

73049-429

12-28-2007

1/10

Mr. Warren L. Smith
International Regulatory Manager
Valent BioSciences Corporation
870 Technology Way, Suite 100
Libertyville, IL 60048

DEC 28 2007

Subject: Valent BioSciences Corporation, V60035 CG
EPA Registration No. 73049-429
Label Amendments to add PATENT PENDING labeling, clarify habitat statements in the Directions for Use, clarify application timing, conditions, and rates in the Directions for Use, add an advisory statement directing the user to "minimize exposure of WSP to humidity", and add the alternate brand name, VectoMax WSP
Application Dated 10/12/2007

Dear Mr. Smith:

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(5), is acceptable provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of a final printed label.

In addition to the label amendments specified above, an error was noted and corrected in the Confidential Statement of Formula (CSF). The new CSF dated December 20, 2007 supersedes the previous CSF dated April 22, 2006 and will be filed in the Agency's records as the official CSF.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. If you have any questions contact Jeannine Kausch at 703-347-8920 or by email at: kausch.jeannine@epa.gov.

A stamped copy of the label is enclosed for your records.

Sincerely,

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

Enclosures

CONCURRENCES

SYMBOL	7511P	7511P	7511P				
SURNAME	KAUSCH	Reynolds	Reilly				
DATE	12/27/2007	12/28/07	12/28/07				

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V60035 CG BIOLOGICAL LARVICIDE

{Alternate Brand Names: VectoMax CG, V60035 Water Soluble Pouch (WSP),
VectoMax WSP}

MASTER LABEL

Sub-label A: VectoMax CG – Alternate Brand Name

Sub-label B: VectoMax WSP – Alternate Brand Name

Active Ingredients:

Bacillus sphaericus Serotype H5a5b, Strain 2362 Fermentation Solids, Spores,
and Insecticidal Toxins.....2.7%

Bacillus thuringiensis subsp. *israelensis* Serotype H-14, Strain AM65-52
Fermentation Solids, Spores, and Insecticidal Toxins.....4.5%

Other Ingredients.....92.8%

Total.....100.00%

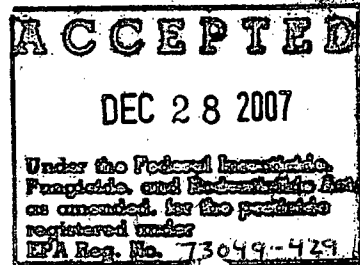
Potency: This product contains 50 BsITU/mg or 0.023 Billion BsITU/lb

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

EPA Registration No. 73049-429

EPA Est. No. 33762-IA-001

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



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VectoMax CG

Biological Larvicide

(Sub-label A)



For Organic Production

ACTIVE INGREDIENTS:

<i>Bacillus sphaericus</i> Serotype H5a5b, Strain 2362 Fermentation Solids, Spores, and Insecticidal Toxins.....	2.7%
<i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> Serotype H-14, Strain AM65-52 Fermentation Solids, Spores, and Insecticidal Toxins.....	4.5%
OTHER INGREDIENTS.....	92.8%
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

PATENT PENDING

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

EPA Reg. No. 73049-429

EPA Est. 33762-IA-001

Net Weight:

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 or doctor 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.
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further 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 inhaled or absorbed through the skin. Causes moderate eye irritation. Prolonged or frequent repeated skin contact may cause allergic reactions in some individuals. Avoid breathing dust. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

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 apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human consumption.

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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

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. Then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration. Do not burn, unless allowed by State and local ordinances.

DIRECTIONS FOR USE

APPLICATION DIRECTIONS

MOSQUITO CONTROL

VectoMax CG is a selective microbial insecticide for use against mosquito larvae in a variety of habitats. VectoMax CG can be applied to areas that contain fish, other aquatic life, and plants. VectoMax 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 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, roadside ditches, retention, detention, and seepage ponds.	5-20 lbs/acre*
Marine/Coastal Areas: Tidal water, salt marshes, mangroves, estuaries.	5-20 lbs/acre*

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Water Bodies:

Natural and manmade aquatic sites such as lakes, ponds, canals, rivers and streams (including river & stream edges), floodplains, swamps, marshes, irrigation ditches, flood water, woodland pools, snow melt pools and livestock watering ponds and troughs. 5-20 lbs/acre*

Waste Tires:

Tires stockpiled in dumps, landfills, recycling plants, and other similar sites. 20-80 lbs/acre¹

⁽¹⁾ 0.5 – 2 lbs / 1000 sq. ft.

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

Habitat	Rate Range
Rice fields, pastures/hay fields, orchards (including citrus groves, peaches, almonds, dates, walnuts), asparagus fields, corn fields, cotton fields, alfalfa fields, vineyards	5-20 lbs/acre*

Apply uniformly by aerial or conventional ground equipment. Reapply as needed (after 1-4 weeks under typical environmental conditions).

* Use higher rates (10 to 20 lbs/acre) in areas where 4th instar *Aedes* or *Ochlerotatus* spp. larvae predominate, or very high densities of late instar larvae are present, or under conditions where local experience indicates the need for higher rates to achieve extended residual control.

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.

Warranty and Disclaimer

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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V60035 WSP
Water Soluble Pouches
Biological Larvicide
{Alternate Brand Name: VectoMax WSP}

(Sub-label B)



For Organic Production

ACTIVE INGREDIENTS:

<i>Bacillus sphaericus</i> Serotype H5a5b, Strain 2362 Fermentation Solids, Spores, and Insecticidal Toxins.....	2.7%
<i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> Serotype H-14, Strain AM65-52 Fermentation Solids, Spores, and Insecticidal Toxins.....	4.5%
OTHER INGREDIENTS.....	92.8%
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**

PATENT PENDING

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

EPA Reg. No. 73049-429
EPA Est. No. 33762-IA-001 (Lot No. Suffix 'N8')
EPA Est. No. 33967-NJ-1 (Lot No. Suffix '05')
Net Weight:
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	
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. Prolonged or frequent repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Environmental Hazards

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.

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STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store in a cool, dry place.

PESTICIDE DISPOSAL

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container. As long as WSP is unbroken, dispose of the empty outer foil pouch in the trash or by other procedures approved by state and local authorities or offer for recycling, if available.

DIRECTIONS FOR USE

VECTOMAX WATER SOLUBLE POUCHES (WSP): Once the foil bag containing Water Soluble Pouches is opened, minimize exposure of WSP to humidity.

APPLICATION DIRECTIONS

MOSQUITO CONTROL

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

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I. For control of mosquito larvae in the following sites:

Habitat Rate Range

Drainage/Drainage Systems¹:

Catch basins and storm drains 1 pouch/50 sq. ft.

Treatment Areas (For Use In)²:

Ponds	Flood water	Abandoned swimming pools
Lagoons	Standing water	Unused swimming pools or spas
Hollow trees	Storm water	Flooded basements
and tree holes	retention areas	Pool covers
Urns	Birdbaths	Gutters and drains
Rain barrels	Fountains	Wheelbarrows
Livestock watering	Flowerpots	Garbage cans and covers
troughs/ponds/	and planters	Discarded tires
tanks	Snowmelt pools	
Irrigation ditch	Septic tanks	
Roadside ditches		
Water gardens		
Impounded wastewater associated with fruit and vegetable processing		
Retention, detention and seepage ponds		
Animal waste lagoons		

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) VectoMax Water Soluble Pouch for up to 50 square feet of treatment area. Re-apply as needed (after 6-8 weeks under typical environmental conditions).

⁽²⁾ Treat on basis of surface area of potential mosquito breeding sites by placing one (1) VectoMax Water Soluble Pouch for up to 50 square feet of treatment area. Re-apply as needed (after 1-4 weeks under typical environmental conditions).

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.

Warranty and Disclaimer

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.