

73049-451

09/29/2009

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

September 29, 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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

RE: Product Name: VBC-60092 (Bactimos Briquette)
EPA Reg. No: 73049-451
Application for Label Notification Dated July 21, 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 (PR) Notice 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PR Notice 98-10 and it has been determined that the action(s) requested falls within the scope of PR Notice 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)

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Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73049-451	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VBC-60092 (Bactimos Briquette)	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: <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 _____
<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.

NOTIFICATION
Date Reviewed: 9-29-09
Reviewed By: D. Hudson

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of label per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. (see 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
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
		If "Yes" Package wgt.	No. per container	<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 10 LB		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) 847-953-4724
2. Signature 		6. Date Application Received (Stamped)
3. Title Regulatory Manager		
4. Typed Name Doina Bujor		
5. Date Jul 21, 2009		



July 21, 2009

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: VBC-60092 (Bactimos Briquette) (EPA Reg. No. 73049-451) Notification

Dear Ms. Reilly:

Valent BioSciences Corporation is submitting a notification for VBC-60092 (Bactimos Briquette) (EPA Reg. No. 73049-451) in accordance with PR Notice 2007-4. The changes made to the label are to the Storage and Disposal statement and include the changes to the container disposal language required by the PR Notice 2007-4.

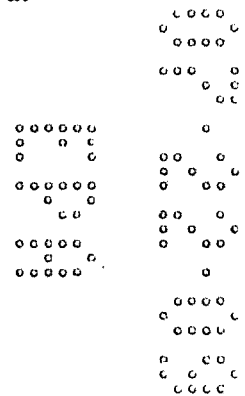
Present submission consists of:

- 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



Date Reviewed: 9-29-09

VBC-60092 (Bactimos Briquette)

Reviewed By: D. Hudson

Floating and Sustained Release Biological Mosquito Larvicide

(MASTER LABEL)

For Organic Production

ACTIVE INGREDIENT:

Bacillus thuringiensis Subsp. *israelensis* Serotype H-14, Strain AM65-52

Fermentation Solids, Spores, Insecticidal Toxins..... 10.3%

Inert Ingredients 89.7%

TOTAL..... 100.0%

Potency: This product contains 700 ITU/mg or 0.318 Billion ITU/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

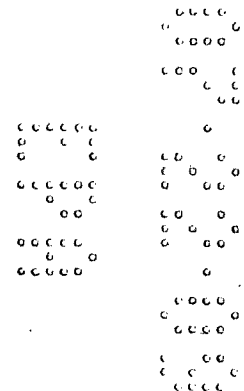
Valent BioSciences Corporation
870 Technology Way, Suite 100
Libertyville, IL 60048

Lot No. : _____

EPA Reg. No. 73049-451
EPA Est. 33762-IA-001

SEE OTHER PANEL FOR PRECAUTIONARY STATEMENTS

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. • Call a poison control center 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

Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Water proof gloves
- Shoes plus socks

Mixer/loaders and applicators must wear 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.

Follow manufacturers instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

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.

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: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available or dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

APPLICATION DIRECTIONS

MOSQUITO CONTROL

VBC-60092 (Bactimos Briquette) is a selective microbial insecticide for use against mosquito larvae in a variety of habitats. VBC-60092 (Bactimos Briquette) can be applied to areas that contain fish, other aquatic life, and plants. VBC-60092 (Bactimos Briquette) can be applied to areas used by or in contact with humans, pets, horses, livestock, birds, or wildlife including natural or manmade aquatic habitats other than finished drinking water.

VBC-60092 (Bactimos Briquette) is a donut-shaped briquette designed for direct application to mosquito larval habitats. The briquettes are buoyant and will float, releasing and dispersing the active ingredient for more than 50 days. The floating action and formulation components of VBC-60092 (Bactimos Briquette) assure continuous release and dispersal of the active ingredient at the surface of the water where it is available for ingestion by mosquito larvae.

VBC-60092 (Bactimos Briquette) may also be used for pre-flood treatment. If applied to dry areas known or expected to become larval habitats when flooded, the briquettes will float to the surface when flooded and release effective doses of the active material. Alternative wetting and drying will not reduce the effectiveness of VBC-60092 (Bactimos Briquette).

If necessary to prevent VBC-60092 (Bactimos Briquette) from being flushed out of certain sites, they may be anchored in place using a string tied through the center of the briquette.

APPLICATION RATE

For control of mosquito larvae in both crop and non-crop sites, apply VBC-60092 (Bactimos Briquette) at the rate of 1 briquette for up to 100 square feet of surface area regardless of depth.

For smaller areas, VBC-60092 (Bactimos Briquette) may be broken into smaller pieces for application. For areas less than 25 square feet in surface area, one-half of a briquette may be used, and for areas less than 5 square feet in surface area, apply one-quarter of a briquette may be used.

For pre-flood treatment, apply 1 briquette per 100 square feet of dry surface bed in area expected to flood and become habitat for mosquito larvae.

Treatment Areas (for use in):

- | | |
|--|-------------------------------|
| Ponds | Flood water |
| Lagoons | Standing water |
| Water gardens | Storm water retention areas |
| Bird baths | Catch basins |
| Evaporative Coolers | 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 |

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

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.

NOTICE TO USER

To the fullest extent consistent with applicable 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.

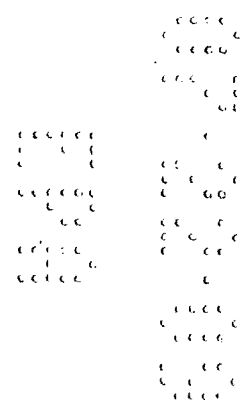
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Optional Label Claims

- Biological Mosquito Control
- Mosquito Biolarvicide Briquette
- Highly selective microbial larvicide
- Targets mosquitoes in their breeding habitats
- Reduces the number of adult mosquitoes developing
- When ingested by mosquito larvae, VBC-60092 (Bactimos Briquette) prevents larvae from becoming (developing into) breeding, biting adults.
- When ingested by mosquito larvae, VBC-60092 (Bactimos Briquette) prevents the development of adults.
- Kills mosquito larvae upon ingestion.
- Kills mosquito larvae upon ingestion of *Bti* 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, dengue fever, chikungunya virus 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
- Up to 7 weeks between applications
- Biodegradable components

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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.
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

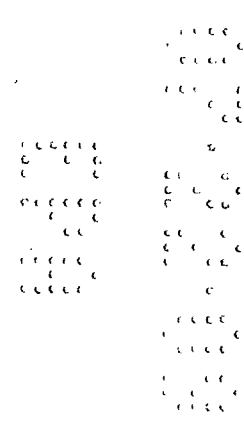
Causes moderate eye irritation. Avoid breathing dust. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

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: 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 or refill this container. Offer for recycling, if available.

APPLICATION DIRECTIONS

For residential use.

MOSQUITO CONTROL

VBC-60092 (Bactimos Dunk) is a selective microbial insecticide for use against mosquito larvae in a variety of habitats. VBC-60092 (Bactimos Dunk) can be applied to areas that contain fish, other aquatic life, and plants. VBC-60092 (Bactimos Dunk) can be applied to areas used by or in contact with humans, pets, horses, livestock, birds, or wildlife including natural or manmade aquatic habitats other than finished drinking water.

VBC-60092 (Bactimos Dunk) is a donut-shaped dunk designed for direct application to mosquito larval habitats. The dunks are buoyant and will float, releasing and dispersing the active ingredient for more than 50 days. The floating action and formulation components of VBC-60092 (Bactimos Dunk) assure continuous release and dispersal of the active ingredient at the surface of the water where it is available for ingestion by mosquito larvae.

VBC-60092 (Bactimos Dunk) may also be used for pre-flood treatment. If applied to dry areas known or expected to become larval habitats when flooded, the dunks will float to the surface when flooded and release effective doses of the active material. Alternative wetting and drying will not reduce the effectiveness of VBC-60092 (Bactimos Dunk).

If necessary to prevent VBC-60092 (Bactimos Dunk) from being flushed out of certain sites, they may be anchored in place using a string tied through the center of the dunk.

APPLICATION RATE

For control of mosquito larvae in both crop and non-crop sites, apply VBC-60092 (Bactimos Dunk) at the rate of 1 dunk for up to 100 square feet of surface area regardless of depth.

For smaller areas, VBC-60092 (Bactimos Dunk) may be broken into smaller pieces for application. For areas less than 25 square feet in surface area, one-half of a dunk may be used, and for areas less than 5 square feet in surface area, apply one-quarter of a dunk may be used.

For pre-flood treatment, apply 1 dunk per 100 square feet of dry surface bed in area expected to flood and become habitat for mosquito larvae.

Treatment Areas (for use in):

- | | |
|--|-------------------------------|
| Ponds | Flood water |
| Lagoons | Standing water |
| Water gardens | Storm water retention areas |
| Bird baths | Catch basins |
| Evaporative Coolers | 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 |

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Optional Label Claims

- Biological Mosquito Control
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- Targets mosquitoes in their breeding habitats
- Reduces the number of adult mosquitoes developing
- When ingested by mosquito larvae, VBC-60092 (Bactimos Dunk) prevents larvae from becoming (developing into) breeding, biting adults.
- When ingested by mosquito larvae, VBC-60092 (Bactimos Dunk) prevents the development of adults.
- Kills mosquito larvae upon ingestion.
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- Kills mosquito larvae upon ingestion by destroying the insect digestive tract.
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- 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
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