

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 30, 2008

Dr. Nasser A. Assaf, Ph.D. Regulatory Manager, ESD SOPYRWA c/o Valent BioSciences Corporation 870 Technology Way Libertyville, IL 60048-5350

Subject:

Amended Labeling, Response to Agency Letter of October 11, 2007

CRUDE PYRETHRUM EXTRACT, EPA Registration No. 36426-3

Your Submission Dated July 17, 2008

Dear Dr. Assaf:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable with the following provision(s):

Warranty & Disclaimer section comment(s):

- 1. Within forty-five (45) days from the date of this letter, SOPYRWA/Valent should submit a label amendment revising the "WARRANTY & DISCLAIMER" section (label statement at bottom of page 2 of 2, starting with "NOTICE: Seller warrants that this product ...") in accordance with the guidance document entitled, "Guidance on Warranty Statements," dated October 17, 2006. This update can be found at the following hyperlink: http://www.epa.gov/pesticides/regulating/labels/warranty.pdf.
- The "WARRANTY & DISCLAIMER" section heading must be placed on the top and in a central position above the WARRANTY & DISCLAIMER section.

SOPYRWA/Valent should note that a notice of availability of EPA's reregistration eligibility decision (RED) document for products containing pyrethrins was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42387-42389). As a result, additional data and/or labeling changes may be required for products containing pyrethrins.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

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If you have any questions about this label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at *Rodia.Carmen@epa.gov*.

Sincerely yours,

Richard J. Gebken, Product Manager (10) Insecticide Branch,

Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments"

CRUDE PYRETHRUM EXTRACT

ACTIVE INGREDIENT: OTHER INGREDIENTS*: TOTAL: *Contains Petroleum Distillate

EPA REG. NO. 36426-3

EPA EST. NO.

KEEP OUT OF REACH OF CHILDREN **CAUTION**

See Side Panel for Additional Precautions

FIRST AID	
If in Eyes:	 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 Swallowed:	Call a poison control center or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.
If on Skin or Clothing:	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.
If Inhaled:	 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. Call a poison control center or doctor for further treatment advice.
	HOT LINE NUMBER
	label with you when calling a poison control center or doctor, or going for treatment. For additional neluding health concerns, medical emergencies or pesticide incidents) you may call the Poison.
	NOTE TO PHYSICIAN
Contains petroleum distillate	- vomiting may cause aspiration pneumonia.

SOCIÉTÉ DE PYRÈTHRE AU RWANDA **BOITE POSTALE 79** RUHENGERI, RWANDA, AFRICA

PRODUCT OF RWANDA

NET CONTENTS:

ACCEPTED with COMMENTS In EPA Letter Dated

Under the Federal insecticide. Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 36426-3



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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 USE ONLY

Mix well in drum before sampling and use.

This product is to be refined into a manufacturing use product labeled for formulation into insecticides for the following uses:
Terrestrial Food/Feed and Non-Food/Feed, Aquatic Food and Non-Food, Greenhouse Food and Non-Food, Domestic Indoor (household) and 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 the 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 indoors 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: Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly, after emptying. Offer for recycling if available, 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.