



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Wednesday April 15, 2009

Dr. Nasser Assef, Ph.D. Regulatory manager, ESD Valent Biosciences Corporation 870 Technology Way Libertyville, IL 60048

Subject: Submission of revised labeling in response to Agency letter dated April 16, 2008. and the

mitigation measures required in the Allethrin's RED.

Product name: Bioallethrin Technical EPA Registration Number: 73049-359 Date of Submission: January 30, 2009

## Dear Dr. Assef;

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable subject to the comments listed below.

1. Remove the statement "Including food areas of food handling establishments" from the label. At this time, the Agency has not approved this use, and when the tolerance is approved, Valent Biosciences Corporation may reapply to insert this text within the label.

Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If you have any questions, you may contact Richard J. Gebken, at (703) 305-6701.

Sincerely,

Richard Gebken Product Manager 10 Insecticide Branch

Registration Division (7505C)

I for & Cell

Enclosure

# ACCEPTED with COMMENTS In EPA Letter Dated APR 15 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No.

100.00 %

# **BIOALLETHRIN TECHNICAL**For Manufacturing and Formulating Use

For Formulation Of Insecticides Only

ACTIVE INGREDIENT:	
Bioallethrin	.93.40 %
OTHER INGREDIENTS:	6.60 %

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. 73049-359

EPA EST. NO.

# KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID	
If Swallowed:	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
If on Skin or Clothing:	<ul> <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>
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.
If in Eyes:	<ul> <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>
	HOT LINE NUMBER

See Side Panel For Additional Precautionary Statements

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,

### **NET CONTENTS:**

information may be obtained by calling 1-877-315-9819.

## PRECAUTIONARY STATEMENTS Hazards To Humans & Domestic Animals

#### CAUTION

Harmful if swallowed, inhaled or absorbed through skin. Avoid breathing vapors. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating or using tobacco. Remove contaminated clothing and wash clothing before reuse.

#### **Environmental Hazards**

This pesticide is toxic to fish and aquatic invertebrates. 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 local State Water Board or Regional Office of the Environmental Protection Agency.

### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

#### FOR FORMULATION OF INSECTICIDES ONLY

Formulators using this product are fully responsible for obtaining EPA registrations for their formulated products.

Only for formulation into an insecticide for: Domestic Indoor (Household), Domestic Outdoor (localized treatments only including total release foggers, space, spot and crack and crevice sprays), Commercial/Industrial/Institutional Uses (Including food areas of food handling establishments as a space, general surface, spot and crack and crevice application) and Greenhouse Ornamentals.

Not for formulation into end-use products with directions for use as an application directly to pets.

Formulation into ready-to-use total release foggers with directions for use outdoors is limited to a maximum of 1.5 ounces of product per container.

Formulation into products with directions for use as a spot treatment in residential settings is limited to a maximum 0.25% a.i. dilution strength.

Formulations with greater than 0.1% a.i. dilution strength must contain directions for use limiting applications in indoor residential settings to spot treatments only. Indoor broadcast use must be prohibited.

Formulation into products with directions for use as a broadcast spray outdoors is prohibited. Outdoor use is limited to spot treatments only. (NOTE: outdoor broadcast use with ready-to-use total release foggers is permitted.)

Not for formulation into products for use in or on drainage systems, golf course turf, airports/landing fields, uncultivated agricultural areas, boat/ship hulls and paved areas such as sidewalks and roads.

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

#### STORAGE AND DISPOSAL

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

PESTICIDE STORAGE AND SPILL PROCEDURES: Store upright in a cool, dry place. Keep container closed. 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. Clean container promptly after emptying.

[containers 5 gallons or less] Triple rinse as follows: Empty the remaining contents into mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with solvent used to formulate the end-product and recap. Shake for 10 seconds. Pour rinsate into 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.

[containers over 5 gallons] Triple rinse as follows: Empty the remaining contents into mix tank. Fill the container ¼ full with solvent used to formulate 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. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into 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.

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