

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

NOV 0 5 2009

Ms. Julie Schlekau
Federal Registration Manager
Registration & Regulatory Affairs
Valent U.S.A Corporation, as Agent for Sumitomo Chemical Co., Ltd.
1600 Riviera Avenue, Suite 200
Walnut Creek, CA 94596

Dear Ms. Schlekau,

Subject: New Use - add additional new food uses, bundled six or more

SUMILARV Technical Grade EPA Reg. No. 10308-11

Submission dated December 5, 2008

Following review of the residue data submitted in support of the IR-4 petition [(PP# 8E7492) (74 FR 15971) (FRL-8407-4)], EPA established pyriproxyfen tolerances for: artichoke, globe; asparagus; fruit, small, vine climbing subgroup 13-07E, except grape; vegetable foliage of legume, group 7; vegetable leafy except Brassica, group 4; vegetable, leaves of root and tuber, group 2; and watercress (74 FR 55463, October 28, 2009). Therefore, the labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, is acceptable provided you:

- 1. Submit the results of guideline acute and subchronic neurotoxicity studies in the rat (OPPTS Guideline 870.6200) by January 2, 2011. Please see the attached human health risk assessment for more information.
- 2. Submit the results of a guideline immunotoxicity study (OPPTS 870.7800) by January 2, 2012. Please see the attached human health risk assessment for more information.

Submit three (3) copies of your final printed labeling 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 acceptance of these conditions.

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A stamped copy of the label and copies of the data evaluation reviews are enclosed for your records. If you any questions or require more information, please contact Kevin Sweeney, at (703) 305-5063. Thank you for your cooperation in this matter.

Sincerely

Richard Gebken

Product Manager 10

Insecticide Branch

Registration Division (7505P)

Enclosure

SUMITOMO CHEMICAL COMPANY, LTD.



# AN INSECTICIDE FOR FORMULATING USE ONLY

Active Ingredient		
*Pyriproxyfen		 98.7%
Other Ingredients		
Total		
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\*2-[1-Methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine

# **KEEP OUT OF REACH OF CHILDREN**

# **CAUTION**

SEE NEXT PAGE FOR ADDITIONAL PRECAUTIONARY STATEMENTS

with COMMENTS
In EPA Letter Dated
NOV 0 5 2005
Inder the Federal Insecticide,
ungicide, and Rodenticide Act,
s amended, for the pesticide
egistered under EPA Reg. No.

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# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS CAUTION

Harmful if swallowed, inhaled or absorbed through skin or eyes. Causes moderate eye irritation. Do not breathe the vapor and avoid getting on skin or in eyes. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling and before eating or smoking.

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> </ul>			
	Do not give anything by mouth to an unconscious person.			
If inhaled:	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>			
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>			
If on skin or	Take off contaminated clothing.			
clothing:	<ul> <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>			

#### **HOT LINE 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 **1-800-892-0099** for emergency medical treatment information.

## **ENVIRONMENTAL HAZARDS**

This product is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this pesticide 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 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.

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#### 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 Sumitomo. 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 AGREES THAT ALL SUCH RISKS ASSOCIATED WITH THE APPLICATION AND USE ARE ASSUMED BY THE BUYER.

Sumitomo 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

Sumitomo 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, SUMITOMO MAKES NO OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED. No agent or representative of Sumitomo or Seller is authorized to make or create any other express or implied warranty.

#### LIMITATION OF LIABILITY

In no event shall Sumitomo or Seller be 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. THE EXCLUSIVE REMEDY OF THE BUYER, AND THE EXCLUSIVE MAXIMUM LIABILITY OF SUMITOMO 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 SUMITOMO OR SELLER, THE REPLACEMENT OF THE PRODUCT.

#### PROMPT NOTICE OF CLAIM

Sumitomo must be provided notice as soon as Buyer has reason to believe it may have a claim, but in no event later than twenty-one days from date of planting, or twenty-one days from the date of application, whichever is latter, so that an immediate inspection of the affected property and growing crops can be made.

If Buyer does not notify Sumitomo of any claims, in such period, it shall be barred from obtaining any remedy.

#### NO AMENDMENTS

Sumitomo 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 PYRIPROXYFEN CONTAINING INSECTICIDE PRODUCTS ONLY.

This product is intended only for use in the formulation of pyriproxyfen containing insecticide products. Products formulated with Sumilarv Technical will require registration with the Environmental Protection Agency.

## **DIRECTIONS FOR USE**

# Only for formulation into insecticide products intended for the following uses:

Indoor, Food Indoor, Non-Food/Feed Indoor Residential Terrestrial Food Use on:

**Crop Groupings:** 

Vegetables, Root and Tuber Group (No. 1)

Vegetables, Leaves of Root and Tuber (Human Food or Animal Feed) Group (No. 2)

Vegetables, Bulb Group (No. 3)

Vegetables, Leafy (Except Brassica Vegetables) Group (No. 4)

Vegetables, Brassica (Cole) Leafy Group (No. 5)

Vegetables, Legume (Succulent or dried) Group (No. 6)

Vegetables, Foliage of Legume Group (No. 7)

Vegetables, Fruiting Group (No. 08)

Vegetables, Cucurbits Group (No. 09)

Fruit, Citrus Group (No. 10)

Fruit, Pome Group (No. 11)

Fruit, Stone Group (No. 12)

Berries Group (No. 13)

Small Fruit Vine Climbing Crops (Except Grape) Subgroup (No.13-07E)

Tree Nuts Group (No.14)

Cereal Grains Group (No. 15)

Forage, Fodder and Straw of Cereal Grains Group (No. 16)

Grass, Forage, Fodder and Hay Group (No. 17)

Nongrass Animal Feeds Group (No. 18)

Individual Crops (Not included in crop groupings): Acerola, Artichoke (Globe), Asparagus, Atemoya, Avocado, Banana, Biriba, Black Sapote, Cacao Bean, Canola, for seed only; Canistel, Cherimoya, Cranberry, Custard Apple, Cotton, Dates, Feijoa, Fig, Guava, Grape, Ilama, Jaboticaba, Longan, Lychee, Mamey Sapote, Mango, Okra, Olive, Passionfruit, Papaya, PawPaw, Peanuts, Pineapple, Pistachio, Plantain, Pomegranate, Pulasan, Rambutan, Rangeland, Safflower; Sapodilla, Sesame; Soursop, Spanish Lime, Star Apple, Starfruit, Strawberry, Sugar Apple, Tea, Turnip, Ugli Fruit, Watercress, White Sapote and Wax Jambu.

Formulators who use this product are responsible for providing data to support their own registrations.

## STORAGE AND DISPOSAL

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

## **PESTICIDE STORAGE**

Keep pesticide in original container. Keep container closed when not in use. Containers should be stored in a cool, dry, secure place. Do not store or transport near feed or food.

# **PESTICIDE DISPOSAL**

Wastes resulting from use of this product may be disposed of on site or at an 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.

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Manufactured by: Sumitomo Chemical Company, Ltd. 27-1 Shinkawa 2-Chome, Chuo-ku Tokyo, 104-8260, Japan

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