

73049-24

11/21/2008

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

November 21, 2008

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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

RE: Product Name: Xentari Technical Powder
EPA Reg. No: 73049-24
Application for Label Notification Dated October 23, 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.

Sincerely,

Sheryl K. Reilly

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



United States
Environmental Protection Agency
Washington, DC 20480

<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 73049-24	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) XENTARI Biological Insecticide Technical Powder	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: 11-21-08 Reviewed By: D. Hudson
<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	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 <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	
<p align="center">Certification</p> <p>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.</p>					6. Date Application Received (Stamped)
2. Signature <i>Doina Bujor</i>		3. Title Regulatory Manager			
4. Typed Name Doina Bujor		5. Date Oct 23, 2008			

Notification of Storage and Disposal Statement (PR Notice 2007-4) for XENTARI
Technical Powder, EPA Reg. No. 73049-24 (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.

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Oct 23, 2008

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October 23, 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: XENTARI Technical Powder (EPA Reg. No. 73049-24) Notification

Dear Ms. Reilly:

Valent BioSciences Corporation is submitting the present notification for XENTARI Biological Insecticide Technical Powder (EPA Reg. No. 73049-24) in accordance with PR Notice 2007-4. The changes made to the label are to the Storage and Disposal statement.

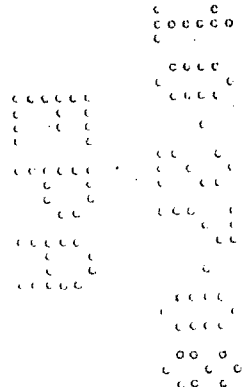
Present submission consists of:

- 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



XENTARI
BIOLOGICAL INSECTICIDE
TECHNICAL POWDER

NOTIFICATION
Date Reviewed: 11-21-08
Reviewed By: D. Hudson

FOR MANUFACTURING USE ONLY

Active ingredient:

Bacillus thuringiensis, subsp. *aizawai*, strain ABTS 1857, fermentation solids and solubles.....89%
Other Ingredients.....11%
Total.....100%

Potency: 65,000 Diamondback Moth Units per mg of product or 29.5 billion Diamondback Moth Units per pound of product.

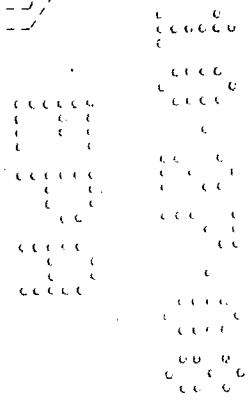
There is no direct relationship between intended activity (potency) and the Percent Active Ingredient by Weight.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

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

EPA Registration No. 73049-24 _____ Batch Code: _____
EPA Est. No. 33762-IA-1 _____ Net Weight: _____

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STORAGE AND DISPOSAL

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

PESTICIDE STORAGE:

Reclose containers of unused XenTari Technical Powder. Store in a 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. Offer for recycling, if available.
Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles.
Empty residue into manufacturing equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities. Perforate or crush drum and dispose of in the same manner.

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Deleted: Do not reuse liner or drum. Completely empty liner by tapping sides and bottom to loosen clinging particles. Empty residue into manufacturing equipment. 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

NOTICE TO USER

Seller makes no warranty, express or implied, of 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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