

73049-218

7-16-2008

1/5



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 16, 2008

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

**Subject: Revised Labeling in Response to PR Notice 2007-4
PYRENONE® O.T. 75-7.5 INSECTICIDE, EPA Reg. No. 73049-218
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:

1. 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. Revise the footnote on the label for piperonyl butoxide as follows: "*Equivalent to 60.0% of (butylcarbityl)(6-propylpiperonyl) ether and 15.0% 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.**"¹

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 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). 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). As a result, additional data and/or labeling changes may be required for products containing pyrethrins and piperonyl butoxide.

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.

2/5

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)

Enclosure: Copy of label stamped "Accepted with Comments"

073049-00218 D392360

3/5

PYRENONE[®] O.T. 75-7.5 INSECTICIDE

ACCEPTED
with COMMENTS
In EPA Letter Dated
July 16, 2008
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
73049-218

• For The Formulation Of Insecticides Only

ACTIVE INGREDIENTS:

Pyrethrins	7.5%
Piperonyl Butoxide*	75.0%
OTHER INGREDIENTS**:	<u>17.5%</u>
	100.0%

* Equivalent to 40.0% (butylcarbityl)(6-propylpiperonyl) ether and 10% related compounds.

** 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. 73049-218
Item No. 15383/15384

EPA EST. NO.

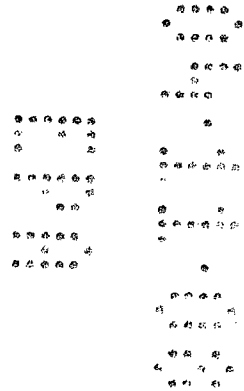
KEEP OUT OF REACH OF CHILDREN

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 Medical 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 Statement

NET CONTENTS:



PRECAUTIONARY STATEMENTS Hazards To Humans & Domestic Animals

CAUTION

Harmful if swallowed or absorbed through skin. Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. Avoid contamination of feed and foodstuffs.

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. Do not contaminate water by cleaning of equipment or disposal of wastes.

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 insecticides for the following uses: Terrestrial Food/Feed and Non-Food Crops, Aquatic Non-Food, Greenhouse Food and Non-Food, Domestic Indoor and Outdoor, Indoor Food and Non-Food.

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 1/4 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 into application 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 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.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, VALENT BIOSCIENCES CORPORATION MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Valent BioSciences Corporation is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Valent BioSciences Corporation disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT

LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT VALENT BIOSCIENCES CORPORATION'S ELECTION, THE REPLACEMENT OF PRODUCT.

©Valent BioSciences Corporation, 2008

Pyrenone is a registered trademark of Bayer AG.

Valent BioSciences Corporation
Environmental Science Division
870 Technology Way
Libertyville, IL 60048
List No. 73049218
02-0346/R2

Small, faint, illegible text or markings located in the bottom right corner of the page.