

73049-452

06/04/2008

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

June 4, 2008

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Warren Lee Smith
Regulatory Affairs Manager
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

RE: Product Name: Vectobac Pellet
EPA Reg. No: 73049-452
Your Application Dated May 6, 2008 for an Alternate Brand Name: Bactimos PT

Dear Mr. Smith:

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)

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NOTIFICATION

Date Reviewed: 6-4-08

Reviewed By: D. Hudson

**BACTIMOS® PT
BIOLOGICAL LARVICIDE**

Active Ingredient:

Bacillus thuringiensis subsp. *israelensis* strain AM 65-52 fermentation solids, spores,
and insecticidal toxins.....12.3%

Other Ingredients.....87.7%

Total.....100.0%

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
Libertyville, IL 60048

EPA Reg. No. 73049-452
EPA Est. No.

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 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.
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.	

APPLICATION DIRECTIONS

Midge Habitat (such as the following examples):	Suggested Rate Range*
Man-made or natural lakes, ponds, lagoons	25-30 kg/ha(22.3- 26.8 lbs/acre)
Sewage oxidation ponds	
Channels, ditches used for industrial discharges	

* Use higher rate in deeper water >0.5 meters (20 inches) of water.
 Repeat applications as needed after 2-3 weeks. Control of midges may be gradual over a period of two weeks.

Application Methods

Apply **BACTIMOS PT** uniformly over the entire surface of the lake or pond. In large lakes/ponds where complete surface treatments are not possible, applications concentrated along the perimeter may be effective in reducing midge populations; most of the nuisance midge larvae of many species will occur within 2 meters of the pond perimeter in < 1 meter deep water.

Apply **BACTIMOS PT** using conventional ground application equipment such as, hand or motorized spreaders or backpack blowers. A uniform application over the surface of the area to be treated is essential for optimum midge population reduction.

Midges Controlled with BACTIMOS PT

Only a small percentage of the thousands of pestiferous species of "non-biting midges" have been tested for susceptibility to **BACTIMOS PT**. Members of the subfamily Chironomini and Tanytarsini are generally susceptible; members of the subfamily Tanyptodinae are not susceptible at the **BACTIMOS PT** labeled-use rate.

When initially using **BACTIMOS PT** in a midge control program, it is recommended that only a small test area be treated if the species of midge(s) to be controlled has not been identified.

NOTICE TO USER

To the fullest extent permitted by law, seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning 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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	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 73049-452	2. EPA Product Manager Alan Reynolds	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VECTOBAC PELLET	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 _____

NOTIFICATION

Date Reviewed: 6-4-08

Section - II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.
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Reviewed By: D. Hudson

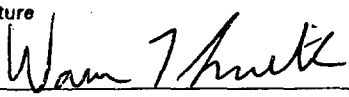
Explanation: Use additional page(s) if necessary. (For section I and Section II.)

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 the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR-Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and may be subject to enforcement action and penalties under section 12 and 14 of FIFRA.
 NOTIFICATION OF NEW ALTERNATE BRAND NAME: BACTIMOS PT

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 type="checkbox"/> No		<input 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"/>	
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 Warren Lee Smith / warren.smith@valent.com	Title Regulatory Affairs Manager	Telephone No. (Include Area Code) (847) 968-4771	
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 Affairs Manager	5. Date May 6, 2008	
4. Typed Name Warren Lee Smith			



May 6, 2008

Alan Reynolds
 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

Re: Notification to add alternate brand name
 EPA Reg. No. 73049-452

Dear Dr. Reynolds:

Valent BioSciences Corporation (VBC) would like to notify EPA of the addition of the alternate brand name, BACTIMOS PT to the subject registration.

In support of this notification, please find enclosed the following:

- EPA form 8570-1
- Copy of labeling with the changes clearly marked.
- Clean copy of labeling.

If there are any questions on this notification, please do not hesitate to contact me.

Sincerely,

Warren L. Smith
 Regulatory Manager
 847-968-4771
 warren.smith@valent.com

