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10-26-2010

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 26, 2010

Mr. Nasser A. Assaf, Ph.D.,
Regulatory Manager, ESD
Valent BioSciences Corporation
870 Technology Way, Suite 100
Libertyville, IL 60048-6316

**Subject: Label Notification(s); Pesticide Registration Notification (PRN) 2007-4
REFINED PYRETHRUM CONCENTRATE, EPA Reg. No. 36426-1
Your Submission Dated August 18, 2010**

Dear Mr. Assaf:

The Agency is in receipt of your application for Pesticide Notification under Pesticide Registration Notification (PRN) 2007-4, dated August 18, 2010, for the referenced product. The Registration Division 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.

Please be reminded that 40 CFR §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/PRN 98-10) or durably marked on the container itself.

The label submitted with the application has been time-stamped "Notification" and will be placed in our records. If you have any questions, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely yours,

A handwritten signature in black ink that reads "Richard J. Gebken".

Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)



United States
Environmental Protection Agency
 Washington, DC 20460

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

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 36426-1	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Refined Pyrethrum Concentrate	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) SOPYRWA c/o 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

OCT 26 2010

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.

Explanation: Use additional page(s) if necessary. (For section I and Section II.) Notification of label change per PR-Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4, and the requirement of EPA regulations at 40 CFR 156.10, 156.140, 156.144, 156.146, and 153.156. 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 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.
 NOTIFICATION OF: Container Disposal per PR-Notice 2007-4; Addition of "non-refillable container" and "Do not reuse or refill this container", deletion of rinsing instructions.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph Paper glued 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) 968-4844
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>N. ASSAF</i>	3. Title Manager, Product Safety and Regulatory Affairs	
4. Typed Name Nasser A. Assaf, Ph.D.	5. Date August 18, 2010	

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PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals

CAUTION

Contains Petroleum Distillate. Harmful if swallowed, absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes and gloves. Remove and wash contaminated clothing before reuse.

Environmental Hazards

This pesticide is highly toxic to aquatic organisms, including fish and invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with 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. Do not contaminate water when disposing of equipment wash-waters or rinsate.

Physical and Chemical Hazards

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

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

FOR MANUFACTURING INSECTICIDES ONLY

Mix well in drum before sampling and use.

This product is intended for formulation use only. The formulator using this concentrate is fully responsible for obtaining EPA registration for their formulated products.

Only for formulation into an insecticide for the following uses: Terrestrial Food/Feed and Non-Food/Feed; Aquatic Food and Non-Food; Greenhouse Food and Non-Food; Domestic Indoor (household); Domestic Outdoor (perimeters, lawns and ornamental and vegetable gardens); Commercial/Industrial/Institutional Food/Feed & Non-Food/Feed (indoor & outdoor); Treatments of Animals (including livestock & pets).

Not for formulation into wettable powder end-use products (EUP), unless the EUP is packaged in water soluble bags.

Not for formulation into granular end use products.

This product may be used to formulate products for specific uses(s) not listed on manufacturing product label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).

STORAGE AND DISPOSAL

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

Pesticide Storage and Spill Procedures: Keep this product dry in a tightly closed container, when not in use. Store indoor in an upright position and in a cool, dry, well-ventilated area away from heat or open flame. If container is damaged, check for any leaks. If leaking, transfer contents into another suitable container. Avoid contamination with other chemicals. In case of spill, flood areas with large quantities of water. Product or rinsates that cannot be used should be diluted with water before disposal into a sanitary sewer. Do not reuse damaged container but place in trash collection. Spillage should be washed off with a 5% sodium hydroxide solution then rinsed with water. Do not contaminate food or feed by storage, disposal or cleaning of equipment.

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 approved state and local procedures.

Note: Seller warrants that this product complies with the specifications expressed in this label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, Seller's liability or default, breach or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.