23049-24





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)

,	. ()		Company of the Company				
Please read instructions on reverse before completing form.	Form Approv	ed. OMB No. 2070-0	OSO Print Form				
United States		Registration					
Environmental Protectio	n Agency	Amendmen					
Application for Pesticide - Section I							
1. Company/Product Number 73049-24	2. EPA Product Manager Sheryl Reilly		3. Proposed Classification				
Company/Product (Name) XENTARI Biological Insecticide Technical Powder	PM# 9 2	X None Restricted					
5. Name and Address of Applicant (Include ZIP Code)	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)						
Valent BioSciences Corporation	(b)(i), my product is similar or identical in composition and labeling						
870 Technology Way	to:						
Libertyville, IL 60048	EPA Reg. No.						
Check if this is a new address Product Name							
Section - II							
Amendment - Explain below.	Final printed I	abels in respondent for	TEIO ATEM				
Agency letter dated 1401FICATION							
Resubmission in response to Agency letter dated	Mile 100" Ap	Date Revie	ewed: 11-21-28				
Resubmission in response to Agency letter dated "Me Too" Applicationate Reviewed: 11-21-08 X Notification - Explain below: Other - Explain below: Reviewed By: D. Audson							
Explanation: Use additional page(s) if necessary. (For section	i and Section II.)		Dy. The state of t				
NAME OF THE PROPERTY OF THE PR	. La caracidada de la car	i- DD N-+i 2007					
Notification of label per PR Notice 2007-4. This notification EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 15							
Confidential Statement of Formula for this product. (see no		Inanges have been	made to the labeling of the				
,	p g - -,						
	Section - III						
1. Material This Product Will Be Packaged In:							
Child-Resistent Packaging Unit Packaging							
Yes* Yes	Yes	tai					
X No X No	X No Plastic Glass						
If "Yes" No. per	If "Yes" No. per	Pap	· ·				
* Certification must Unit Packaging wgt. container Package wgt container Other (Specify)							
3. Location of Net Contents Information 4. Size(s) Retail Container 5. Location of Label Directions							
		On Label On Labeling ac	ccompanying product				
6. Manner in Which Label is Affixed to Product Lithogo	raph Other						
6. Manner in Which Label is Affixed to Product Lithog Paper Stencil							
	Section - IV						
Contact Point Complete items directly below for identification	· 						
Name Doina Bujor	I Daguilatani Managar		phone No. (Include Area Code) -968-4724				
Certification 6. Deta & polication							
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 (Starched)							
l acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.							
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4. Typed Name	5. Date	(((
Doina Bujor	Oct 23, 2008	, c ι'					

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.

Mohua My or

Oct 23, 2008



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 Bujør

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, str bles			0%	
Other Ingredients			11%	
Potency: 65,000 Diamondback Moth Unit Units per pound of product.	ts per mg of product or 2	29.5 billion Diamondbac	k Moth	
There is no direct relationship between in dient by Weight.	ntended activity (potency) and the Percent Active	Ingre-	
KEEP OUT O	OF REACH OF CHILD CAUTION	PREN		·
Valent BioSciences Corporation 870 Technology Way, Suite 100 Libertyville, IL 60048		·		·
EPA Registration No. 73049-24 EPA Est. No. 33762-IA-1		Batch Code: Net Weight:		
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XENTARI TP 10-23-2008 dmb Page I of 3				ι (
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FIRST AID

If in eves

- 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.

If on skin or clothing

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15 20 minutes.
- Call a poison control center or doctor for treatment advice.

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 1-800-892-0099 for emergency medical treatment and/or transport emergency information. For all other information, call 1-800-6-Valent.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS (AND DOMESTIC ANIMALS) **CAUTION**

Harmful if swallowed, inhaled, or absorbed through the skin. May cause eye irritation. Avoid breathing dust. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Mixer/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.

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 a violation of federal law to use this product in a manner inconsistent with its labeling. XenTari Technical Powder is intended for formulation into end-use products for terrestrial and greenhouse food and nonfood crop uses and for use on agricultural commodities in storage.

This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with US EPA requirements regarding support of such use(s).

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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.

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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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

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XENTARI TP.10-23-2008.dmb _ _ _

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