

73049-57

05/12/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MAY 12 2010

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 Notification Dated: 11/24/2009 to update and change the source of the inert ingredients suppliers; and application for Label Notification dated 01/12/2010 to add alternate names for pests per PR Notice 98-10 and 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 label submitted with this application has been stamped as "Notification, received and accepted" and will be placed accordingly in our records.

Questions concerning this action should be directed to Mary Paden (703) 308-0411 or email at paden.mary@epa.gov.

Sincerely,

Sheryl K. Reilly

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

MAY 12 2010

CONCURRENCES

| | | | | | | | |
|---------|-----------|--|--|--|--|--|--|
| SYMBOL | 7511(P) | | | | | | |
| SURNAME | Paden | | | | | | |
| DATE | 12 MAY 10 | | | | | | |



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|--|---|---|
| 1. Company/Product Number 73049-57 | 2. EPA Product Manager S. Reilly | 3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) VectoLex WDG Biological Larvicide | PM# 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: Notification Accepted <input checked="" type="checkbox"/> EPA Reg. No. _____ Date: <u>05/12/2010</u> Product Name _____ | |

Section - II

| | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <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 'Product Chemistry, Inert Ingredient, Change Source' per PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. (continue on 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 <input type="checkbox"/> Glass <input 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 | 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 both under applicable law. | | 8. Date Application Received (Stamped) |
| 2. Signature | 3. Title Regulatory Manager | |
| 4. Typed Name Doina Bujor | 5. Date Nov 24, 2009 | |



January 12, 2010

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 98-10, Other Revisions. The changes made are adding the alternate name for pests already approved. These alternate names were on the 2003 stamped approved label but were lost in the notification for PR Notice 2007-4.

Aug 6, 2003

Sept 29, 2009

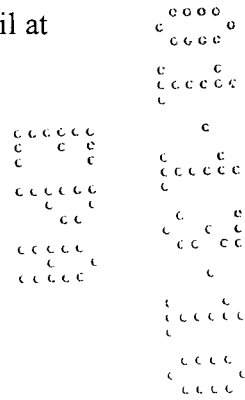
Present submission consists of:

- 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 Accepted

VECTOLEX® WDG
BIOLOGICAL LARVICIDE

Date: 05/12/2010

Reviewer: *M. J. Baker*

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 | |
| <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 1-877-315-9819 for emergency medical treatment and/or transport emergency information. For all other information, call 1-800-323-9597.</p> | |

**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

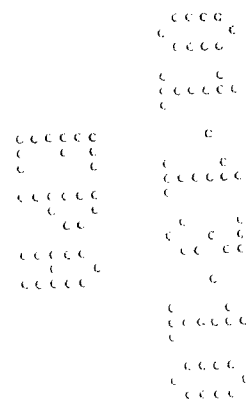
Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

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:

.5-1.5 lbs/acre

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

(8oz-24oz/acre)

Stormwater/Drainage Systems:

.5-1.5 lbs/acre

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

(8oz-24oz/acre)

Marine/Coastal Areas:

.5-1.5 lbs/acre

Salt marshes, mangroves, estuaries

(8oz-24oz/acre)

Water Bodies:

.5-1.5 lbs/acre

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

(8oz-24oz/acre)

Habitats

Rate Range

Dormant Rice Fields:

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

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

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.

Aedes vexans

Ochlerotatus melanimon (*Aedes melanimon*)

Ochlerotatus stimulans (*Aedes stimulans*)

Ochlerotatus nigromaculis (*Aedes nigromaculis*)

Psorophora columbiae

Psorophora ferox

Ochlerotatus triseriatus (*Aedes triseriatus*)

Ochlerotatus sollicitans (*Aedes sollicitans*)

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 helicopter 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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