

73049-447

9/15/2009

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

September 15, 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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

RE: Product Name: Vectobac DT Biological Larvicide
EPA Reg. No: 73049-447
Application for Label Notification Dated July 21, 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 (PR) Notice 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PR Notice 98-10 and it has been determined that the action(s) requested falls within the scope of PR Notice 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

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73049-447	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VectoBac DT	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: 9-15-09
<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.)

Reviewed By: D. Hudson

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	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
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
2. Signature 		6. Date Application Received (Stamped)
3. Title Regulatory Manager		
4. Typed Name Doina Bujor		
5. Date Jul 21, 2009		

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July 21, 2009

Sheryl Reilly
 Biopesticides & Pollution Prevention Division
 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
 703-308-8269

RE: VectoBac DT (EPA Reg. No. 73049-447) Notification

Dear Ms. Reilly:

Valent BioSciences Corporation is submitting a notification for VectoBac DT (EPA Reg. No. 73049-447) in accordance with PR Notice 2007-4. The changes made to the label are to the Storage and Disposal statement and include the changes to the container disposal language required by the PR Notice 2007-4.

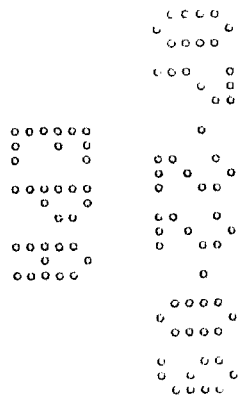
Present submission consists of:

- 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



NOTIFICATION

Date Reviewed: 9-15-09

Reviewed By: D. Hudson

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**VECTOBAC® DT
BIOLOGICAL LARVICIDE**

Active Ingredient:

Bacillus thuringiensis subsp. *israelensis* strain AM 65-52 fermentation solids, spores,
and insecticidal toxins.....37.4%

Other Ingredients.....62.6%

Total.....100.0%

[Potency: 2200 International toxic units (ITU) per mg]. Equivalent to 1.0 billion ITU/lb.

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

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

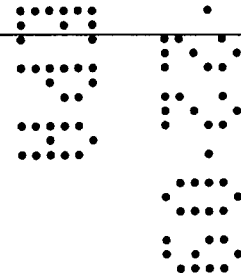
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

Lot No.: _____

EPA Reg. No. 73049-447
EPA Est. No.

Net Contents:

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. - Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-877-315-9819 (24 hours) for emergency medical treatment and or transportation emergency information. For all other information, call 1-800-323-9597.	



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

ENVIRONMENTAL HAZARDS

Do not apply directly to treated, finished drinking water supply systems. Apply only to mosquito breeding habitats (See Directions for Use for specific use sites).

STORAGE AND DISPOSAL

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

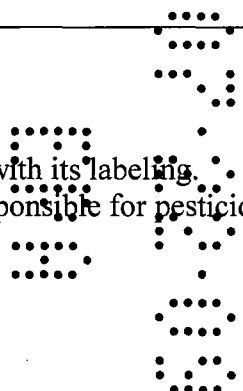
Storage: Store in cool [59-86°F (15-30°C)], dry place.

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: Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. 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. Offer for recycling, if available 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.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.



APPLICATION DIRECTIONS

For residential use. Do not apply directly to treated, finished water supply systems as these systems are not considered mosquito breeding sites.

For use in artificial containers used for water collection to control the mosquito larvae of *Aedes aegypti* and *Ae. albopictus*.

Artificial water containers may include drums, storage tanks, jars, roof top catchments, ornamental fish ponds, ornamental pools or fountains, unused swimming pools, floor drains and roof gutters.

Application Rate: 1 tablet per 50 liters.

Reapply at monthly intervals as needed (when late stage larval numbers return to pre-treatment threshold levels).

NOTICE TO USER

To the fullest extent permitted by law, seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning use of this product other than as indicated on the label. User assumes all risks of use, storage or handling not in strict accordance with accompanying directions.

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