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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY JAN -5 Washington, D.C. 20460

JAN - 5 2010

2010

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

P. Leanne Pruett
Verolit Chemical Manufacturing Co., Ltd.
c/o Makhteshim Agan of North America, Inc.
4515 Falls of Neuse Road, Suite 300
Raleigh, NC 27609

Subject:

Label Amendment (New Use on Carrot, Celeriac, Cilantro, Okra, Parsley, and Leaf Petioles (Crop Subgroup 4B))

Prometrex Technical EPA Reg. No.46386-2 Application Dated September 3, 2008

Dear Ms. Pruett:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable, provided you agree in writing that:

- 1. Submit the following data for prometryn within two (2) years from the date of this letter as a condition of registration for the new uses stated above:
 - a. <u>Guideline 850.1350: Aquatic Invertebrate Life-cycle (Saltwater)</u> Study must be conducted on mysid shrimp (*Mysidopsis bahia*)
 - b. <u>Guideline 850.1400: Fish Early-Life Stage Toxicity Test (Saltwater)</u> Recommend using sheepshead minnow (*Cyprinodon variegatus*)
 - c. <u>Guideline 860.1300: Nature of the Residue Plants</u> A metabolism study reflecting application of prometryn to carrot or another root crop.
 - d. Guideline 860.1380 Storage Stability

i. In the Residue Chemistry Chapter of the Prometryn RED, HED concluded that the requirements for storage stability data were not fully satisfied for reregistration because information regarding sample storage intervals and conditions was needed for celery and cotton seed samples from studies reviewed in the 10/86 Prometryn Registration Standard. These data remain outstanding. To support the proposed use on the leaf petioles subgroup, information on sample storage conditions and intervals is required from the celery studies (MRIDs 00034043, 00093529, and 00093548). If

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the storage intervals for celery samples from these studies exceeded 37 months, or if storage conditions differed from those represented in the storage stability studies, additional storage stability data or new crop field trials may be required.

- ii. To support the field rotational crop study (MRID 45190601), storage stability data are required reflecting the stability of residues of prometryn in samples of beet root and wheat hay, or straw stored frozen for up to 20-24 months.
- e. <u>Guideline 860.1500: Crop Field Trials Carrot</u> Three additional carrot trials are required in NAFTA Zones 5, 10, and 11 reflecting application according to the maximum proposed use pattern, including use of a surfactant; one of the trials should generate residue decline data.
- f. <u>Guideline 860.1900: Field Accumulation in Rotational Crops</u> Additional information is required concerning the soil characteristics and sample harvest and handling procedures at the CA and MS sites for the study reported in MRID 45190601.
- g. Guideline 870.6200: Acute & Subchronic Neurotoxicity
- h. Guideline 870.7800: Immunotoxicity
- 2. You will submit and/or cite all data required for registration/registration review of your product when the Agency requires all registrants of similar products to submit data.
- 3. You will submit production information (in pounds or gallons produced) for this product for the fiscal year in which the uses on <u>Carrot, Celeriac, Cilantro, Okra, Parsley, and Leaf</u> <u>Petioles (Crop Subgroup 4B)</u> are conditionally registered, in accordance with FIFRA §29. The fiscal year begins October 1 and ends September 30. The production information will be submitted to the Agency no later than November 15, following the end of the preceding fiscal year.

This information must be submitted to:

Mr. Owen F. Beeder U.S. Environmental Protection Agency Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Avenue, NW Washington, DC 20460

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- 4. You must make the following changes to the labeling:
 - a. Change the heading from "INERT INGREDIENTS" to "OTHER INGREDIENTS".
 - b. Change the use site from "fennel" to "Florence fennel".
 - c. Change the "Pesticide Storage and Disposal" section by separating it into "Pesticide Storage" and "Pesticide Disposal".
 - d. Revise the Container Disposal section in accordance with PR Notice 2007-4.

A stamped copy of your label is enclosed for your records. This label supercedes all previously accepted labels. You must submit one (1) copy of the final printed label before you release the product for shipment. Products shipped after eighteen (18) months from the date of this letter or the next printing of the label, whichever occurs first, must bear the new revised label. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA §6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Sincerely,

Jim Tompkins Product Manager 25 Herbicide Branch Registration Division (7505P)

PROMETREX®

TECHNICAL

For Manufacture of Herbicides Use Only

ACTIVE INGREDIENT:

	/
Prometryne: 2,4-bis (isopropyl-amino)-6-(methyl-thio)-s-triazine	
INERT INGREDIENTS:	

TOTAL 100.0%

% BY WT.

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID IF ON SKIN OR . Take off contaminated clothing. CLOTHING: Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eve. Call a poison control center or doctor for treatment advice. IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have 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 by mouth 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. Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Prosar at 1-877-250-9291 for emergency medical treatment information.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Harmful if swallowed, inhaled, or absorbed through skin. Do not breathe dust or spray mist. Avoid contact with eyes, skin, or clothing.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with 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 further guidance, contact your State Water Board or Regional Office of the EPA.

NET CONTENTS: ____ POUND(S)

ACCEPTED with COMMENTS in EPA Letter Detect JAN - 5 2010

EPA Reg. No. 46386-02 EPA Est. No. Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. Manufactured for: Verolit Chemical Manufacturing Co., Ltd. c/o Makhteshim Agan of North America, Inc. 4515 Falls of Neuse Road, Suite 300 Raleigh, NC 27609

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For the manufacture of herbicides only. Only for formulation into a herbicide for the following uses: carrot, celeriac, cilantro, leafy petioles crop group 4B (cardoon, celery, Chinese celery, celtuce, fennel, rhubarb, Swiss chard), okra, parsley, pigeon peas, cotton, and dill (CA only). This product may be used to formulate products for specific use(s) not listed on the PROMETREX label if the formulator, user group, or grower has complied with the U.S. EPA submission requirements regarding the support of such use(s).

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE AND DISPOSAL: Store in a dry place. Improper disposal of unused spray mixture or rinse water is a violation of federal law. If these wastes cannot be used according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance in proper disposal methods.

CONTAINER DISPOSAL: Completely empty bag. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. For minor spills, follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes. In the event of a major spill, fire, or other emergency, call INFOTRAC at 1-800-535-5053 day or night.

LIMITATION OF WARRANTY AND LIABILITY

Read the entire directions for use, conditions 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. Crop injury, 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 Verolit Chemical Manufacturing Co., Ltd. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Verolit Chemical Manufacturing Co., Ltd. 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 Verolit Chemical Manufacturing Co., Ltd. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Verolit Chemical Manufacturing Co., Ltd. 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 Verolit Chemical Manufacturing Co., Ltd.'s election, the replacement of product.

Prometrex is a registered trademark of Agan Chemical Manufacturers, Ltd.

Prometrex Technical (46386-02) (7-23-08 Notif)(IR-4 Crops 9-4-08) PLP