

73049-57

09/29/2009

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

September 29, 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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

RE: Product Name: Vectolex WDG Biological Larvicide
EPA Reg. No: 73049-57
Application for Label Notification Dated July 15, 2009 to Update Storage and
Disposal Statement in 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.

If you have any questions concerning this action, please feel free to 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)



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 73049-57	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VECTOLEX WDG	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: 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: 9-29-09 Reviewed By: D. Hudson
<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 checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" 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 <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 lb, 25 lb		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 <i>Doina Bujor</i>	3. Title Regulatory Manager	
4. Typed Name Doina Bujor	5. Date Jul 15, 2009	

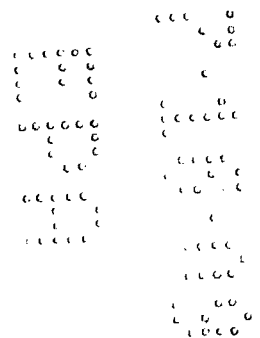
Notification of Storage and Disposal Statement (PR Notice 2007-4) for VectoLex WDG,
EPA Reg. No. 73049- 57 (continuation from the previous page)

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

07-15-2009





July 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: VectoLex® WDG (EPA Reg. No. 73049-57) Notification

Dear Ms. Reilly:


Valent BioSciences Corporation is submitting a notification for VectoLex WDG (EPA Reg. No. 73049-57) in accordance with PR Notice 2007-4. The changes made to the label are to the Storage and Disposal statement and include the changes to the container disposal language required by the PR Notice 2007-4.

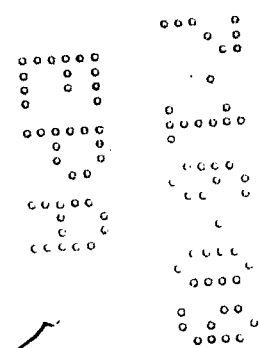
Present submission consists of:

- 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



Date Reviewed: 9-29-09

Reviewed By: D. Hudson

VECTOLEX® WDG
BIOLOGICAL LARVICIDE

Active Ingredient:

<i>Bacillus sphaericus</i> Serotype H5a5b, Strain 2362 dried concentrate	51.2% w/w
Other Ingredients.....	48.8% w/w
Total.....	100.0% w/w

Potency: This product contains 650 BsITU/mg or 0.299 Billion BsITU/lb.

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

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

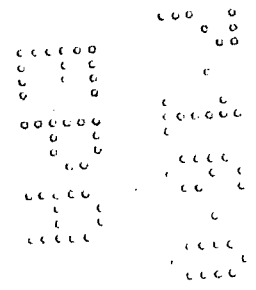
Valent BioSciences Corporation
870 Technology Way, Suite 100
Libertyville, IL 60048

EPA Reg. No. 73049-57
EPA Est. No. 33762-IA-1

Batch Code: _____

Net Contents:

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. <p>Call a poison control center or doctor for treatment advice.</p>
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 1-877-315-9819 for emergency medical treatment and/or transport emergency information. For all other information, call 1-800-323-9597.	



**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)
CAUTION**

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

Mixer/loaders and applicators not in enclosed cabs or aircraft 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 contaminate water when cleaning equipment or disposing of equipment washwaters.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply directly to treated finished drinking water reservoirs or drinking water receptacles.

Chemigation

Do not apply this product through any type of irrigation system.

STORAGE AND DISPOSAL

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

Storage:

Store in cool [59-86° F (15-30° C)], 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:

Rigid container: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after flow begins to drip. Repeat this procedure two more times. Once cleaned, offer container for recycling, if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Non-rigid container: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available.

APPLICATION DIRECTIONS

Do not apply when wind speed favors drift beyond the area of treatment.

I. For control of mosquito larvae species* in the following non-crop sites.

Habitats

Rate Range

Wastewater:

Sewage effluent, sewage lagoons, oxidation ponds, septic ditches, animal waste lagoons, impounded wastewater associated with fruit and vegetable processing

.5-1.5 lbs/acre
(8oz-24oz/acre)

Stormwater/Drainage Systems:

Storm sewers, catch basins, drainage ditches, retention, detention and seepage ponds

.5-1.5 lbs/acre
(8oz-24oz/acre)

Marine/Coastal Areas:

Salt marshes, mangroves, estuaries

.5-1.5 lbs/acre
(8oz-24oz/acre)

Water Bodies:

Natural and manmade aquatic sites such as lakes, ponds, rivers, canals and streams

.5-1.5 lbs/acre
(8oz-24oz/acre)

Habitats

Rate Range

Dormant Rice Fields:

.5-1.5 lbs/acre
(8oz-24oz/acre)

Impounded water in dormant rice fields (For application only during the interval between harvest and preparation of the field for the next cropping cycle)

II. For control of mosquito larvae species* in agricultural/crop sites where mosquito breeding occurs.

Habitats

Rate Range

Rice, pastures/hay fields, orchards, citrus groves, irrigated crops.

.5-1.5 lbs/acre
(8oz-24oz/acre)

Use higher rates (1 to 1.5 lbs/acre) in areas where extended residual control is necessary, or in habitats having deep water or dense surface cover.

Apply uniformly by aerial or conventional ground equipment. Reapply as needed after 1-4 weeks.

*Mosquito species effectively controlled by VectoLex WDG.

Culex spp.

Psorophora columbiae

Aedes vexans

Psorophora ferox

Aedes melanimon

Aedes triseriatus

Aedes stimulans

Aedes sollicitans

Aedes nigromaculis

Anopheles quadrimaculatus

Coquillettidia perturbans

GROUND AND AERIAL APPLICATION

VectoLex WDG may be applied using conventional ground or aerial application equipment with quantities of water sufficient to provide uniform coverage of the target area. For application, first add the VectoLex WDG to water to produce a final spray mixture.

The amount of water will depend on weather, spray equipment, and mosquito habitat characteristics. For application, fill the mix tank or plane hopper with the desired quantity of water. **Start the mechanical or manual agitation to provide moderate circulation of water before adding the VectoLex WDG.** Backpack and compressed air sprayers may be agitated by shaking after adding VectoLex WDG to the water in the sprayer. VectoLex WDG suspends readily in water and will stay suspended over normal application periods. Brief recirculation may be necessary if the spray mixture has sat for several hours or longer. Do not mix more VectoLex WDG than can be used in a 48 hour period. **AVOID CONTINUOUS AGITATION OF THE SPRAY MIXTURE DURING SPRAYING.**

For ground spraying, apply 8-24 oz./acre (227-680 g/acre) of VectoLex WDG in 5-100 gallons of water per acre using hand-pump, airblast, mist blower, or other spray equipment. For aerial application, apply 8-24 oz./acre (227-680 g/acre) of VectoLex WDG through fixed-wing or heli-

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copter aircraft equipped with either conventional boom and nozzle systems or rotary atomizers at a convenient dilution rate. For aerial application, apply 0.5-10 gallons/acre of the final spray mixture to provide uniform coverage of the target area.

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 spray drift. The applicator and treatment coordinator are responsible for considering all these factors.

Rinse and flush spray equipment thoroughly following each use.

Amount of VectoLex WDG needed to treat small areas:

Area to Treat	Rate of VectoLex WDG/Acre		
	8 oz	16 oz	24 oz
¼ Acre	2 oz	4 oz	6 oz
½ Acre	4 oz	8 oz	12 oz
10 Acres	5 lb	10 lb	15 lb
20 Acres	10 lb	20 lb	30 lb

NOTICE TO USER

Seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning 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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