

73049-405

09/29/2009

1/7



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

September 29, 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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

RE: Product Name: BTI Technical Powder Bioinsecticide
EPA Reg. No: 73049-405
Application for Label Notification Dated July 23, 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

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73049-405	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BTI 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 Date Reviewed: <u>9-29-09</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:

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	2. Type of Container <input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. _____ No. per container _____	If "Yes" Package wgt. _____ No. per container _____

3. Location of Net Contents Information
 Label Container

4. Size(s) Retail Container _____

5. Location of Label Directions
 On Label On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
 Lithograph Paper glued Stenciled 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 both under applicable law.

2. Signature 	3. Title Regulatory Manager	6. Date Application Received (Stamped)
4. Typed Name Doina Bujor	5. Date Jul 23, 2009	



July 23, 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: BTI Technical Powder (EPA Reg. No. 73049-405) Notification

Dear Ms. Reilly:

Valent BioSciences Corporation is submitting a notification for BTI Technical Powder (EPA Reg. No. 73049-405) 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.

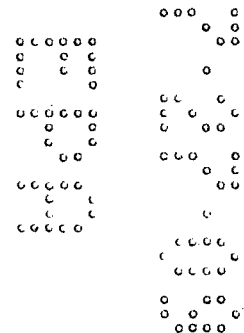
Present submission consists of:

- 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



Date Reviewed: 9-29-09

Reviewed By: D. Hudson

BTI TECHICAL POWDER BIOINSECTICIDE

FOR MANUFACTURING USE ONLY

Active Ingredient:

Bacillus thuringiensis, subsp. *israelensis*, strain EG2215,
solids, spores and insecticidal toxins100%

Potency: 16,000 International Toxic Units (ITU) per milligram (Equivalent to 6,067 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**

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

Lot No.: _____

EPA Registration No. 73049-405
EPA Est. No.

Page 1 of 3

FIRST AID	
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth to mouth, if possible. • Call a poison control center or doctor for further 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 poison control center or doctor for treatment advice.
HOT LINE NUMBER	
<p>Have 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.</p>	

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

Harmful if inhaled. 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. Remove and wash contaminated clothing before reuse.

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 public waters unless in accordance with the requirement 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.

DIRECTIOS FOR USE

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

For manufacture of bioinsecticide end-use products for application to Mosquito Habitats such as: irrigation ditches, roadside ditches, flood water, standing ponds, woodland ponds, snow melt pools, pastures, catch basins, storm water retention areas, tidal water, salt marches, and rice fields.

STORAGE AND DISPOSAL

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

Storage: Store closed containers in a cool, dry place inaccessible to children.

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

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping the bottom to loosen clinging particles. Empty residue into manufacturing equipment. Offer for recycling, if available. or dispose of liner in a sanitary landfill, or by incineration, if allowed by state and local authorities. Perforate or crush drum and dispose of it 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 risks of use, storage or handling not in strict accordance with accompanying directions.

2009