

73049-13

9/1/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

SEP 01 2010

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Ms. Doina Bujor
Regulatory Manager
Valent BioSciences Corporation
870 Technology Way, Suite 100
Libertyville, IL 60048

Re: Product Name: Vectobac® Technical Powder
EPA Reg. No.: 73049-13
Your application dated August 11, 2010 to add an alternate brand name, Vectobac® Biological Larvicide Technical Powder
Decision #438979

Dear Ms. Bujor:

The Biopesticides and Pollution Prevention Division (BPPD) is in receipt of your application, as indicated above, for notification under Pesticide Registration (PR) Notice 98-10. 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 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 Accepted" and will be placed accordingly in our records.

Questions concerning this action should be directed to Ms. Jeannine Kausch at (703) 347-8920 or email at kausch.jeannine@epa.gov.

Sincerely,

Sheryl K. Reilly, Ph.D., Chief *for*
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

CONCURRENCES

SYMBOL	7511P	7511P					
SURNAME	KAUSCH	Reynolds					
DATE	09/01/2010	9/1/10					



United States
Environmental Protection Agency
Washington, DC 20460

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

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73049-13	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VectoBac Technical Powder	PM#	
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 Accepted Date: 09/01/2010
<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.)

Reviewer: J. KAUSCH

Notification of Alternate Brand Name per PR Notice 98-10. This notification is consistent with the 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 for this product. (see next page)

Section - III

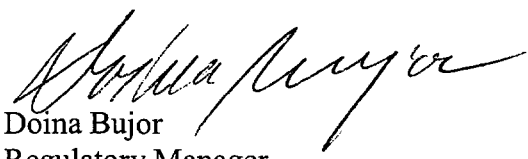
1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <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	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
		If "Yes" Package wgt	No. per container	<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
2. Signature 		3. Title Regulatory Manager
4. Typed Name Doina Bujor		5. Date Aug 11, 2010
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)

Notification of Alternate Brand Name (PR Notice 98-10) for VectoBac Technical Powder, EPA Reg. No. 73049- 13 (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 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 section 12 and 14 of FIFRA.



Doina Bujor
Regulatory Manager

08-11-2010

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List No. 5620

**VECTOBAC®
TECHNICAL POWDER**

ABN: VECTOBAC® BIOLOGICAL LARVICIDE TECHNICAL POWDER

FOR MANUFACTURING USE ONLY

Active Ingredient:

Bacillus thuringiensis, subsp. *israelensis*, strain AM 65-52, fermentation solids and solubles.....99%

Other Ingredients.....1%

Total.....100%

Potency: 6000 International Toxic Units (ITU) per milligram (Equivalent to 2,275 Billion ITU per pound of undiluted powder).

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

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Notification Accepted

Date: 09/01/2010

Reviewer: J. KAUSCH

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

EPA Registration No. 73049-13
EPA Est. No. 3372-IA-1

Lot No.:

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eyes and rinse slowly and gently with water for 15-20 minutes • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes • Call a poison control center or doctor for treatment advice.

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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 1-877-315-9819 (24 hours) for emergency medical treatment and/or transport emergency information. For all other information, call 1-800-323-9597

**PRECAUTIONARY STATEMENT
HAZARD TO HUMANS (AND DOMESTIC ANIMALS)
CAUTION**

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

Mixers/loaders and applicators not in enclosed cabs or aircraft must wear a dust/mist 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.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NDPES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is in violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into an insecticide for the following uses: control of mosquito larvae. This product may be used in formulate products for any additional use(s) not listed on the MP label of the formulator, user group, or grower has complied with US EPA requirements regarding support of such uses(s).

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STORAGE AND DISPOSAL

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

Storage: Store tightly closed containers in a cool, dry place.

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

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Offer for recycling, if available. If recycling is not available dispose of liner in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. Perforate or crush drum and dispose of in the same manner.

NOTICE TO USER

Seller makes no warranty, express or implied, or merchantability, fitness or otherwise concerning the use of this product other than as indicated on the label. User assumes all risk of use, storage or handling not in strict accordance with accompanying directions.

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