

36426-1

07/11/2007

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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

July 11, 2007

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

**Subject: Revised Labeling, Response to PR Notice 2001-1  
Refined Pyrethrum Concentrate, EPA Registration No. 36426-1  
Your Submission Dated June 20, 2007**

Dear Mr. 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):

First Aid section comment(s), page 1 of 2:

1. Replace the **HOT LINE NUMBER** portion of this section with the following:

"Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-xxx-xxxx or the National Pesticide Information Center at 1-800-858-7378.<sup>1</sup>

Precautionary Statements section, Hazards to Humans and Domestic Animals subsection comment(s), page 2 of 2:

2. Replace the existing 7<sup>th</sup> sentence with: "Remove and wash contaminated clothing before reuse."

Directions for Use section comment(s), page 2 of 2:

3. Replace the last text grouping with: "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA submission requirements regarding support of such use(s)."

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.

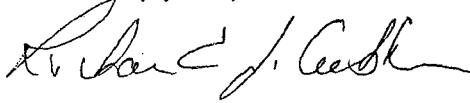
<sup>1</sup> Please note that the "1-800-xxx-xxxx" must be substituted with a valid phone number that is available twenty-four (24) hours per day, seven (7) days per week for answering and responding to any medical emergencies or health concerns.

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Within forty-five (45) days from the date of this letter, you should submit a label amendment revising the "Warranty & Disclaimer" section of this label in accordance with the guidance document entitled, "Guidance on Warranty Statements" and dated October 17, 2006. This update can be found at the following hyperlink: <http://www.epa.gov/pesticides/regulating/labels/warranty.pdf>.

A stamped copy of the referenced label is enclosed for your records. Please submit two (2) copies of the final printed labeling before releasing the product for shipment. If you have any questions regarding the label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at [Rodia.Carmen@epa.gov](mailto:Rodia.Carmen@epa.gov).

Sincerely yours,



Richard J. Gebken,  
Product Manager (10)  
Insecticide Branch,  
Registration Division (7505P)

Enclosure

034621-00001 D-380844

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# REFINED PYRETHRUM CONCENTRATE

**ACTIVE INGREDIENT:**

Pyrethrins ..... 50.0%

**OTHER INGREDIENTS\*:** ..... 50.0%

**TOTAL:** ..... 100.0%

\*Contains Petroleum Distillate

EPA REG. NO. 36426-1

EPA EST. NO.

**KEEP OUT OF REACH OF CHILDREN**

## CAUTION

See Side Panel for Additional Precautions

FIRST AID	
<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> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If Swallowed:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give any liquid to the person.</li> <li>• Do not give anything by mouth to an unconscious person.</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> <li>• Call a poison control center or doctor for treatment advice.</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> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents) you may call the National Pesticide Information Center at 1-800-858-7378.	
NOTE TO PHYSICIAN	
Contains petroleum distillate - vomiting may cause aspiration pneumonia.	

**SOCIÉTÉ DE PYRÉTHRE AU RWANDA**

**BOITE POSTALE 79**

**RUHENGERI, RWANDA, AFRICA**

**PRODUCT OF RWANDA**

**NET CONTENTS:**

**ACCEPTED  
with COMMENTS  
In EPA Letter Dated  
July 11, 2007  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
36426-1**

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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 contaminated clothing and wash 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 this 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:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other approved state and local procedures.

**IMPORTANT: READ BEFORE USE:**

By using this product, user or buyer accepts the following conditions and warranties.

**CONDITIONS:** The directions for use of this product are believed to be adequate and should 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 SOCIÉTÉ DE PYRÉTHRE AU RWANDA. All such risks shall be assumed by the user or buyer.

**WARRANTY STATEMENT:** Our recommendations for use of this product are based upon tests believed to be reliable. The use of this product being beyond the control of the manufacturer, no guarantee, express or implied is made as to the effects of such or the results to be obtained if not used in accordance with directions or established safe practice. The buyer must assume all responsibilities, including injury or damage, resulting from its misuse as such or in combination with other materials.