



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: ABG-6346 Biological Insecticide
EPA Reg. No: 73049-28
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 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	<input type="checkbox"/> Registration	OPP Identifier Number
		<input type="checkbox"/> Amendment	
		<input checked="" type="checkbox"/> Other	

Application for Pesticide - Section I

1. Company/Product Number 73049-28	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) ABG-6346 Biological Insecticide	PM# <u>92</u>	
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

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION Date Reviewed: <u>9-15-09</u> Reviewed By: <u>D. Hudson</u>
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<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:				2. Type of Container	
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		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
		If "Yes" Package wgt	No. per container	<input type="checkbox"/> Other (Specify) _____	
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 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 (Stamped)
2. Signature 	3. Title Regulatory Manager	
4. Typed Name Doina Bujor	5. Date Jul 17, 2009	

Notification of Storage and Disposal Statement (PR Notice 2007-4) for ABG-6346, EPA Reg. No. 73049-28 (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 17, 2009



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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-6346 Biological Insecticide (EPA Reg. No. 73049-28) Notification

Dear Ms. Reilly:

Valent BioSciences Corporation is submitting a notification for ABG-6346 (EPA Reg. No. 73049-28) 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.

Sincerely,



Doina Bujor
Regulatory Manager

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NOTIFICATION

Date Reviewed: 9-15-09

Reviewed By: D. Hudson

**ABG-6346
BIOLOGICAL INSECTICIDE
TECHNICAL POWDER**

FOR MANUFACTURING USE ONLY

Active Ingredient:

<i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain ABTS 1857, fermentation solids, spores, and insecticidal toxins.....	83%
Other Ingredients:.....	17%
Total.....	100%

Potency: 21,000 Diamond Back Moth Units per mg of product or 9.51 Billion Diamond Back Moth Units per pound of product.

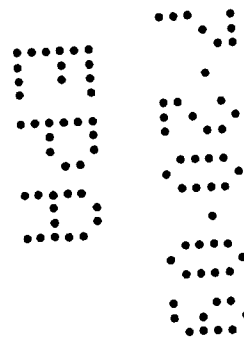
The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

**KEEP OUT OF REACH OF CHILDREN
DANGER**

Valent BioSciences Corporation
870 Technology Way, Suite 100
Libertyville, IL 60048

EPA Registration No. 73049-28
EPA Est. No. 33762-IA-1

Lot No.: _____



FIRST AID	
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.
If on skin or clothing	<ul style="list-style-type: none"> • 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	
<p>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.</p>	
NOTE TO PHYSICIAN	
<p>Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

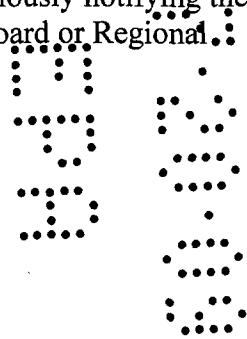
**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
DANGER**

Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

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 public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.



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STORAGE AND DISPOSAL

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

Storage: Reclose containers of unused ABG-6346 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 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.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling. ABG-6346 Technical Powder is intended for formulation into end-use products for terrestrial and greenhouse food crop uses as well as tobacco and turf.

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

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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