

73049-355

11/4/2008

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

November 4, 2008

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

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

RE: Product Name: Vectobac Biological Larvicide Primary Powder  
EPA Reg. No: 73049-355  
Application for Label Notification Dated October 20, 2008 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 PR Notice 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](mailto:hudson.diana@epa.gov).

Sincerely,

*Sheryl K. Reilly*

Sheryl K. Reilly, 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 73049-355	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VECTOBAC BIOLOGICAL LARVICIDE PRIMARY POWDER	PM# 72	
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 _____	<b>NOTIFICATION</b> Date Reviewed: <u>11-4-08</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	<input 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
				<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
<b>Certification</b> 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 Oct 20, 2008	

Notification of Storage and Disposal Statement (PR Notice 2007-4) for VectoBac Biological Insecticide Primary Powder, EPA Reg. No. 73049-355 (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.

*Handwritten signature*

10-20-2008

U.S. DEPARTMENT OF AGRICULTURE  
OFFICE OF THE ASSISTANT SECRETARY FOR  
REGISTRATION AND COMPLIANCE  
1400 TOMPKINS AVE., SUITE 200  
WASHINGTON, DC 20250-4000  
TEL: (202) 720-1800  
WWW.ASAP.USDA.GOV

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October 20, 2008

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: VectoBac® Biological Insecticide Primary Powder (EPA Reg. No. 73049-355)  
Notification**

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Dear Ms. Reilly:

Valent BioSciences Corporation is submitting a notification for VectoBac Biological Insecticide Primary Powder (EPA Reg. No. 73049-355) in accordance with PR Notice 2007-4. The changes made to the label are to the Storage and Disposal statement and include the container disposal language for rigid, nonrefillable container.

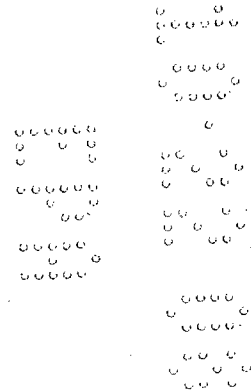
Present submission consists of:

- 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](mailto:doina.bujor@valent.com).

Sincerely,

Doina Bujor  
Regulatory Manager



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**VECTOBAC®  
BIOLOGICAL LARVICIDE  
PRIMARY POWDER**

**NOTIFICATION**

Date Reviewed: 11-4-08

Reviewed By: D. Hudson

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)

There is no direct relationship between intended activity (potency) and the Percent Active Ingredient by Weight.

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

**NOP**

The ingredients in this product meet the requirements of USDA National Organic Program.

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

EPA Registration No. 73049- 355 \_\_\_\_\_ Batch Code: \_\_\_\_\_  
EPA Est. No. 3372-1A-1

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

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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 contaminate water when disposing of equipment washwaters. Do not apply directly to treated finished drinking water reservoirs or drinking water receptacles when water is intended for human consumption.

**DIRECTIONS FOR USE**

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

**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 an approved waste disposal facility.

**Container Disposal:** ~~Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Completely empty liner by shaking and tapping the bottom to loosen clinging particles. Empty residue into manufacturing equipment. Then 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.~~  
VectoBac Primary Powder must be diluted before application by suitable aerial or ground equipment at a suggested rate range\* of 0.455 to 0.91 billion ITUs per acre for usual mosquito habitats and 0.91 to 1.82 billion ITUs per acre on polluted water, sewage lagoons, etc.

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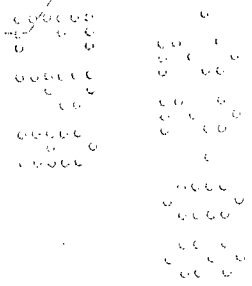
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Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the treatment coordinator are responsible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

\*Use higher rate when late 3rd or 4th instar larvae predominate, mosquito populations are high water is heavily polluted, and/or algae are abundant.

A 7 to 14 day interval between applications should be employed.

### GENERAL GRANULATION DIRECTIONS

Rotating Type Mixer:

1. Place suitable diluent, such as sand, in rotating mixer (cement mixer, ribbon blender, or equivalent).
2. Add Golden Bear-1356<sup>1</sup> or Golden Bear-1111<sup>1</sup> while mixer is running (GB-1356 and GB-1111 may be sprayed on or gradually poured over sand; spraying is the preferred method instead of pouring).
3. Mix 5-10 minutes to insure that sand particles are covered with GB-1356 or GB-1111.
4. While mixer continues to run, add the calculated amount of VectoBac Primary Powder (as shown in table below). Continue mixing 15-30 minutes or until sand granules are uniformly coated with VectoBac Primary Powder.

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A typical blend would consist of:

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<u>Materials</u>	<u>% W/W</u>	<u>Based on 100 lbs sand</u>	<u>Based on 100 lbs final product</u>
VectoBac Primary Powder	4	4.3 lbs	4.0 lbs
GB-1356 <sup>1</sup> or GB-1111 <sup>1</sup>	1.3 - 1.5*	24-28 oz	23-26 oz
Sand (washed/dry)	<u>94.7-94.5</u>	<u>100 lbs</u>	<u>94.7-94.5 lbs</u>
	1,005	105.68-105.9	100 lbs

<sup>1</sup>GB 1356 and GB 1111 are available from Golden Bear Division, Witco Chemical Corporation.

\*Use 1.3% GB-1356 or GB-1111 for fine sand granules 16/30 mesh size and 20/30 mesh size. For coarse sand granules, 10/20 mesh size, use 1.5% of GB 1356 or GB 1111.

Note: It is recommended that a small batch formulation be produced to determine percent GB 1356 or GB 1111 required to give a free-flowing and dust-free granular formulation.

Following preparation of the sand granular formulation, store in a cool, dry place. Storing in sealed containers will help prevent drying out of the sand granules.

### END-USE PRODUCT APPLICATION DIRECTIONS

#### Mosquitoes Habitat

**Suggested Rate Range\***

(Such as the following examples):

Irrigation ditches, roadside ditches, flood water, standing ponds, woodland pools, snow melt pools, pastures, catch basins, storm water retention areas, tidal water, salt marshes and rice fields.

5-10 lbs/acre

In addition, standing water containing mosquito larvae in fields growing alfalfa, almonds, asparagus, corn, cotton, dates, grapes, peaches and walnuts, may be treated at the recommended rates.

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**NOTIFICATION**

Date Reviewed: 11-4-08

Reviewed By: D. Hudson

**VECTOBAC®  
BIOLOGICAL LARVICIDE  
PRIMARY POWDER**

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Valent BioSciences Corporation  
870 Technology Way, Suite 100  
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EPA Registration No. 73049-355  
EPA Est. No. 3372-IA-1

Batch Code: \_\_\_\_\_

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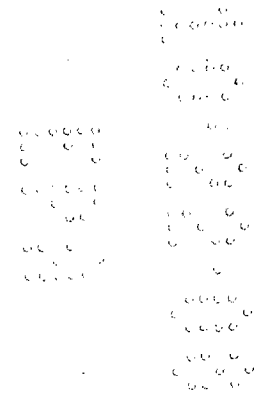
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**Mosquitoes Habitat**

**Suggested  
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5-10 lbs/acre

In addition, standing water containing mosquito larvae in fields growing alfalfa, almonds, asparagus, corn, cotton, dates, grapes, peaches and walnuts, may be treated at the recommended rates.

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\*Use 10-20 lbs/acre when late 3rd and early 4th instar larvae predominate, mosquito populations are high, water is heavily polluted, (sewage lagoons, animal waste lagoons) and/or algae are abundant.

**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 risks of use, storage or handling not in strict accordance with accompanying directions.

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