

59639-107

7/14/2009

10f9

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



JUL 14 2009

OFFICE OF  
PREVENTION, PESTICIDES,  
AND TOXIC SUBSTANCES

Leslie Garcia  
Valent USA Corporation  
P.O. Box 8025  
Walnut Creek, CA 95696

Dear Ms. Garcia:

Subject: Etoxazole amendments  
**Etoxazole Technical**  
EPA Reg. No. 59639-107  
EPA Decision No. 392976  
**Zeal WP Miticide**  
EPA Reg. No. 59639-138  
EPA Decision No. 392379  
**TetraSan 5 WDG**  
EPA Reg. No. 59639-108  
EPA Decision No. 392378  
Your submission dated April 15, 2008

The following amendments are reflected with these label approvals:

- Use of etoxazole on stone fruit, cucumber, tomato and mint
- Aerial application to melons
- Supplemental label to Zeal WP Miticide for use on cucumber, mint and stone fruit
- Supplemental label to Zeal WP Miticide for aerial application on melons
- Supplemental label to TetraSan 5 WDG for use on indoor grown tomatoes

The subject amendments submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act are amended as acceptable with the following comments:

1. On both the master and supplemental label for Zeal WP Miticide, EPA Reg No. 59639-138 add the following restriction under the cucumber and mint sections of the labels: "Do not rotate with non-registered crops for 365 days following application of etoxazole."

2. On both the master and supplemental labels for each Zeal WP Miticide, EPA Reg No. 59639-138 and TetraSan 5 WDG EPA Reg. No. 59639-108, under “Special Instructions,” revise all statements that read “Apply Zeal WP/TetraSan 5 WDG at threshold for your area” to read: “Apply Zeal WP/TetraSan 5 WDG at threshold for your area but not greater than the maximum rate listed.”
3. On both the master and supplemental labels for each Zeal WP Miticide, EPA Reg No. 59639-138 and TetraSan 5 WDG EPA Reg. No. 59639-108, under “Special Instructions,” revise all statements that read “Apply Zeal WP/TetraSan 5 WDG at or prior to threshold for your area” to read: “Apply Zeal WP/TetraSan 5 WDG at or prior to threshold for your area but not greater than the maximum rate listed.”

In addition, the following conditional data are due within 18 months of the date of this letter:

Health and Human Effects Data Requirements

- 90-Day inhalation toxicity (40 CFR Part 158 conditional requirement based on significant expected inhalation exposure to greenhouse workers).
- Immunotoxicity study in rats is required under current EPA regulations (40 CFR part 158).
- Acute and subchronic neurotoxicity studies (40 CFR Part 158 requirements).
- A new confined rotational crop study to support proposed uses on cucumbers and mint. For mint, the study needs to be conducted at the higher seasonal use rate (.36 lb ai/A). Until these studies are reviewed, the rotation restriction for non-registered crops, as noted above will remain on the label.
- Plum processing study at an exaggeration (5x) application rate

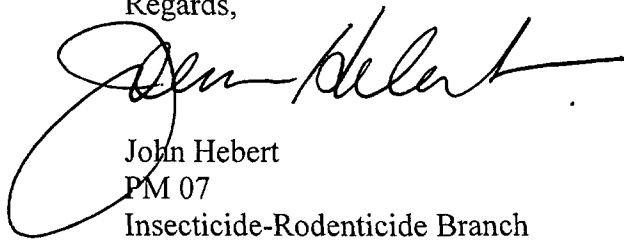
Environmental Fate and Effects Data Requirements

- Acute Sediment Testing. An acute 10-day freshwater sediment test under Guideline 850.1735, with equilibrium, is needed for risk assessment due to the propensity of extoxazole to attach to sediments (Kd value is equal to or greater than 50) and the very high acute toxicity of etoxazole to aquatic invertebrates. The study previously submitted did not have equilibration. A protocol needs to be submitted for approval prior to conducting this study.
- Chronic Sediment Testing (with equilibration). Chronic sediment testing Kd value is equal to or greater than 50, and the half-life in sediment is greater than 10 days in both the aerobic soil and aquatic metabolism studies. The US EPA publication EPA /600/R-01/020: *Chronic Estuarine/Marine Sediment Testing* provides an appropriate protocol for 28-day test with *Leptocheirus plumulosus*. A protocol needs to be submitted for approval prior to conducting this study.
- 122-2 Aquatic Plant Growth (Tier I). The submitted study with *Selenastrum* (MRID 45621705) is considered Supplemental; additional testing with this green alga is not needed at this time. However, Level I screening studies are needed with the remaining four test species for this guideline.

Submit one copy of your final printed labeling incorporating the changes above before you release the products for shipment.

A copy of the Environmental Fate and Effects review and a stamped copy of the labeling are enclosed for your records. If you have any questions, please contact Autumn Metzger at (703) 305-5314 or metzger.autumn@epa.gov.

Regards,



John Hebert  
PM 07  
Insecticide-Rodenticide Branch  
Registration Division (7505P)

Enclosure



ACCEPTED

JUL 14 2009

Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended, for the  
pesticide registered under:

EPA. Reg. No: 59639-107

# Etoxazole Technical

Active Ingredient	By Wt.
*Etoxazole .....	97.2%
Other Ingredients .....	<u>2.8%</u>
Total .....	100.0%

\*2-(2-6-difluorophenyl)-4-[4-(1, 1-dimethylethyl)-2-ethoxyphenyl]-4,5-dihydrooxazole

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**SEE NEXT PAGE FOR ADDITIONAL PRECAUTIONARY STATEMENTS**

EPA Reg. No. 59639-107

EPA Est. No.

**TRANSPORTED IN BULK**

**FIRST AID**

- If in eyes:**
  - Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.
  - Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
  - Call a poison control center or doctor for further treatment advice.
  - Take off contaminated clothing.
- If on skin or clothing:**
  - Rinse skin immediately with plenty of water for 15 to 20 minutes.
  - Call a poison control center or doctor for treatment advice.
- If swallowed:**
  - Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow.
  - Do not induce vomiting unless told to do so by a poison control center or doctor.
  - Do not give anything to an unconscious person.
- If inhaled:**
  - Move person to fresh air.
  - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
  - Call a poison control center or doctor for further treatment advice.

**HOTLINE NUMBER**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact **800-892-0099** for emergency medical treatment information.

60f9

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS & DOMESTIC ANIMALS  
CAUTION**

Causes moderate eye irritation. Avoid contact with eyes, clothing or skin. Harmful if inhaled, swallowed or absorbed through skin. Wash thoroughly with soap and water after handling. Avoid breathing dust. Remove contaminated clothing and wash clothing before reuse.

**ENVIRONMENTAL HAZARDS**

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 (NDPES) 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 Environmental Protection Agency.

**INSTRUCTIONS FOR FORMULATORS**

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

**READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS, AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.**

709

**DISCLAIMER, RISKS OF USING THIS PRODUCT,  
LIMITED WARRANTY  
AND LIMITATION OF LIABILITY**

**IMPORTANT: Read the entire Label including this Disclaimer, Risks of Using this Product, Limited Warranty, and Limitation of Liability before using this product. If the terms are not acceptable THEN DO NOT USE THE PRODUCT; rather, return the unopened product within 15 days of purchase for a refund of the purchase price.**

**RISKS OF USING THIS PRODUCT**

The Buyer and User (referred to collectively herein as "Buyer") of this product should be aware that there are inherent unintended risks associated with the use of this product which are impossible to eliminate. These risks include, but are not limited to, injury to plants and crops to which this product is applied, lack of control of the target pests or weeds, resistance of the target pest or weeds to this product, injury caused by drift, and injury to rotational crops caused by carryover in the soil. Such risks of crop injury, non-performance, resistance or other unintended consequences are unavoidable and may result because of such factors as weather, soil conditions, disease, moisture conditions, irrigation practices, condition of the crop at the time of application, presence of other materials either applied in the tank mix with this product or prior to application of this product, cultural practices or the manner of use or application, (or a combination of such factors) all of which are factors beyond the control of Valent. The Buyer should be aware that these inherent unintended risks may reduce the harvested yield of the crop in all or a portion of the treated acreage, or otherwise affect the crop such that additional care, treatment and expense are required to take the crop to harvest. If the Buyer chooses not to accept these risks, THEN THIS PRODUCT SHOULD NOT BE APPLIED. By applying this product Buyer acknowledges and accepts these inherent unintended risks AND TO THE FULLEST EXTENT ALLOWED BY LAW, AGREES THAT ALL SUCH RISKS ASSOCIATED WITH THE APPLICATION AND USE ARE ASSUMED BY THE BUYER.

Valent shall not be responsible for losses or damages (including, but not limited to, loss of yield, increased expenses of farming the crop or such incidental, consequential or special damages that may be claimed) resulting from use of this product in any manner not set forth on the label. Buyer assumes all risks associated with the use of this product in any manner or under conditions not specifically directed or approved on the label.

**LIMITED WARRANTY**

Valent warrants only that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the label, under average use conditions, when used strictly in accordance with the label and subject to the Risks of Using This Product as described above. EXCEPT AS SET FORTH ABOVE, VALENT MAKES NO OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED. No agent or representative of Valent or Seller is authorized to make or create any other express or implied warranty.

**LIMITATION OF LIABILITY**

To the fullest extent allowed by law, Valent or Seller is not liable for any incidental, consequential, indirect or special damages resulting from the use or handling of this product. The limitation includes, but is not limited to, loss of yield on all or any portion of the treated acreage, increased care, treatment or other expenses required to take the crop to harvest, increased finance charges or altered finance ratings, emotional or mental distress and/or exemplary damages. TO THE FULLEST EXTENT ALLOWED BY LAW, THE EXCLUSIVE REMEDY OF THE BUYER, AND THE EXCLUSIVE MAXIMUM LIABILITY OF VALENT OR SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT SHALL BE THE RETURN OF THE PURCHASE PRICE OF THIS PRODUCT OR, AT THE ELECTION OF VALENT OR SELLER, THE REPLACEMENT OF THE PRODUCT.

**PROMPT NOTICE OF CLAIM**

Valent must be provided with prompt notice of any claim so that an immediate inspection of the affected property or plants can be made. To the extent applicable law allows such requirement, notice of a claim shall be given promptly to Valent, whether the claim is based on contract, negligence, strict liability, or other tort or otherwise be barred from any remedy.

**NO AMENDMENTS**

Valent and Seller offer this product, and Buyer accepts it, subject to the foregoing Disclaimer, Risks of Using This Product, Limited Warranty and Limitation of Liability, which may not be modified by any oral or written agreement.

**FOR FORMULATION OF ETOXAZOLE CONTAINING MITICIDE/OVICIDE USE ONLY**  
THIS PRODUCT IS FOR USE IN FURTHER PREPARATION WITH ETOXAZOLE PRODUCTS. DO NOT USE FOR ANY OTHER PURPOSES. Products formulated with Etoxazole Technical will require registration with the Environmental Protection Agency.

**DIRECTIONS FOR USE**

**Only for Formulation into Miticide/Ovicide Products Intended for:**

**Terrestrial Non-Food Uses on:** Indoor (Greenhouses, Shadehouses, Lathhouses and Interiorscapes) and Outdoor Ornamentals (including: Christmas Trees, Flowering and Foliage Crops, Ground Covers, Shrubs and Ornamental Trees and Non-Bearing Fruit and Nut Trees).

**Terrestrial Food Use on:** Cotton, Cucumber, Grapes, Hops, Melon (Crop Subgroup No. 9A), Mint, Pome Fruit (Crop Group 11), Stone Fruit (Crop Group 12), Strawberry, Tomato and Tree Nuts (Crop Group No. 14).

- Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- Uses for experimental purposes that are in compliance with USEPA requirements.



**STORAGE AND DISPOSAL**

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

**PESTICIDE STORAGE**

Keep pesticide in original container.  
Store in cool, dry place. Protect from excessive heat.  
Do not contaminate food or foodstuffs.  
Do not store or transport near feed or food.  
For help with any spill, leak, fire or exposure involving this material, call 800-892-0099.

**PESTICIDE DISPOSAL**

Wastes resulting from the use of this product may be disposed of on site or at any approved waste disposal facility.

**CONTAINER DISPOSAL**

Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. 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.

Copyright© 2009 Valent U.S.A. Corporation

Manufactured for:  
**Valent U. S. A. Corporation**  
P.O. Box 8025  
Walnut Creek, CA 94596-8025  
www.valent.com

EPA Reg. No. 59639-107  
EPA Est.

059639-00107.20090618.EtoxTech.cucumber.mint.stonefruit.tomato.