

73049-20

3/14/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D C 20460

MAR 14 2011

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Ms Jayne Walz  
Registration Manager  
Valent Biosciences Corporation  
870 Technology Way  
Libertyville, IL 60048

Re Label Amendments for VectoLex CG, VectoLex WDG, and Bacillus sphaericus Slurry to Change the Active Ingredient Name to *Bacillus sphaericus* 2362 serotype H5a5b strain ABTS 1743 EPA Registration Nos 73049-20 73049-57, and 73049-65

Dear Ms Walz

The amendments referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) are acceptable and subject to the following comments

- 1) Submit updated Confidential Statements of Formula and corrected labels for the subject products within thirty (30) days
- 2) On the VectoLex WDG label, correct the spelling of Non-rigide container to read Non-rigid container
- 3) On page two (2) of the Vectolex CG master label, place the statement "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" Directly after the statement "Wash thoroughly with soap and water after handling" Additionally, replace the storage and disposal block on the residential use sublabel to read as follows

STORAGE AND DISPOSAL

Do not contaminate water food or feed by storage and disposal

Pesticide Storage Store in a cool dry place

Pesticide Disposal and Container Handling Nonrefillable container Do not reuse or refill this container If empty Place in trash and offer for recycling if available If partly filled Call your local solid waste agency or (800) 858 7378 (National Pesticide Information Center) for disposal instructions Never place unused product down any indoor or outdoor drain

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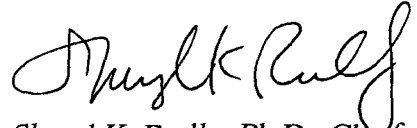
*M. Walz*

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Ms Jayne Walz  
EPA Registration Nos 73049-20, -57, -65

Submit five (5) copies of your final printed labeling before you release the amended products for shipment Your release for shipment of these products constitutes acceptance of these conditions A stamped copy of the label is enclosed for your records

Sincerely



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

Enclosures



| <b>FIRST AID</b>  |  |
|---|--|
| <b>If in eyes</b>   | <ul style="list-style-type: none"> <li>◦ Hold eye open and rinse slowly and gently with water for 15 – 20 minutes</li> <li>◦ Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye</li> <li>◦ Call a poison control center for treatment advice</li> </ul> |
| <b>If on skin or clothing</b>   | <ul style="list-style-type: none"> <li>◦ Take off contaminated clothing</li> <li>◦ Rinse skin immediately with plenty of water for 15 – 20 minutes</li> <li>◦ Call a poison control center or doctor for treatment advice</li> </ul>   |
| <b>HOT LINE NUMBER</b>  |  |
| <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

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

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Storm drains, catch basins, retention, detention, and seepage ponds 1 pouch/50 sq ft<sup>(1)</sup>

**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<sup>(2)</sup>

<sup>(1)</sup>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

<sup>(2)</sup> 0 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)**



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VECTOLEX WSP  
Water Soluble Pouches  
Biological Larvicide

ACTIVE INGREDIENT

|   |        |
|---|--------|
| <i>Bacillus sphaericus</i> 2362, Serotype H5a5b, strain ABTS 1743 Technical Powder<br>(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

Lot No

10/18

| <b>FIRST AID</b>  |  |
|---|--|
| <b>If in eyes</b>   | <ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye</li> <li>• Call a poison control center for treatment advice</li> </ul> |
| <b>If on skin or clothing</b>   | <ul style="list-style-type: none"> <li>• Take off contaminated clothing</li> <li>• Rinse skin immediately with plenty of water for 15 – 20 minutes</li> <li>• Call a poison control center or doctor for treatment advice</li> </ul>   |
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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 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

|         |            |
|---------|------------|
| Habitat | Rate Range |
|---------|------------|

**Drainage/Drainage Systems**

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

1 pouch/50 sq ft<sup>(1)</sup>

**Treatment Areas (For Use In)**<sup>(1)</sup>

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**

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Sub Label B  
For  
Residential Use Applications  
Vectolex CG

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**Sublabel B Residential Use**

VECTOLEX CG  
Biological Larvicide

**ACTIVE INGREDIENT**

*Bacillus sphaericus* 2362, Serotype H5a5b, strain ABTS 1743 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

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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

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**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*)
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- Ochlerotatus sollicitans* (*Aedes sollicitans*)
- Anopheles quadrimaculatus*
- Coquillettidia perturbans*

**NOTICE TO USER**

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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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