





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

September 8, 2009

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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

RE:

Product Name: ABG-6345 Technical Powder

EPA Reg. No: 73049-27

Application for Label Notification Dated July 17, 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 <a href="https://numbers.ncbi.nlm.new.nd.new.new.nd.new.new.nd.new.n

Sincerely,

Sheryl K. Reilly

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

Please read instructions on n	everse before completi	ng form.	Form Appro	oved AB No. 20	70-0060	HIMELOIN	
<b>\$EPA</b>	Environmental	ited States Protection Age pton, DC 20460	ncy	Registra Amendr  Other		OPP Identifier Number	
Application for Pesticide - Section I							
1. Company/Product Number 73049-27			2. EPA Product Manager Sheryl Reilly				
<b>4. Company/Product (Name)</b> ABG-6345 Technical Powder			PM#92 X None Restricted				
5. Name and Address of Applicant (Include ZIP Code)  Valent BioSciences Corporation  870 Technology Way  Libertyville, IL 60048  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:  EPA Reg. No.  Product Name				
Section - II							
Amendment - Explain Resubmission in respo	Final printed labels in response to Agency letter date Date Reviewed: "Me Too" Application.  Other - Explain below. Reviewed By: D. Hudson						
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)							
		Sec	tion - III				
1. Material This Product Will	T'			· · · · · · · · · · · · · · · · · · ·			
Child-Resistant Packaging Yes*  No * Cartification must be submitted	Unit Packaging Yes X No If "Yes" Unit Packaging wgt,	No. per     Yes	Yes No No No. per ye wgt container		2. Type of Container  Metal Plastic Glass Paper Other (Specify)		
3. Location of Net Contents Information 4. Size(s) Retained  Label Container			5. Location of Label Directions On Label On Labeling accompanying product				
6. Manner in Which Label is Affixed to Product Lithograph Other Paper glued Stenciled							
		Sect	ion - IV				
1. Contact Point  Complete	items directly below for	r identification of indiv	idual to be contacted,	if necessary, to pr	ocess this	application.)	
Name Doina Bujor			Title Regulatory Manager		Telephone No. (Include Area Code) 847-968-4724		
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.  6. Date Application Received  (Stangped)							
2. Signature					000	0 (0 0	
Whole a present			ory Manager		, , , , , c c c c c c c c c c c c c c c	((C)) ((C))	
4. Typed Name	/ /	5. Date			ررردد		
Doina Bujor		Jul 17, 2	2009			<b>(</b>	

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Notification of Storage and Disposal Statement (PR Notice 2007-4) for ABG-6345 Technical Powder, EPA Reg. No. 73049-27 (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

July 17, 2009

Regulatory manager

July 17, 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: ABG-6345 Technical Powder (EPA Reg. No. 73049-27) Notification

Dear Ms. Reilly:

Valent BioSciences Corporation is submitting a notification for ABG-6345 Technical Powder (EPA Reg. No. 73049-27) 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.

Singerely,

Doina Bujor

Regulatory Manager

NOTIFICATION

Date Reviewed: 9-8-09
Reviewed By: D. Hudso

# **ABG-6345 BIOLOGICAL INSECTICIDE** TECHNICAL POWDER

## FOR MANUFACTURING USE ONLY

EPA Registration No. 73049-27

EPA Est. No. 33762-IA-1

Active Ingredient:	
Bacillus thuringiensis, subsp. kurstaki, strain ABTS-351, fermentation solids and solu-	
bles	.0%
Other Ingredients:	.0%
Total:	0.09
Potency: 34,000 International Units per mg/64,000 cabbage looper units per mg of product of 15.4 billion International Units/29 billion cabbage looper units per pound of product.	r
There is no direct relationship between intended activity (potency) and the Percent Active Ingdient by Weight.	gre
KEEP OUT OF REACH OF CHILDREN CAUTION	
Valent BioSciences Corporation 870 Technology Way, Suite 100 Libertyville, IL 60048	

Lot No.:

FIRST AID				
If in eyes	Hold dye 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.			
<u></u>	• 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 min-			
	utes.			
	Call a poison control center or doctor for treatment			
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 HUMAN AND DOMESTIC ANIMALS CAUTION

Harmful if swallowed, inhaled, or absorbed through the skin. 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. Manufacturing operators must at a minimum wear a dust mask when handling this product.

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 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. ABG-6345 Technical Powder is intended for formulation into end-use products for terrestrial and greenhouse food crop uses as well as tobacco and turf.

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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 U.S. 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 ABG-6345 Technical Powder. Store in a dry place inaccessible to children and out of sunlight.

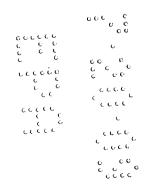
**Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

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.

®2009



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