

73049-61

8/10/2011  
AUG 10 2011

10f6

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

Dear Ms. Bujor:

Subject: *Bacillus thuringiensis* subsp. *israelensis* Slurry (for VectoBac Technical Powder and DF formulations)  
EPA Reg. No. 73049-61  
Notification dated June 6, 2011; application for amendment dated July 8, 2011 and subsequent CSF  
submission dated August 4, 2011

On June 6, 2011, you submitted a label notification to change the product name of *Bacillus thuringiensis* subsp. *israelensis* Slurry (EPA Reg. No. 73049-61) to *Bacillus thuringiensis* subsp. *israelensis* Slurry (for VectoBac Technical Powder and DF formulations). On July 8, 2011, you submitted an application to remove the Basic Formulation for the product and to change the status of the Alternative Formulation to be the new Basic Formulation. Subsequently, a revised (basic) CSF was submitted on August 4, 2011. The amended Confidential Statement of Formula (CSF) (dated August 4, 2011) is acceptable under the Federal Insecticide, Fungicide, and Rodenticide Act and has been added to the product file. All other CSFs have been superseded by the CSF dated August 4, 2011. To review, the following formulation is now on file for this product:

- Basic Formulation (CSF dated August 4, 2011)

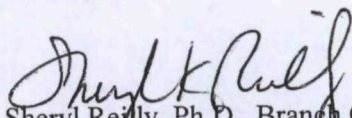
The following change was made to the product label via notification:

- Product name changed to *Bacillus thuringiensis* subsp. *israelensis* Slurry (for VectoBac Technical Powder and DF formulations)

The notification of the label change has been determined to fall within the scope of Pesticide Registration Notice 98-10. Our records have been duly noted, and the label submitted with this application has been stamped as "Notification, received and accepted" and will be placed accordingly in our records.

If you have any questions, please contact Sally Johnson of my staff at (703) 347-0278 (e-mail: johnson.sally@epa.gov).

Sincerely,



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

#### CONCURRENCES

SYMBOL	7511P	7511P	7511P					
SURNAME	Johnson	Reynolds	Reilly					
DATE	8/9/11	8/9/11	8/10/11					



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 73049-61	2. EPA Product Manager Seryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Bacillus thuringiensis subsp. israelensis Slurry	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: EPA Reg. No. _____ Product Name _____	

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Change the status of Alternate Formulation to become the Basic Formulation and remove the current Basic Formulation.

## 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	
<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 		3. Title Regulatory Manager			
4. Typed Name Dona Bujor		5. Date Jul 8, 2011			





June 6, 2011

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: *Bacillus thuringiensis* subsp. *israelensis* Slurry (EPA Reg. No. 73049-61)**

Dear Ms. Reilly:

Valent BioSciences Corporation is submitting the present label notification for *Bacillus thuringiensis* subsp. *israelensis* Slurry (EPA Reg. No. 73049-61) to change the product name to read ***Bacillus thuringiensis* subsp. *israelensis* Slurry (for VectoBac Technical Powder and DF formulations)**.

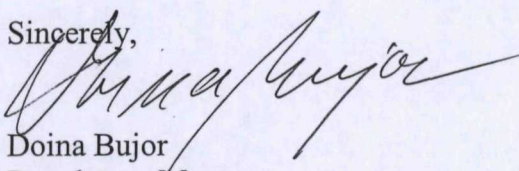
Additionally to this action we would like to cancel the basic formulation (attached CSFs) for the above registration number and change the status of alternative formulation to new basic formulation. A separate submission will be made to register the Bti slurry used in formulating liquid VectoBac products.

Present submission consists of:

- Application for Registration (EPA form 8570-1)
- One copy of the red-lined label
- Five copy of the clean label.
- Current CSF
- New basic formulation CSF

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





July 8, 2011

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: *Bacillus thuringiensis* subsp. *israelensis* Slurry (EPA Reg. No. 73049-61)**

Dear Ms. Reilly:

Valent BioSciences Corporation is submitting the present amendment to change the status of Basic and Alternative Formulations.

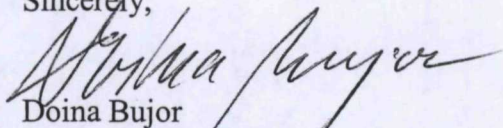
Valent BioSciences Corporation would like to remove the Basic Formulation (attached CSF) for the EPA Reg. No. 73049-61 and change the status of Alternative Formulation (attached CSF) to become the Basic Formulation.

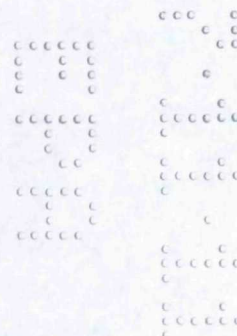
Present submission consists of:

- Application for Registration (EPA form 8570-1)
- One copy of the removed CSF
- Two copies of new Basic Formulation CSF

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





***Bacillus thuringiensis* subsp. *israelensis* Slurry**  
**(for VectoBac Technical Powder and DF formulations)**

BIOLOGICAL INSECTICIDE

FOR MANUFACTURING USE ONLY

KEEP OUT OF REACH OF CHILDREN

**CAUTION**

**ACTIVE INGREDIENT:**

*Bacillus thuringiensis* subsp. *israelensis*, strain AM 65-52 solids, spores and  
insecticidal toxins.....14.0% w/w

**OTHER INGREDIENTS:**.....86.0% w/w

**Total:** 100% w/w

**The % active ingredient does not indicate product performance**

EPA Registration No. 73049-61  
EPA Establishment No.

Lot No: \_\_\_\_\_

Manufactured for: Valent BioSciences Corporation  
870 Technology Way  
Libertyville, IL 60048  
1-800-323-9597

**Notification Accepted**

**Date:** 8/10/2011

**Reviewer:** S. Johnson

Net Contents:

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

**CAUTION**

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

<b>FIRST AID</b>	
<b>If in eyes:</b>	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.
<b>HOT LINE NUMBER</b>	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies, you may also call toll-free 1-877-315-9819 for treatment information.	

## 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 (NPDES) 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 a violation of Federal Law to use this product in a manner inconsistent with its labeling. This slurry is intended for formulation into insecticidal products for control of mosquito larvae.

## STORAGE AND DISPOSAL

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

### PESTICIDE STORAGE:

Store in cool, dry conditions.

### PESTICIDE DISPOSAL:

Wastes resulting from the use of this product must be disposed of on-site or at an approved waste disposal facility.

### CONTAINER HANDLING:

Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances.