Northwest Agricultural Products c/o Product & Regulatory Associates P.O. Box 1683 Voorhees, NJ 08043-9998 <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 _____	NOTIFICATION Date Reviewed: 9-12-08 Reviewed By: D. Hudson
<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 for PR-Notice 2007-4 as described in the cover letter. This notification is consistent with the provisions of PR Notice 2007-4 and EPA regulations at 40 CFR 156.10, 156.140, 156.44, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for 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 2007-4 and 156.10, 156.140, 156.44, 156.146, and 156.156, 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.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> 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 <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Jeanette A. Covert		Title Authorized Representative	
		Telephone No. (Include Area Code) 856.751.3432	
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 		3. Title Authorized Representative for Northwest Agricultural Products	
4. Typed Name Jeanette A. Covert		5. Date 8/21/08	
6. Date Application Received (Stamped)			

30f8

Product & Regulatory Associates, L.L.C.

August 21, 2008

Ms. Sherada Hobgood
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Bloomtime Biological Products
EPA Reg. No. 71975-1
PR Notice 2007-4

Dear Ms. Hobgood:

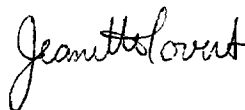
As its authorized representative, Northwest Agricultural Products (NAP) wishes to revise the subject label to include container disposal language per PR Notice 2007-4. This notification is consistent with PR Notice 98-10.

To complete this notification application, enclosed please find:

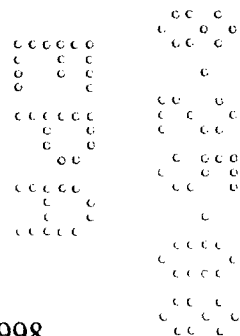
- Application for Pesticide: Notification (EPA Form 8750-1)
- One copy of the revised labeling dated 08/21/08
- One CD e-label file name 071975-00001.20080821.PrNotice 2007-4.pdf

I trust that this information will assist the Agency in its efforts to complete this notification. If you have any question in regard to this mater, feel free to contact me at (856) 751-3432 or jacovert@comcast.net.

Sincerely,



Jeanette Covert
Product & Regulatory Associates, LLC
Authorized Representative for Northwest Agricultural Products



P.O. Box 1683
Telephone 856 424-1528

Voorhees, NJ 08043-9998
FAX 856 424-1073

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NOTIFICATION

Date Reviewed: 9-12-08

Reviewed By: D. Hudson



Bloomtime Biological™ FD Biopesticide

ACTIVE INGREDIENT:

Pantoea agglomerans strain E325;

NRRL B-21856*..... 7.0%
Other ingredients:..... 93.0%
100.0%

* Minimum *Pantoea agglomerans* sps 1×10^{10} cfu/g

U.S. Patent No.: 5,919,446

EPA Reg. No. 71975-1

EPA Est. No. 71975-WA-001

Northwest Agricultural Products

P.O. Box 3453

Pasco, WA 99302

(509)547-8234



KEEP OUT OF REACH OF CHILDREN

CAUTION

Net Contents: 150 grams (0.33 lb.)

FIRST AID	
IF INHALED:	
<ul style="list-style-type: none">▪ Move person to fresh air.▪ If person is not breathing, call 9-1-1 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 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:	
<ul style="list-style-type: none">▪ Take off contaminated clothing.▪ Rinse skin with plenty of water for 15-20 minutes.▪ 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 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. You may also contact Infotrac at 1-800-535-5053 for emergency medical treatment information.

PRECAUTIONARY STATEMENTS – Agricultural Use HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Harmful if inhaled. Avoid breathing spray mist. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks
- NIOSH approved respirator with any N, R, P or HE filter

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

OPTIONAL STATEMENT: [When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.]

USER SAFETY RECOMMENDATIONS

Users should:

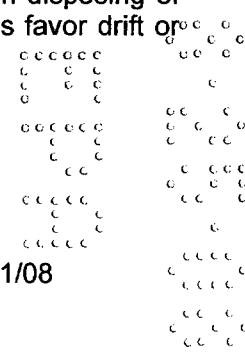
Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Remove PPE 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- Agricultural Use

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 equipment washwaters or rinsate. Do not apply when weather conditions favor drift or runoff from treated areas.



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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, forest, nurseries and greenhouses and handlers of agriculture 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 requirement in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow workers 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
- Water proof gloves
- Shoes plus socks

GENERAL INFORMATION

Bloomtime Biological™ contains a naturally occurring strain of beneficial *Pantoea* bacteria that was isolated from Gala apple blossoms in Washington State by USDA/ARS tree fruit researchers.

Mode of Action: **Bloomtime Biological™** is a bacterial antagonist. Its mode of action has been characterized as competitive inhibition against the fire blight bacteria, *Erwinia amylovora* (*Ea*). When **Bloomtime Biological™** is applied to open pear or apple flowers, it rapidly colonizes the floral tissues. Because it colonizes the same sites and utilizes the same nutrients as *Ea*, this competitive exclusion by **Bloomtime Biological™** can greatly suppress the ability of *Ea* from reaching the critical numbers necessary to trigger fire blight disease development.

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 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.

DO NOT APPLY THROUGH ANY TYPE OF IRRIGATION SYSTEM

Do not apply Bloomtime Biological™ FD Biopesticide on orchards abutting newly planted conifer forestry blocks.



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Dilution Rates: Use the following dilution rates when applying **Bloomtime Biological™**. Use the coverage characteristics of the application equipment and overall plant size to determine the proper volume of water needed. Spray solutions should be used within 24 hours of mixing.

Application Rates: **Apply Bloomtime Biological™ to flowering apple and pear trees at the following times and rates:**

15%-20% Bloom: Use 150 grams (0.33 lb) per acre in enough water to thoroughly cover the open flowers.

Full Bloom – Petal Fall: Use 150 grams (0.33 lb) per acre in enough water to thoroughly cover the open flowers.

Note: Suggested gallonage is 50-150 gallons of water per acre. At lower rates the spray must be adjusted so as to thoroughly cover the open blooms.

Note: If more dilute sprays are necessary (200-350 gallons per acre) to get thorough flower coverage, then use 200 grams (0.44 lb) **Bloomtime Biological™** per acre.

DO NOT APPLY AFTER FRUIT SET

Compatibility: Do not mix with copper-based compounds. **Bloomtime Biological™** is compatible with streptomycin. For enhanced results, when mixing with other crop protection products, run compatibility tests prior to large scale applications. Allow a minimum of 7 days between application of **Bloomtime Biological™** and Terramycin®. **Copper-based formulations are incompatible with the performance of Bloomtime Biological™. Observe the most restrictive of the labeling limitations and precautions of all products used in mixtures.**

STORAGE AND DISPOSAL

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

Pesticide Storage: Bloomtime Biological™ FD must be kept in the original container at temperatures between -4°F and 40°F, frozen or refrigerated.

Pesticide Disposal: Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then dispose of bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Conditions of Sale and Limitation of Warranty and Liability:

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions beyond the control of NORTHWEST AGRICULTURAL PRODUCTS or Seller. To the extent consistent with applicable law all such risks shall be assumed by Buyer and User, and Buyer and User agree to hold NORTHWEST AGRICULTURAL PRODUCTS and Seller harmless for any claims relating to such factors.

Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the Directions for Use when used in accordance with the directions under normal conditions of use. To the extent consistent with applicable law, NORTHWEST AGRICULTURAL PRODUCTS makes no other expressed or implied warranty of fitness or of merchantability or any other express or implied warranty. Any warranties, express or implied, having been made are inapplicable if this product has been used contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to (or beyond the control of) Seller or NORTHWEST AGRICULTURAL PRODUCTS, to the extent consistent with applicable law, the buyer assumes the risk of any such use.

To the extent consistent with applicable law, NORTHWEST AGRICULTURAL PRODUCTS or Seller shall not be liable for any incidental, consequential or special damages resulting from the use or handling of this product. To the extent consistent with applicable law, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF NORTHWEST AGRICULTURAL PRODUCTS AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF NORTHWEST AGRICULTURAL PRODUCTS OR SELLER, THE REPLACEMENT OF THE PRODUCT.

This Conditions of Sale and Limitation of Warranty and Liability may not be amended by any oral or written agreement.

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Terramycin, a trademark of Pfizer Corporation

