

73049-20

02/19/2009

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

February 19, 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 CG BIOLOGICAL LARVICIDE
EPA Reg. No: 73049-20
Application for Label Notification Dated January 19, 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 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 "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)

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060



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: 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 _____
<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 _____

Date Reviewed: 2-19-09
Reviewed By: D. Hudson

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
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<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 of 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 January 19, 2009	

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January 19, 2009

Sheryl Reilly
 Pesticides & Pollution Prevention Division
 Document Processing Desk (NOTIF)
 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 BioSciences Corporation is submitting the present notification for VectoLex CG (EPA Reg. No. 73049-20) in accordance with PR Notice 2007-4. The changes made to the last stamped approved label and are made to the Storage and Disposal statement.

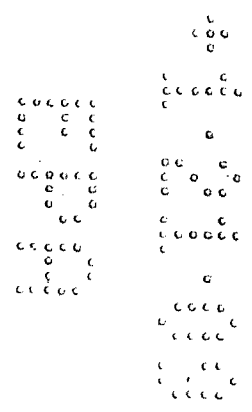
Present submission consists of:

- 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
 Doina Bujor
 Regulatory Manager



5/20

NOTIFICATION

VECTOLEX CG

Date Reviewed: 2-19-09

Biological Larvicide

Reviewed By: D. Hudson

(MASTER LABEL)

ACTIVE INGREDIENT:

Bacillus sphaericus 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

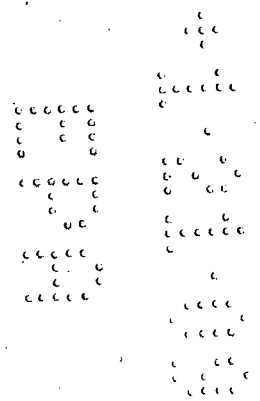
Valent BioSciences Corporation
870 Technology Way, Suite 100
Libertyville, IL 60048

Batch Code: _____

EPA Reg. No. 73049-20

EPA Est. 33762-1A-1

Lot No.



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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.

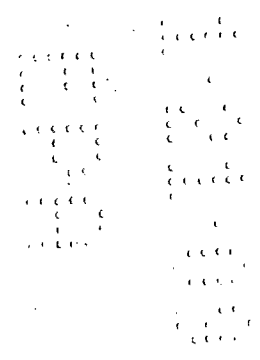
Repeated exposure to high concentrations of microbial proteins can cause allergic sensitizations.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment washwaters or rinsate. Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human consumption.

DIRECTIONS FOR USE

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



STORAGE AND DISPOSAL

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

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: Non refillable container. Do not reuse or refill 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.

For Water Soluble Pouches, dispose of empty outer foil bag in trash.

DIRECTIONS FOR USE – VECTOLEX CG

APPLICATION DIRECTIONS

MOSQUITO CONTROL

VectoLex CG is a selective microbial insecticide for use against mosquito larvae in a variety of habitats. VectoLex CG can be applied to areas that contain fish, other aquatic life, and plants. VectoLex CG can be applied to areas used by or in contact with humans, pets, horses, livestock, birds, or wildlife.

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

Habitat	Rate Range
<p>Wastewater: Sewage effluent, sewage lagoons, oxidation ponds, septic ditches animal waste lagoons, impounded wastewater associated with fruit and vegetable processing.</p>	5-20 lbs/acre**
<p>Stormwater/Drainage Systems: Storm sewers, catch basins, drainage ditches, retention, detention, and seepage ponds.</p>	5-20 lbs/acre**

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

1 pouch/50 sq. ft⁽¹⁾

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⁽²⁾

⁽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.

⁽²⁾ .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 malanimon*)

Ochlerotatus stimulans (*Aedes stimulans*)

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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

To the fullest extent permitted by law, 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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Sub Label A

For

Alternate Brand Name

Vectolex Water Soluble Pouch (WSP)

RECEIVED
VICTOR
10/20/2009
10/20/2009

11/20

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.

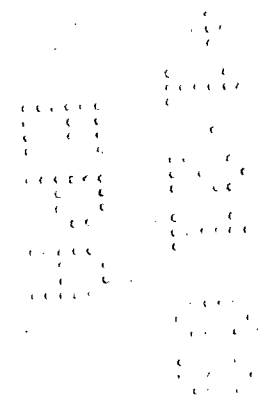
KEEP OUT OF REACH OF CHILDREN
CAUTION

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

Batch Code: _____

EPA Reg. No. 73049-20
EPA Est. 33762-1A-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 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 washwaters or rinsate. Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human consumption.

DIRECTIONS FOR USE

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

STORAGE AND DISPOSAL

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

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: Non refillable container. Do not reuse or refill 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.

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

VectoLex WSP is a selective microbial insecticide for use against mosquito larvae in a variety of habitats. VectoLex WSP can be applied to areas that contain fish, other aquatic life, and plants. VectoLex WSP can be applied to areas used by or in contact with humans, pets, horses, livestock, birds, or wildlife.

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

<u>Habitat</u>	<u>Rate Range</u>
----------------	-------------------

Drainage/Drainage Systems:

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

1 pouch/50 sq. ft.⁽¹⁾

Treatment Areas (For Use In)⁽¹⁾:

Ponds

Lagoons

Water gardens

Bird baths

Fountains

Flower pots and planters

Hollow trees and tree holes
 Urns
 Rain barrels
 Livestock watering troughs/ponds/tanks
 Irrigation ditches
 Roadside ditches
 Flood water
 Standing water
 Storm water retention areas
 Catch basins

Snow melt pools
 Abandoned swimming pools
 Unused swimming pools or spas
 Flooded basements
 Pool covers
 Gutters and drains
 Wheelbarrows
 Garbage cans and covers
 Discarded tires

Any location where water accumulates and remains standing for periods of time, except treated, finished drinking water for human consumption.

(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.

Longer periods of mosquito population suppression may result where sufficient numbers of non-target aquatic invertebrate parasites and predators are present since these are not affected by the product and contribute to mosquito population reduction.

*Mosquito species effectively controlled by VectoLex WSP, including many of those known to carry/transmit West Nile virus:

- Culex* spp.
- Aedes vexans*
- Ochlerotatus melanimon* (*Aedes malanimon*)
- Ochlerotatus stimulans* (*Aedes stimulans*)
- Ochlerotatus nigromaculis* (*Aedes nigromaculis*)
- Psorophora columbiae*
- Psorophora ferox*
- Ochlerotatus triseriatus* (*Aedes triseriatus*)
- Ochlerotatus sollicitans* (*Aedes sollicitans*)
- Anopheles quadrimaculatus*
- Coquillettidia perturbans*

NOTICE TO USER

To the fullest extent permitted by law, 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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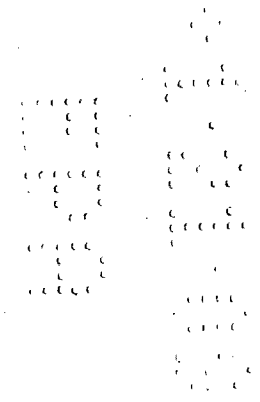
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Sub Label B

For

Residential Use Applications

Vectorex CG



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Sublabel B: Residential Use

VECTOLEX CG
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

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

Batch Code: _____

EPA Reg. No. 73049-20
EPA Est. 33762-1A-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 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.	

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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. Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human consumption.

DIRECTIONS FOR USE

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

STORAGE AND DISPOSAL

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

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: Non refillable container. Do not reuse or refill this container. Offer for recycling if available. Completely empty, 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

VectoLex CG is a selective microbial insecticide for use against mosquito larvae in a variety of habitats. VectoLex CG can be applied to areas that contain fish, other aquatic life, and plants. VectoLex CG can be applied to areas used by or in contact with humans, pets, horses, livestock, birds, or wildlife.

For control of mosquito larvae species* in the following sites:

Mosquitoes

Treatment Areas (For Use In):

- | | |
|--|--------------------------------|
| Ponds | Standing water |
| Lagoons | Storm water retention areas |
| Water gardens | Catch basins |
| Bird baths | Snow melt pools |
| Fountains | Abandoned swimming pools |
| Flower pots and planters | Unused swimming pools or spas. |
| Hollow trees and tree holes | Flooded basements |
| Urns | Pool covers |
| Rain barrels | Gutters and drains |
| Livestock watering troughs/ponds/tanks | Wheelbarrows |
| Irrigation ditches | Garbage cans and covers |
| Roadside ditches | Discarded tires |
| Flood water | |

Any location where water accumulates and remains standing for periods of time, except treated, finished drinking water for human consumption.. Re-apply as needed after 1 to 4 weeks.

How to Apply

Directions for Bulk Granule:

Treats up to 2,178 square feet

Specific Directions:

Sprinkle 1 pound to cover 2,178 square feet.

(Sprinkle ½ pound per 1,089 square feet)

(Sprinkle ¼ pound per 544 square feet) (¼ pound = ½ cup = 4 ounces = 8 tablespoons)

(Sprinkle 1/8 pound per 272 square feet) (1/8 pound = ¼ cup = 2 ounces = 4 tablespoons)

Uniformly apply VectoLex CG with a 1 - 4 week interval between applications. Longer periods of mosquito population suppression may result where sufficient numbers of non-target aquatic invertebrate parasites and predators are present since these are not affected by the product and contribute to mosquito population reduction.

*Mosquito species effectively controlled by VectoLex CG, including many of those known to carry/transmit West Nile virus:

Culex spp.

Aedes vexans

Ochlerotatus melanimon (*Aedes malanimon*)

Ochlerotatus stimulans (*Aedes stimulans*)

Ochlerotatus nigromaculis (*Aedes nigromaculis*)

Psorophora columbiae

Psorophora ferox

Ochlerotatus triseriatus (*Aedes triseriatus*)

Ochlerotatus sollicitans (*Aedes sollicitans*)

Anopheles quadrimaculatus

Coquillettidia perturbans

NOTICE TO USER

To the fullest extent permitted by law, 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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Optional Label Claims

- Biological Mosquito Control
- Mosquito Biolarvicide Granule
- Highly selective microbial larvicide
- Highly selective microbial larvicide
- Targets mosquitoes in their breeding habitats
- Reduces the number of adult mosquitoes developing
- When ingested by mosquito larvae, VectoLex prevents larvae from becoming (developing into) breeding, biting adults.
- When ingested by mosquito larvae, VectoLex prevents the development of adults.
- Kills mosquito larvae upon ingestion.
- Kills mosquito larvae upon ingestion of Bsp toxins.
- Kills mosquito larvae upon ingestion by destroying the insect digestive tract.
- Kills developing mosquitoes (mosquito larvae) including those that may (are known to) transmit (carry) West Nile virus and other mosquito-borne diseases.
- Kills developing mosquitoes (mosquito larvae) including those that may (are known to) transmit (carry) West Nile virus, encephalitis, and equine encephalitis.
- Kills developing mosquitoes (mosquito larvae) including those that may (can) (are known to) transmit (carry) heartworm disease to dogs and cats.
- Apply in water where mosquitoes may breed; see label for specific use sites
- Easy to use
- (Quickly) Controls exposed mosquito larvae in (within) 24 hours
- Up to 4 weeks between applications
- Biodegradable components

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