

73049-14

06/09/2009

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

June 9, 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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

RE: Product Name: Dipel 10G Biological Insecticide Granules
EPA Reg. No: 73049-14
Application for Label Notification Dated April 15, 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 a 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 letter submitted with this application has been stamped "Notification, received and reviewed" and will be placed accordingly in our records.

If you have any questions concerning this action, please contact 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)

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April 15, 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 10G (EPA Reg. No. 73049-14) Notification

Dear Ms. Reilly:

Valent BioSciences Corporation is submitting a notification for DiPel 10G (EPA Reg. No. 73049-14) 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.

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



United States
Environmental Protection Agency
Washington, DC 20460

<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 73049-14	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) DiPel 10G	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 <u>NOTIFICATION</u>	

Section - II

Date Reviewed: 6-9-09

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels reviewed	Reviewed By: <u>D. Hudson</u>
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> Agency letter dated _____	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> "Me Too" Application.	
	<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 type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" 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 _____		

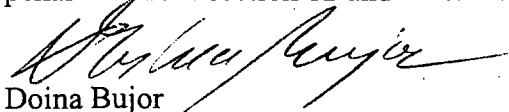
Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Doina Bujur		Title Regulatory Manager		Telephone No. (Include Area Code) 847-958-4724	
<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 			3. Title Regulatory Manager		
4. Typed Name Doina Bujur			5. Date Apr 15, 2009		

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Notification of Storage and Disposal Statement (PR Notice 2007-4) for DiPel 10G, EPA Reg. No. 73049-14 (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

April 15, 2009


s/a

**DIPEL® 10G
BIOLOGICAL INSECTICIDE
GRANULES**

NOTIFICATION

Date Reviewed: 6-9-09

Reviewed By: D. Hudson

 For Organic Production

Active Ingredient:

<i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> strain ABTS-351 fermentation solids, spores, and insecticidal toxins.....	2.3%
Other Ingredients.....	97.7%
Total.....	100.0%

Potency: 1600 Cabbage Looper Units of Potency per mg or 0.726 Billion Cabbage Looper Units/lb.

The percent 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

EPA Reg. No. 73049-14
EPA Est. No. 33762-IA-1

Lot No: _____

FIRST AID	
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 -m 20 minutes • Call a poison control center or doctor for 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.
HOTLINE NUMBER	
Have the product container or labels 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.	

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NOP review HEM

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PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)
CAUTION

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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 and wash contaminated clothing before reuse.

Personal Protective Equipment

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Follow manufacturers instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Mixers/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 high microbial of microbial proteins can cause allergic sensitization.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco products or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate.

This product must not be applied aerially within ¼ mile of any habitats of endangered species or threatened lepidoptera. No manual application can be made within 300 feet of any threatened or endangered lepidoptera.

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DIRECTIONS FOR USE

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

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or tribal agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Shoes plus socks
- Waterproof gloves

STORAGE AND DISPOSAL

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

Storage: Store in a cool, 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. If recycling is not available, dispose of empty bag in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Deleted: Completely empty bag into application equipment. Then

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GENERAL INFORMATION

DiPel 10G is a granular formulation of *Bacillus thuringiensis* variety *kurstaki*, designed specifically as a selective insecticide for control of certain leaf-eating caterpillars (Lepidoptera). For practical determinations of active ingredient, DiPel 10G can be expressed as a 10% formula of DiPel WP. The active ingredient in DiPel 10G is a stomach poison and therefore must be

eaten by larvae to be effective. Climatic extremes such as heavy rain or strong wind shortly after treatment may act to remove DiPel 10G from the feeding zone making re-treatment necessary.

NOTICE

Local conditions may affect the use of DiPel 10G. Consult State Agricultural Extension or Experiment Station Specialists for specific recommendations related to local crop protection problems. Abbott makes no warranty, express or implied, including the warranties of commercially acceptable quality and/or fitness for any particular purpose concerning this material, other than those which are contained on this label.

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APPLICATION

Crop	Pest	Rate	Comments
Seed Corn, Field Corn, Popcorn and Sweet Corn	European Corn Borer, (<i>Ostrinia nubilalis</i>), First and Second Generation	10 lbs/acre	<p>Ground or aerial equipment First Generation: Apply DiPel 10G directly to corn whorls. Treat seed corn when 25 percent of plants show shot hole feeding in the whorls and field corn when 35 percent of whorls show feeding. Larvae should be small and present at this time. Satisfactory control cannot be expected if treatment is delayed to higher injury levels or after larvae have begun stalk boring. Second Generation: Apply DiPel 10G when a field count shows 50 egg masses per 100 plants and the first hatch is occurring or follow your State Extension Service recommendation. Under conditions of intensive population pressure, a second application may be necessary. Ground or aerial equipment Apply DiPel 10G directly to corn whorls. Treat sweet corn when 10-12 percent of plants show feeding in the whorls. Field corn should be treated when 75 percent of the plant whorls show feeding damage. Treatment thresholds vary for different types of corn so consult State Agricultural Extension specialists for specific recommendations. Under high pest pressure, a second application may be necessary.</p>
	Southwestern Corn Borer (<i>Diatraea grandiosella</i>)	5-10 lbs/acre banded over-row with ground application	
	Fall Armyworm (<i>Spodoptera frugiperda</i>)	10 lbs/acre	
Tobacco	Tobacco Budworm (<i>Heliothis virescens</i>)	5-10 lbs/acre	Ground equipment Apply DiPel 10G by hand or properly calibrated mechanical ground equipment.

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all of these factors when making decisions.

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 risk of use, storage or handling not in strict accordance with accompanying directions.

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