

73049-48

4/2/2009

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

April 2, 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Doina Bujor, Regulatory Manager
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

RE: Product Name: NOVODOR FLOWABLE CONCENTRATE
EPA Reg. No: 73049-48
Application for Label Notification Dated February 10, 2009 to Update Storage and
Disposal Language per PR Notice 2007-4

Dear Ms. Bujor:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration Notice (PRN) 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,

Sheryl K. Reilly

Sheryl K. Reilly, Ph.D., Chief
Microbial 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 73049-48	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) NOVODOR BIOLOGICAL INSECTICIDE	PM# 92	
5. Name and Address of Applicant (Include ZIP Code) Valent BioSciences Corporation 870 Technology Way Libertyville, IL 60048 <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: <input checked="" type="checkbox"/> 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: <u>4-2-09</u> Reviewed By: <u>D. Hudson</u>
<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 per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. (see next page)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
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		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
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 Doina Bujor		Title Regulatory Manager		Telephone No. (Include Area Code) 847-968-4724	
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.					6. Date Application Received (Stamped)
2. Signature <i>Doina Bujor</i>		3. Title Regulatory Manager			
4. Typed Name Doina Bujor		5. Date Feb 10, 2009			

Notification of Storage and Disposal Statement (PR Notice 2007-4) for Novodor®
Biological Insecticide, EPA Reg. No. 73049-48 (continuation from the previous page)

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 the amended label is not consistent with the requirements of 40 CFR §§152.46, 56.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and may be subject to enforcement action and penalties under section 12 and 14 of FIFRA.



Doina Bujor
Regulatory Manager

February 10, 2009

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February 10, 2009

Sheryl Reilly
Biopesticides & Pollution Prevention Division
Document Processing Desk (NOTIF)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
703-308-8269

RE: NOVODOR® Biological Insecticide (EPA Reg. No. 73049-48) Notification

Dear Ms. Reilly:


Valent BioSciences Corporation is submitting the present notification for NOVODOR® Biological Insecticide (EPA Reg. No. 73049-48) in accordance with PR Notice 2007-4. The changes made to the label are to the Storage and Disposal statement.

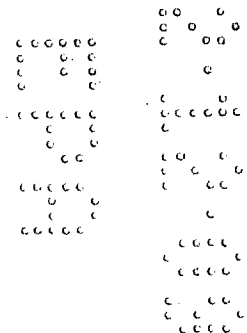
Present submission consists of:

- Application for Registration (EPA form 8570-1)
- One copy of the red-lined label
- One copy of the clean label.

Please contact me if you have any questions at 847-968-4724 or by e-mail at doina.bujor@valent.com.

Sincerely,


Doina Bujor
Regulatory Manager



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NOTIFICATION

**NOVODOR®
BIOLOGICAL INSECTICIDE
FLOWABLE CONCENTRATE**

Date Reviewed: 4-2-09
Reviewed By: D. Hudson

For the Control of Colorado Potato Beetle on Potatoes,
Tomatoes, and Eggplant, and Elm Leaf Beetle on
Shade Trees and Ornamentals

Novodor® is a registered trademark of Valent BioSciences Corporation

Active Ingredient:

<i>Bacillus thuringiensis</i> subsp. <i>tenebrionis</i> strain NB-176 fermentation solids, spores, and insecticidal toxins.....	10.0%
Other Ingredients.....	90.0%
Total.....	100.0%

Potency: 15,000 Leptinotarsa Units (LTU) per gram of product equivalent to 16.3 Million LTU's per quart of product.

The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

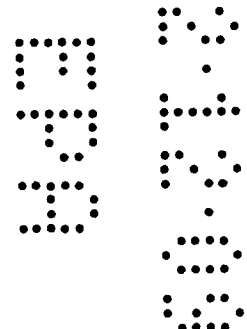
**KEEP OUT OF REACH OF CHILDREN
CAUTION**

EPA Reg. No. 73049-48
EPA Est. No. 33762-IA-1

Lot No. _____

Valent BioSciences Corporation
870 Technology Way, Suite 100
Libertyville, IL 60048

Net Contents: US Gallons



FIRST AID	
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 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 poisoning center or doctor for treatment advice.
HOT LINE NUMBER	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-892-0099 for emergency medical treatment and /or transport emergency information. For all other information, call 1-800-6-Valent.</p>	

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION**

Causes moderate eye irritation. Harmful if absorbed through the skin. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category chart.

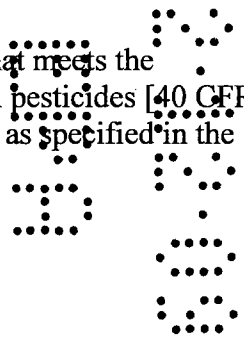
Applicators and other handlers must wear:

- * Long-sleeved shirt and long pants
- * Chemical-resistant gloves such as barrier laminate or butyl rubber or nitrile rubber or neoprene rubber or polyvinyl chloride or viton
- * Shoes plus socks.

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.

Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

When handlers used 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

User should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling the 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. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

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 through any type of irrigation system.

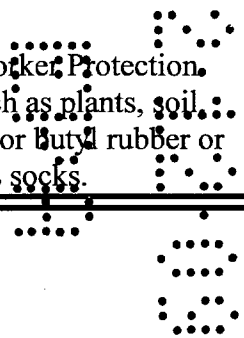
Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

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) and restricted-entry interval. The requirements in this box only 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, chemical-resistant gloves such as barrier laminate or Butyl rubber or nitrile rubber or neoprene rubber or polyvinyl chloride or viton, shoes plus socks.



STORAGE AND DISPOSAL

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

Storage: Store in a cool place. Storage at temperatures between 40 and 50 degrees F. is recommended for maximum product stability. Storage at temperatures above 90 degrees F. for an extended period of time should be avoided.

Keep containers tightly closed when not in use.

Pesticide Disposal: Pesticide waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility in accordance with federal and local regulations.

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 1/4 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 flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

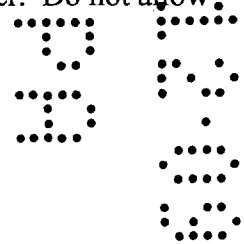
GENERAL USE INSTRUCTIONS

Novodor FC is a highly effective biological insecticide containing the active protein crystal produced by *Bacillus thuringiensis* subspecies *tenebrionis*. Novodor FC is recommended for use against the larval stage of the Colorado Potato Beetle, *Leptinotarsa decemlineata*, and the Elm Leaf Beetle, *Pyrrhalta luteola*. Novodor FC is most effective against first and second instar larvae. Therefore, applications should be timed to coincide with the first egg hatch of the target pest. Applications should be followed by close scouting for signs of reinfestations. Reapply as necessary to maintain control.

Due to its unique mode of action, Novodor FC must be ingested by the target insect larvae to be effective. Therefore, thorough coverage by the crop to be protected is essential for best results. Upon ingestion, the protein is activated under the specific gut conditions of the target insect causing general gut paralysis and cessation of feeding within hours. Death occurs in 2-5 days.

When larvae and adult beetles are present an effective adulticide with rapid knock-down activity should be used.

MIXING: Shake or stir Novodor FC thoroughly before use. Fill spray or mixing tank half full of water and begin agitation. Add the recommended amount of Novodor FC into water while maintaining agitation. Add other spray materials, if any, and balance of water. Do not allow diluted spray to remain in the tank for more than 72 hours.



While Novodor FC is formulated to provide desirable coverage and adherence to crop surfaces, additional adjuvants, spreaders, or stickers may be added to improve product performance, especially under rainy conditions or heavy dew. Avoid application if rainfall is imminent. Combinations with commonly used insecticides, fungicides, or other spray tank adjuvants are generally not deleterious to Novodor FC if the tank mix is used promptly. Before mixing in the spray tank, it is advisable to test physical compatibility by mixing all components in a small container in proportionate quantities. Use of tank mixes should be in accordance with the most restrictive of label limitations and precautions. No label dosage rates should be exceeded. This product cannot be mixed with any product containing a label prohibition against such mixing.

APPLICATION VOLUME

Novodor FC may be applied by ground or aerial equipment with sufficient quantities of water to provide thorough coverage of plant parts to be protected. The amount of water needed per acre will depend upon crop size, weather, spray equipment, and local experience.

Ground Application: Use the recommended amount of Novodor FC in a minimum of 20 gallons of water per acre.

Aerial Application: Use recommended amount of Novodor FC in a minimum of 3 gallons of water per acre.

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all of these factors when making decisions.

APPLICATION RATE: The Novodor FC application rate depends on the population pressure and the stage of the larval development. For light to moderate populations of early instar larvae (newly hatched to 1/4 inch in length) apply 1 to 3 quarts of Novodor FC per acre. Against heavy infestations of early instar larvae apply 2 to 3 quarts per acre. When mixed populations of younger and older larvae are present, apply Novodor FC at 3 to 4 quarts per acre.

NOTICE OF WARRANTY

Valent BioSciences Corporation makes no warranty of merchantability, fitness for any purpose, or otherwise, express or implied, concerning this product or its uses which extend beyond the use of the product under normal conditions in accord with the statements made on this label. In no case shall the seller be liable for consequential, or indirect damages resulting from the use or handling of this product. All such risks shall be assumed by the buyer.

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