

73049-20

07/24/2008

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

July 24, 2008

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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

RE: Product Name: Vectolex CG Biological Larvicide
EPA Reg. No: 73049-20
Application for Label Notification Dated June 3, 2008 to Revise the Container
Disposal Language per PRN 2007-4

Dear Ms. Bujor:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under 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 "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,

Linda Hollis

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)



870 TECHNOLOGY WAY
LIBERTYVILLE, IL 60048 - 800-323-9597

June 3, 2008

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 CG (EPA Reg. No. 73049-20) Notification

Dear Ms. Reilly:

Valent BioScience Corporation is submitting a notification for VectoLex CG (EPA Reg. No. 73049-20) in accordance with PR Notice PR Notice 98-10. The changes made to the label are to the Storage and Disposal statement and include additional methods of disposal if the recycling is not available. These methods were removed by error when the recycling method was added per PR Notice 2007-4.

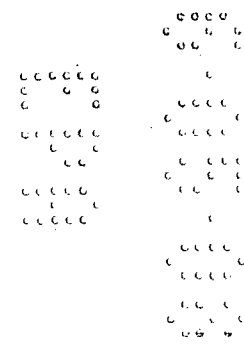
Present submission consists of:

- 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





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 73049-20	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VECTOLEX CG BIOLOGICAL LARVICIDE	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 _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION Date Reviewed: <u>7-24-08</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 of Storage and Disposal Statement (PR Notices 83-3 and 83-1) per PR Notice 1998-10. 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 labeling or the confidential statement of formula of this product.

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 checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Metal <input 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
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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 Jun 3, 2008	

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 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	
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 (24 hours) 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

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.

Mixers/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 sensitizations.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment wash waters or rinsate.

DIRECTIONS FOR USE

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

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STORAGE AND DISPOSAL

Do not contaminate potable water, food or feed by storage or disposal. Do not contaminate potable water when disposing of equipment wash waters.

PESTICIDE STORAGE: Store in a cool, dry place.

PESTICIDE DISPOSAL: Completely empty bag into application equipment. 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 this container. Offer for recycling, if available. Completely empty bag into application equipment then 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.

DIRECTIONS FOR USE – VECTOLEX CG

APPLICATION DIRECTIONS

MOSQUITO CONTROL

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

<u>Habitat</u>	<u>Rate Range</u>
Wastewater: Sewage effluent, sewage lagoons, oxidation ponds, septic ditches animal waste lagoons, impounded wastewater associated with fruit and vegetable processing.	5-20 lbs/acre**
Storm water/Drainage Systems: Storm sewers, catch basins, drainage ditches, retention, detention, and seepage ponds.	5-20 lbs/acre**
Marine/Coastal Areas: Salt marshes, mangroves, estuaries.	5-20 lbs/acre**
Water Bodies: Natural and manmade aquatic sites such as lakes, ponds, rivers, canals, streams, and livestock watering ponds and troughs.	5-20 lbs/acre**

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.) 5-20 lbs/acre**

Waste Tires:

Tires stockpiled in dumps, landfills, recycling plants, and other similar sites. 20-80 lbs/acre⁽¹⁾

⁽¹⁾ .5-2 lbs/1000 sq. ft.

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

Habitats:

Rice, pastures/hay fields, orchards, citrus groves, irrigated crops. 5-20 lbs/acre**

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

*Mosquito species effectively controlled by VectoLex CG:

- 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*

** Use higher rates (10 to 20 lbs/acre) in areas where extended residual control is necessary, or in habitats having deep water or dense surface cover.

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 treatment coordinator are responsible for considering all 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 risks of use, storage or handling not in strict accordance with accompanying directions.

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Faint, illegible text located at the bottom right of the page, likely bleed-through from the reverse side.

Sub Label

For

Alternate Brand Name

VectoLex Water Soluble Pouch (WSP)

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VECTOLEX WSP
Water Soluble Pouches
Biological Larvicide

ACTIVE INGREDIENT:

<i>Bacillus sphaericus</i> Serotype H5a5b, strain 2362 Technical Powder (670 /BsITU/mg).....	7.5%
OTHER INGREDIENTS.....	92.5%
TOTAL.....	100.0%

Potency: This product contains 50 BsITU/mg or 0.023 Billion BsITU/lb
Expiration Date: (Two years from date of manufacture).

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. 73049-20
EPA Est. 33762-1A-1

Batch Code _____

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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 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 1-877-315-9819 (24 hours) 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

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.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment wash waters or rinsate.

DIRECTIONS FOR USE

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

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STORAGE AND DISPOSAL

Do not contaminate potable water, food or feed by storage or disposal. Do not contaminate potable water when disposing of equipment wash waters.

PESTICIDE 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 this container. Offer for recycling, if available. For Water Soluble Pouches, dispose of empty outer foil bag in trash.

DIRECTIONS FOR USE – VECTOLEX WATER SOLUBLE POUCHES (WSP)

Once the foil bag containing Water Soluble Pouches is opened, use pouches within one day.

APPLICATION DIRECTIONS

MOSQUITO CONTROL

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

<u>Habitat</u>	<u>Rate Range</u>
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Drainage/Drainage Systems:

Storm drains, catch basins, retention, detention, and seepage ponds.

1 pouch/50 sq. ft⁽¹⁾

⁽¹⁾Treat on basis of surface area of potential mosquito breeding sites by placing one (1) VectoLex Soluble Pouch for up to 50 square feet of treatment area. Re-apply as needed after 1 to 4 weeks.

*Mosquito species effectively controlled by VectoLex WSP:

- Culex* spp.
- Aedes vexans*
- Ochlerotatus melanimon* (*Aedes melanimon*)
- Ochlerotatus stimulans* (*Aedes stimulans*)
- Ochlerotatus nigromaculis* (*Aedes nigromaculis*)
- Psorophora columbiae*
- Psorophora ferox*

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Ochlerotatus triseriatus (*Aedes triseriatus*)
Ochlerotatus sollicitans (*Aedes sollicitans*)
Anopheles quadrimaculatus
Coquilleidia perturbans

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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