

73049-394

6/11/2010

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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Nasser A. Assaf, Ph.D  
Valent BioSciences Corporation  
870 Technology Way  
Libertyville, IL 60048

JUN 11 2010

Subject: Label Notification(s) for Pesticide Registration 2007-4 & PR Notice 98-10

Dear Dr. Assaf:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 dated for April 15, 2010 for:

**EPA Registration Number: 73049-394      VBC Bioallethrin 90% Concentrate**

The Registration Division (RD) has conducted a review of this request for applicability Under PRN 2007-4 and finds that the label change(s) requested falls within the scope of PRN-2007-4. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact Melody Banks on 703 305-5413.

Sincerely,

Richard Gebken  
Product Manager  
Insecticide Branch  
Registration Division (7504P)

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United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 73049-394	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VBC Bioallethrin 90% Concentrate	PM# 10	
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 _____	<b>NOTIFICATION</b>  JUN 11 2010
<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.	

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

Label Notification - No Fee; e-mail: Nasser.Assaf@valent.com; Fax: (925) 817-5160

See Self Certifications statements on cover letter.

Changes include:

- Revise Storage & Disposal Statements in Compliance with PR Notice 2007-4,
- Updated warranty statement in agreement with US EPA OPP Guidance on Warranty Statements (Oct. 17, 2006)
- Updated First Aid Hot Line Number statement and removed "Not For Resale Under This Label"
- No other changes have been made to the label other than those clearly marked.

## Section - III

1. Material This Product Will Be Packaged In:			
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	2. Type of Container <input checked="" 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 1 to 55 gallons	
		5. Location of Label Directions <input checked="" type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product <input checked="" 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 Nasser A. Assaf, Ph.D		Title Manager, Product Safety and Regulatory Affairs	
		Telephone No. (Include Area Code) (847) 963-4788	
<b>Certification</b> 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 <i>NASSAF</i>		3. Title Manager, Product Safety and Regulatory Affairs	
4. Typed Name Nasser A. Assaf, Ph.D		5. Date April 15, 2010	

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April 15, 2010

Document Processing Desk (NOTIF)  
Registration Division  
Office of Pesticide Programs (7504P)  
US Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

ATTN: Richard Gebken  
Product Manager 10  
Insecticide Branch

SUBJECT: APPLICATION FOR PESTICIDE LABEL NOTIFICATION – No PRIA Service Fee Required  
Submission of Revised Labeling Per:  
- PR-Notice 2007-4, Container Disposal  
- PR-Notice 98-10, Warranty Statement update  
VBC Bioallethrin 90% Concentrate; EPA Reg. No. 73049-394

Dear Mr. Gebken:

This application for label notification for the above subject product is being submitted to comply with the PR Notice 2007-4, Labeling Revisions Required by the Final Rule "Pesticide Management and Disposal; Standards for Pesticide Containers and Containment Revision of Container Disposal and US EPA OPP Guidance on Warranty Statements (Oct. 17, 2006) among other minor changes which are clearly marked.

VBC Bioallethrin 90% Concentrate; EPA Reg. No. 73049-394; is for indoor, manufacturing use only.

Due to the limited space on EPA Form 8570-1, Section II, the self certification statements are as follows:

PR Notice 2007-4, Labeling Revisions Required by the Final Rule "Pesticide Management and Disposal Notification of label change per PR-Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the 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. 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 the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

US EPA OPP Guidance on Warranty Statements (Oct. 17, 2006)

This notification is consistent with the provisions of PR Notice 98-10 and the EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula for 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

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Sincerely,

Nasser A. Assaf, Ph.D.  
Manager, Product Safety and Regulatory Affairs

15 dot patterns arranged in a 5x3 grid. The patterns are numbered 1 through 15, with the numbers placed to the right of each pattern.

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**BIOALLETHRIN®  
CONCENTRATE 90%**

- *An Insecticide For Formulating/Manufacturing Use Only*
- *Only For Formulation Into End-Use Insecticides*
- *Not For Resale Under This Label*

**NOTIFICATION**

JUN 11 2010

**ACTIVE INGREDIENT:**

Bioallethrin..... 90.0%  
**OTHER INGREDIENTS:**..... 10.0%  
 100.0%

**PRECAUCION AL CONSUMIDOR:** Si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.

**(TO THE USER:** If you cannot read English, do not use this product until the label has been fully explained to you.)

EPA Reg. No.: 73049-394

EPA Est. No.:

**KEEP OUT OF REACH OF CHILDREN****CAUTION****See Side Panel for Additional Precautions**

<b>FIRST AID</b>	
Call a poison control center or doctor immediately for further treatment advice.	
<b>If Swallowed:</b>	<ul style="list-style-type: none"> <li>• Have person sip glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<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> </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> </ul>
<b>If Inhaled:</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> </ul>
<b>HOT LINE NUMBER</b>	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. In case of Medical emergencies or health and safety inquiries or in case of fire, leaking or damaged containers, information may be obtained by calling 1-877-315-9819. <i>For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-877-315-9819.</i>	

**NET CONTENTS:**

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## PRECAUTIONARY STATEMENTS

### Hazards to Humans & Domestic Animals

#### CAUTION

Harmful if swallowed, inhaled or absorbed through skin. Avoid breathing vapors. Avoid contact with skin, eyes and clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

#### Environmental Hazards

This product is highly toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

#### DIRECTIONS FOR USE

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

FOR FORMULATION OF INSECTICIDES ONLY.

INSTRUCTIONS TO FORMULATORS: Formulators using this product are responsible for obtaining EPA registration of their formulated products.

Only for Formulation into an insecticide for the following uses: Domestic Indoor (household); Domestic Outdoor (household, ornamentals); Commercial/Industrial Institutional (indoor & outdoor); Treatments of Animals Not Intended for Food (including pets) and Terrestrial Non-Food.

#### STORAGE AND DISPOSAL

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

**Storage:** Store in a cool, dry place away from heat or open flame. Avoid extremes in temperature. If the container is leaking and/or material is spilled, on floor or paved surfaces, absorb on sawdust or other commercially available absorbing material, sweep up and remove to chemical waste area for disposal. Stable at normal storage temperatures.

**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. Triple-rinse (or equivalent). Then Offer for recycling if available, or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.*

#### IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following conditions, disclaimer of warranties and limitations of liability.

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully.

However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Valent BioSciences Corporation. All such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, VALENT BIOSCIENCES CORPORATION MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Valent BioSciences Corporation is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Valent BioSciences Corporation disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

**LIMITATIONS OF LIABILITY:** TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT VALENT BIOSCIENCES CORPORATION'S ELECTION, THE REPLACEMENT OF PRODUCT.

