

73049-36

9/15/2009

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

September 15, 2009

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

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

RE: Product Name: DiTera Technical Powder  
EPA Reg. No: 73049-36  
Application for Label Notification Dated July 20, 2009 and Revised Label Dated  
September 14, 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](mailto: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 73049-36	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) DiTera 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

Amendment - Explain below.  Final printed labels in response to Agency letter dated \_\_\_\_\_

Resubmission in response to Agency letter dated \_\_\_\_\_  "Me Too" Application.

Notification - Explain below.  Other - Explain below.

**NOTIFICATION**  
Date Reviewed: 9-15-09  
Reviewed By: D. Hudson

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 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) 647-568-4724
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**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 or both under applicable law.

2. Signature  
*Doina Bujor*

3. Title  
Regulatory Manager

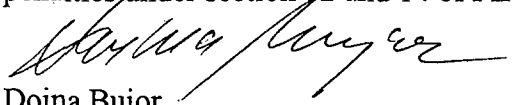
4. Typed Name  
Doina Bujor

5. Date  
Jul 20, 2009

6. Date Application Received  
(Stamped)

Notification of Storage and Disposal Statement (PR Notice 2007-4) for DiTera Technical Powder, EPA Reg. No. 73049-36 (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.



Doina Bujor  
Regulatory manager

July 20, 2009



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July 20, 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: DiTera Technical Powder (EPA Reg. No. 73049-36) Notification**

Dear Ms. Reilly:


Valent BioSciences Corporation is submitting a notification for DiTera Technical Powder (EPA Reg. No. 73049-36) in accordance with PR Notice 2007-4 and PR. The changes made to the label are to the Storage and Disposal statement and include the container disposal language for non-refillable rigid 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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**NOTIFICATION**

Date Reviewed: 9-15-09

Reviewed By: D. Hudson

**DiTera TECHNICAL POWDER**

**Biological Nematicide**

**FOR MANUFACTURING USE ONLY**

**ACTIVE INGREDIENT:**

Dried fermentation solids and solubles of *Myrothecium verrucaria*\*.....99.0% w/w

**OTHER INGREDIENTS**.....1.0% w/w

**Total**.....100.0% w/w

\*U.S. Patent No. 5,051,255

**POTENCY:** 62,500 RKU (Root-knot Units) per gram 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**

EPA Reg. No. 73049-36

Lot No. \_\_\_\_\_

EPA Est. No.

Registrant:  
Valent BioSciences Corporation  
870 Technology Way  
Libertyville, IL 60048

Net Contents:

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<b>FIRST AID</b>	
If in eyes	--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.
<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. You may also contact 1-800-892-0099 (24 hours) for emergency medical treatment and/or transport emergency information. For all other information, call 1-800-6-VALENT.	

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

Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

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 sensitizations.

**ENVIRONMENTAL HAZARDS**

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters. Do not apply where run-off is likely to occur.

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**STORAGE AND DISPOSAL**

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

**PESTICIDE STORAGE.** Keep container tightly closed when not in use. Store in a cool, dry place. Avoid extreme temperatures.

**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 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. If drum is contaminated and cannot be reused, dispose of in the same manner.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. DiTera Technical Powder is intended for formulation into nematicidal end products for use on agricultural commodities and certain non-agricultural use patterns.

**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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