

73049-395

06-11-2010

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JUN 11 2010

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

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:

Alternate Brand Name Esbiol Concentrate 90%

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.

EPA Registration Number 73049-395 VBC Esbiol Concentrate

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
Insecticide Branch
Product Manager
Registration Division (7504P)



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73049-395	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VBC Esbiol 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 _____	NOTIFICATION 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)
- Alternate brand name (Esbiol Concentrate 90%), 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:				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	* Certification must be submitted	<input checked="" type="checkbox"/> Metal	Other (Specify) _____
If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt		<input type="checkbox"/> Plastic	
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 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) 968-4788	
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 <i>MASSAF</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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Esbiol® 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:
 S-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. 73049-395

EPA Est. No.

KEEP OUT OF THE REACH OF CHILDREN
WARNING
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONS

FIRST AID	
Call a poison control center or doctor immediately for further treatment advice.	
If Swallowed:	<ul style="list-style-type: none"> • Have person sip glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
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.
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,
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.
HOT LINE NUMBER	
<p>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></p>	

NET CONTENTS:

PRECAUTIONARY STATEMENTS
Hazards To Humans & Domestic Animals

WARNING

May be harmful or fatal if swallowed. 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 with sawdust or other commercially available absorbing material, sweep up and remove to chemical waste area for disposal.

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.

[Or alternate text

