73049-222

7-17-2008

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

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OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

July 17, 2008

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

Subject:

Revised Labeling in Response to PR Notice 2007-4

INTERMEDIATE CONCENTRATE INSECTICIDE, EPA Reg. No. 73049-222

Your Submission Dated April 2, 2008

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):

General Statement:

Delete all text throughout the label marked with "strikethrough."

Ingredient Statement comment(s):

- 2. Revise the ingredient listed as "Piperonyl Butoxide*" to read: "Piperonyl Butoxide: Technical*"
- 3. Add a footnote on the label for piperonyl butoxide as follows: "*Equivalent to 14.4% of (butylcarbityl)(6-propylpiperonyl) ether and 3.6% of related compounds."

First Aid Statement section comment(s):

4. Replace the 2nd sentence from the next-to-last statement in this section with: "For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-877-315-9819."

Storage and Disposal Statement section, Container Disposal subsection comment(s):

5. Insert the statement "Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities." immediately following the word "emptying" at the end of this subsection.

Valent BioSciences Corporation should note that a notice of availability of EPA's RED for products containing pyrethrins was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42387-42389). In addition, EPA's RED for products containing piperonyl butoxide was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42385-42386). Further, EPA's RED for products containing MGK® 264 was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42381-42383). As a result, additional data and/or labeling changes may be required for products containing pyrethrins, piperonyl butoxide and MGK® 264.

¹ Please note that the "1-877-315-9819" number listed must be available twenty-four (24) hours per day, seven (7) days per week for answering and responding to any medical emergencies or health concerns.

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 FIFRA section 6(e). Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

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

Richard J. Gebken

Product Manager (10)

Insecticide Branch

Registration Division (7505P)

Land & Celle-

Enclosure:

Copy of label stamped "Accepted with Comments"

073049-00222 D392361

INTERMEDIATE CONCENTRATE INSECTICIDE

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.

· For The Formulation Of Insecticides Only

ACTIVE INGREDIENTS:

Pyrethrins	9.0 %
Piperonyl Butoxide	
N-octyl bicycloheptene dicarboximide	
OTHER INGREDIENTS*:	
•	100.0 %

^{*}Contains petroleum distillate.

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:	 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:	 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	
	container or label with you when calling a poison control center or doctor, or going for treatment. In case of cies or health and safety inquiries or in case of fire, leaking or damaged containers, information may be obtained 315-9819.	j
	NOTE TO PHYSICIAN	20
Contains petrolei	um distillate - vomiting may cause aspiration pneumonia.	D EQ

See Side Panel For Additional Precautionary Statements

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PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Harmful if swallowed. Avoid contact with skin or 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.

This product is intended for formulation use only. 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).

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 commercial, industrial and institutional.

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:

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying.

[5 gallons or less]

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with solvent used in the end use product and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

[Greater than 5 gallons/50 lbs.]

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with solvent used in the end use product. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate integraphication equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

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 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.

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REPLACEMENT OF PRODUCT.

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