



73049-222

10/21/2003

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

OCT 21 2003

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Janice K. Sharp, Ph.D.
Valent Biosciences
Environmental Sciences Division
870 Technology Way, Suite 100
Libertyville, IL 60048

Dear Dr. Sharp:

Subject: Intermediate Concentrate Insecticide
EPA Reg. No. 73049-222
Submission dated 4/7/03

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. One copy of the finished labeling must be submitted prior to releasing the product for shipment.

Add the statement "Contains petroleum distillate" to the ingredient statement.

You have not submitted a justification for modifying the Precautionary statements related to skin exposure. Revise the first sentence of the Precautionary statements to read as follows:

Harmful is swallowed or absorbed through the skin.

Under the directions for use, delete the second sentence about formulators being fully responsible for obtaining EPA registration for their formulated products. Instead, use one of the following statements from PR Notice 94-1:

"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 U.S. EPA data submission requirements regarding the support of such uses(s)" or

"This product may be used to formulate products for any additional uses not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such uses."

Under the Directions for Use, delete "Indoor Medical (air treatments, medical institutions, laboratory animals, etc.)" and insert in lieu thereof "commercial, industrial and institutional".

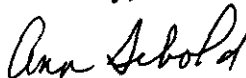
Revise the Container Disposal statement to read as follows:

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

A copy of the dermal sensitization study is enclosed. This study was found acceptable. The reviewer has noted a deficiency in the acute inhalation study (accession number 242959) that was submitted to support this registration. Within one year, you must submit or cite another inhalation study to support this registration.

If you have questions, please call Ann Sibold at 703 305-6502.

Sincerely,



for Linda Arrington
Acting Product Manager 10
Insecticide Branch
Registration Division (7505C)

INTERMEDIATE CONCENTRATE INSECTICIDE

**ACCEPTED
with COMMENTS**
In EPA Letter Dated:
OCT 21 2003
**Under the FIFRA Insecticide,
Fungicide, and Rodenticide Act,
as amended, this pesticide
registered under EPA Reg. No.
73049-222**

- FOR THE FORMULATION OF INSECTICIDES ONLY
- NOT FOR RESALE UNDER THIS LABEL

ACTIVE INGREDIENTS:

Pyrethrins:	9.0 %
Piperonyl Butoxide:	18.0 %
N-octyl bicycloheptene dicarboximide:	30.0 %
OTHER INGREDIENTS:	<u>43.0 %</u>
	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. 73049-222
 Item No. 15300/15301/15302

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If swallowed:	<ul style="list-style-type: none"> • Immediately call a poison control center or doctor. • 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:	<ul style="list-style-type: none"> • 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.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. In case of <i>Medical</i> 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.	
NOTE TO PHYSICIAN	
Contains petroleum distillate - vomiting may cause aspiration pneumonia.	

See Side Panel For Additional Precautionary Statements

NET CONTENTS:

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Harmful if swallowed. Avoid contact with skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. 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.

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

Only for formulation into an insecticide for the following uses: Domestic Indoor and Outdoor (including pets), Indoor Food (food handling establishments) and Non-Food and Indoor Medical (air treatments, medical institutions, laboratory animals, etc.).

STORAGE AND DISPOSAL

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

Pesticide Storage And Spill Procedures: Store upright at room temperature. Avoid exposure to extreme temperatures. In case of spill or leakage, soak up with an absorbent material such as sand, sawdust, earth, fuller's earth, etc. Dispose of with chemical waste.

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, by incineration or, if allowed by state and local procedures.

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.

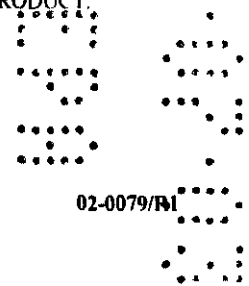
CONDITIONS: The directions for use of this product are believed to be adequate and should be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as weather conditions,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

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Valent BioSciences Corporation
Environmental Science Division
870 Technology Way
Libertyville, IL 60048
List No. 73049222



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