73049-12



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

5/12/2009

May 12, 2009

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES 5

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

RE: Product Name: Dipel Biological Insecticide Technical Powder
 EPA Reg. No: 73049-12
 Application for Label Notification Dated April 9, 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 Pesticides Registration Notice (PRN) 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 letter 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 <u>hudson.diana@epa.gov</u>.

Sincerely,

Sheryl K. Reilly

Sheryl K. Reilly, Ph.D., ChiefMicrobial Pesticides BranchBiopesticides and Pollution PreventionDivision (7511P)

	nited States			-	ion	OPP Identifier Number
		lency			ent	
	Application for	Pesticide - S	Section I			• • • • • • • • • • • • • • • • • • •
br		2. EPA Product Sheryl Reilly	Manager	•		posed Classification
) ide Technical Powde	r	PM# 92			אך	None Restricted
oplicant <i>(Include ZIP Co</i>	de)	1				
poration		(b)(i), my prod to:	uct is simi	lar or identic	al in co	mposition and labeling
	·		o			
s is a new address		Product Nan	ne			•
	Se					
n below.		Final p	rinted labels	in respon	OTIFI	CATRON
			y letter date	d		
X Notification - Explain below. Other - Explain			- Explain bei	<u>"Řeview</u>	ed By	. D. Hudson
nal page(s) if necessary	y. (For section I and	Section II.)				
	Se	ction - III				
ill Be Packaged In:						
Unit Packaging	14/					
	wat	er Soluble Packagin	a .	2. Type of C	ontainer	
Yes		er Soluble Packagin Yes	a	2. Type of C	Metal	
× No	×	Yes No		2. Type of C	Metal Plastic Glass	
	No. per If *)	Yes No (es" No.		2. Type of C	Metal Plastic	
X No	No. per If *)	Yes No Yes No. (age wgt cont	per tainer	ation of Labe	Metal Plastic Glass Paper Other (S	pecify)
X No If "Yes" Unit Packaging wgt.	No. per container	Yes No Yes No. (age wgt cont	per tainer	ation of Label	Metal Plastic Glass Paper Other (S	pecify)
No If "Yes" Unit Packaging wgt.	No. per container	Yes No Yes No. Kage wgt cont Lainer	per tainer	ation of Label	Metal Plastic Glass Paper Other (S	pecify)
X No If "Yes" Unit Packaging wgt. Information Container & Affixed to Product	No. per container If * Pack 4. Size(s) Retail Con Lithograph Paper glued Stencifed Sec	Yes No (es" No. (age wgt cont tainer	per tainer 5. Loc X Other	etion of Label On Label On Label	Metal Plastic Glass Paper Other (S Directio g accom	pacify) ins ipanying product
X No If "Yes" Unit Packaging wgt. Information Container	No. per container If * Pack 4. Size(s) Retail Con Lithograph Paper glued Stencifed Sec	Yes No (es" No. (age wgt cont tainer	per tainer 5. Loc X Other	etion of Label On Label On Label	Metal Plastic Glass Paper Other (S Directio g accom	pacify) ins ipanying product
X No If "Yes" Unit Packaging wgt. Information Container & Affixed to Product	No. per container If *) Pack 4. Size(s) Retail Con Lithograph Paper glued Stencifed Secor identification of inconstruction Title	Yes No (es" No. (age wgt cont tainer	per tainer 5. Loc X Other	ation of Label On Label On Labelin	Metal Plastic Glass Paper Other (S Directio g accom	a No. (Include Area Code)
No If "Yes" Unit Packaging wgt. Information Container Affixed to Product	No. per container If * Y econtainer Pack 4. Size(s) Retail Con Lithograph Paper glued Stenciled Secon identification of incon Title Regul Certification this form and all atta	Yes No (es" No. cage wgt cont tainer Ction - IV dividual to be contact atory Manager	per tainer 5. Loc X Other Cted, if nece	ation of Labei On Labei On Labein	Metal Plastic Glass Paper Other (S Directio g eccom cess this elephone 347-968	pecify) penying product penying product penying product application.) a No. (Include Area Code) -4724 c cccc 6. (Date Application Received
No If "Yes" Unit Packaging wgt. Information Container Affixed to Product	No. per container If * Y econtainer Pack 4. Size(s) Retail Con Lithograph Paper glued Stenciled Secon identification of incon Title Regul Certification this form and all atta	Yes No (es" No. cage wgt cont tainer Ction - IV dividual to be contact atory Manager	per tainer 5. Loc X Other Cted, if nece	ation of Labei On Labei On Labein	Metal Plastic Glass Paper Other (S Directio g eccom cess this elephone 347-968	apecify) perify) penying product appnying product application.) a No. (Include Area Code) -4724 a cocco B.(Dete Application Received C.C. C.
No If "Yes" Unit Packaging wgt. Information Container Affixed to Product a items directly below for terments I have made on my knowingly false or molew.	No. per container If * Y econtainer Pack 4. Size(s) Retail Con Lithograph Paper glued Stenciled Secon identification of incon Title Regul Certification this form and all atta	Yes No Kage wgt teiner Ction - IV dividual to be contact atory Manager	per tainer 5. Loc X Other Cted, if nece	ation of Labei On Labei On Labein	Metal Plastic Glass Paper Other (S Directio g eccom cess this elephone 347-968	specify) panying product application.) a No. (Include Area Code) -4724 a coccu Received Coccu application a coccu coccu coccu coccu coccu coccu coccu coccu coccu cocu c
No If "Yes" Unit Packaging wgt. Information Container Affixed to Product a items directly below for ements I have made on my knowingly false or m	No. per container If * Pack 4. Size(s) Retail Con Lithograph Paper glued Stencifed Secon identification of inco Title Regul Certification this form and all attan isleading statement 3. Title	Yes No Kage wgt teiner Ction - IV dividual to be contact atory Manager	per tainer 5. Loc X Other Cted, if nece	ation of Labei On Labei On Labein	Metal Plastic Glass Paper Other (S Directio g eccom cess this elephone 347-968	specify) ms panying product spplication.) a No. (Include Area Code) -4724 c c c c c c S. (Bate Application Received c c c c (Stämped) o c c c c c c c c c c c c c c c c c c c
No If "Yes" Unit Packaging wgt. Information Container Affixed to Product a items directly below for terments I have made on my knowingly false or molew.	No. per container If * Pack 4. Size(s) Retail Con Lithograph Paper glued Stencifed Secon identification of inco Title Regul Certification this form and all attan isleading statement 3. Title	Yes No (es" No. cage wgt cont tainer Ction - IV dividual to be contact atory Manager atory Manager	per tainer 5. Loc X Other Cted, if nece	ation of Labei On Labei On Labein	Metal Plastic Glass Paper Other (S Directio g eccom cess this elephone 347-968	a No. (Include Area Code) -4724 c c c c c c Bible Application -4724 c c c c c c Bible Application -6. (Stämped) o c c c c c c c c c c c c c c c c c c c
	Environmental Washir er er e) cide Technical Powde pplicent <i>(Include ZIP Co</i> poration <i>is is a new address</i> in below. ponse to Agency letter n below. PR Notice 2007-4. Thi CFR §§ 156.10, 156.14 of Formula for this pr	Washington, DC 20460 Application for  er  er  a) cide Technical Powder pplicent (Include ZIP Code) poration is is a new address Se in below. ponse to Agency letter dated	Environmental Protection Agency Washington, DC 20460         Application for Pesticide - S         er       2. EPA Product Sheryl Reilly         e)       9.         cide Technical Powder       PM# 9 2         pplicent (Include ZIP Code)       6. Expedited         poration       6. Expedited         is is a new address       Product Nar         is is a new address       Product Nar         Section - II       Final p         in below.       Final p         openal page(s) if necessary.       (For section I and Section II.)         PR Notice 2007-4. This notification is consistent with the g       CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. NO         of Formula for this product. (see next page)       Section - III	Environmental Protection Agency         Washington, DC 20460         Application for Pesticide - Section I         er       2. EPA Product Manager         sheryl Reilly         e)       PM# 9 2         cide Technical Powder       6. Expedited Review.         pplicant (Include ZIP Code)       6. Expedited Review.         poration       b)(ii), my product is simito:         E       EPA Reg. No         is is a new address       Product Name         Section - II       Section - II         in below.       Image: Sing prime to Agency letter dated is ponse to Agency letter date is ponse to Agency letter da	Environmental Protection Agency Washington, DC 20460       Amendm Other         Application for Pesticide - Section I         er       2. EPA Product Manager Sheryl Reilly         er       6. Expedited Review. In accordance (b)(i), my product is similar or identic to:         poration       6. Expedited Review. In accordance (b)(i), my product is similar or identic to:         is is a new address       Product Name         Section - II       The Too* Applicat Me Too* Applicat Date Re         other - Explain below.       Other - Explain below Review         ponse to Agency letter dated       Me Too* Applicat Me Too* Applicat Date Re         other - Explain below.       Other - Explain below Review         ponel page(s) if necessary. (For section I and Section II.)         PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. NO other changes have be of Formula for this product. (see next page)         Section - III	Environmental Protection Agency Washington, DC 20460       Amendment Other         Application for Pesticide - Section I         er       2. EPA Product Manager Sheryl Reilly         ei       PM# 9 2         eide Technical Powder       PM# 9 2         pplicent (Include ZIP Code)       6. Expedited Review. In accordance with (b)(i), my product is similar or identical in con to:         poration       EPA Reg. No.         is is a new address       Product Name         Section - II       Met Too" Application Edited Review dated         in below.       Final printed labels in respon NGTIFI         in below.       Final printed labels in respon NGTIFI         in below.       Other - Explain below         Product Name       Other - Explain below         Previewed Ba       Other - Explain below

Notification of Storage and Disposal Statement (PR Notice 2007-4) for DiPel Technical Powder, EPA Reg. No. 73049-12 (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.

1 under Doina Bujor Regulatory manager

April 9, 2009

3

000 0000

.....



1"

April 9, 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: DiPel Technical Powder (EPA Reg. No. 73049-12) Notification

Dear Ms. Reilly:

Valent BioSciences Corporation is submitting a notification for DiPel Technical Powder (EPA Reg. No. 73049-12) 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 container.

0000

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.

Sincere

Doina Bujor / Regulatory Manager

This FSC and SFI certified paper contains 10% recycled post-consumer waste.

## NOTIFICATION

# DIPEL<sup>®</sup> BIOLOGICAL INSECTICIDE TECHNICAL POWDER

Date Reviewed: <u>5-12-09</u> Reviewed By: <u>D. Huds</u>en 5/

## FOR MANUFACTURING USE ONLY

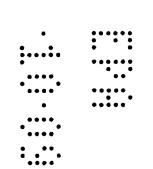
Active Ingredient:	•
Bacillus thuringiensis subsp. kurstaki, strain ABTS-351, ferr	nentation solids, spores and
insecticidal	_
toxins	91% w/w
Inert Ingredients	
Total	

The percentage active ingredient does not indicate product performance.

EPA Registration No. 73049-12 EPA Est. No. 33762-IA-1 Lot No.:

Valent BioSciences Corporation 870 Technology Way Libertyville, IL 60048

Net Contents:



### KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID				
If in eyes:	Hold eyes 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 advise.			
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 advise.			

### **HOT LINE NUMBER**

Have the product container 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.

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

### **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. DiPel Technical Powder is used in the formulation of end-use products registered for use on terrestrial and greenhouse raw agricultural commodities, as well as stored agricultural commodities, turf and forestry. This product may be used to formulate products for any additional use(s) not listed on the For Manufacturing Use label if the formulator, user group, or grower has complied with US EPA requirements regarding support of such use(s).

#### STORAGE AND DISPOSAL

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

**Storage**: Reclose containers of unused DiPel Technical Powder. Store in a dry place inaccessible to children and out of sunlight.

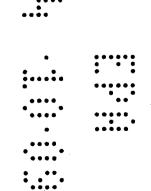
**Pesticide Disposal**: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**Container Disposal**: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Completely empty liner by 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. 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.

<sup>©</sup>2009



DiPel TP/notification/04-04-09/dmb