

71711-16

02/29/2008

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

FEB 29 2008

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Marie A. Maks, Manager, Regulatory Affairs
Nichino America, Inc.
Linden Park, Suite 501
4550 New Linden Hill Road
Wilmington, DE 19808

Subject: Agency review of petitions 5E6979 and 5E6980 requesting that 40 CFR 180.511 be amended by establishing tolerances for residues of buprofezin in or on the following agricultural commodities: Fruit, stone. group 12, except peach 2 ppm, grape 0.8 ppm, grape, raisin 1.2 ppm, papaya 0.8 ppm, star apple 0.8 ppm, black sapote 0.8 ppm, mango 0.8 ppm, sapodilla 0.8 ppm, canistel 0.8 ppm, and mamey sapote 0.8 ppm, and an associated submission to lengthen the plant back interval for several crops based on a storage stability study review for MRID # 46804701.

EPA Reg. Nos.: Buprofezin Technical (EPA Reg. No. 71711-16), Applaud® 7OWP Insect Growth Regulator (EPA Reg. No. 71711-15), and/or Applaud 70DF Insect Growth Regulator (EPA Reg. No. 71711-21) to stone fruit, grape, papaya, star apple, black sapote, mango, sapodilla, canistel, and mamey sapote.

Dates of submissions: August 18, 2005, September 16, 2005, and August 22, 2007 (EPA Reg. No. 71711-15), November 21, 2007 (EPA Reg. No. 71711-16), and a supplemental label (EPA Reg. No. 71711-21).

EPA Decision Numbers: D360264, D360267, and D360269.

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.

Nichino must provide a signed letter within 30 days of this approval, agreeing to satisfy all confirmatory data requirements as identified in Items #2 thru #3 below (further described in the attached data evaluation reports (DERs)), and provide five copies of the finished labeling to the Agency prior to releasing the product for shipment. In addition, all of the crops and directions for use must be added to the master label within 18 months from the date of this approval letter as amendments for any supplemental labels associated with these decisions.

1. Label revisions:

- a. Applaud® 70DF Insect Growth Regulator (EPA Reg. No. 71711-21) revise the label which indicates a retreatment interval (RTI) of 14 days for papaya, star apple, black sapote, mango, sapodilla, canistel, and mamey sapote.

2. Data requirements associated with the Health Effects review for the use of Buprofezin in/on Grapes:

- a. Nichino America Inc. must agree to submit an additional four grape field trials in Region 10. Refer to the 2/21/2007 Agency Summary of Analytical Chemistry and Residue Data DER enclosed.

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- b. Nichino America must agree to submit a grape processing study using the currently proposed application scenario (5X rate) and monitoring for BF4 conjugates.

Data requirements associated with the Environmental Fate and Effects Risk Assessment dated May 17, 2007:

Mysid acute toxicity study Guideline 72-3(c)

Freshwater and Saltwater Fish Full Life-Cycle stuffy 72-5

850.1735: Acute Sediment (freshwater)

850.1790: Acute Sediment *Chironomus tentans* (three part study)

850.1740: Acute Sediment (Estuarine/Marine)

EPA/600/R01/020: Chronic Estuarine/Marine Sediment Studying: 28 day study in *Leptocheirus plumulosus*.

The chronic sediment study (EPA/600/R-99/064) is reserved pending the results from the other required sediment organism toxicity studies.

3. Submit revised Section Fs as follows:

| Table 1: HED Recommended Tolerance Levels. | |
|--|---------------------------------|
| Commodity Definition | HED Recommended Tolerance (ppm) |
| fruit, stone, group 12, except apricot and peach | 1.9 |
| apricot | 9.0 |
| grape | 2.5 |
| papaya | 0.90 |
| star apple | 0.90 |
| black sapote | 0.90 |
| mango | 0.90 |
| sapodilla | 0.90 |
| canistel | 0.90 |
| mamey sapote | 0.90 |

Five copies of the finished labeling must be submitted prior to releasing the product for shipment. If you have any questions, you may contact Melody Banks at (703)-305-5413.

Sincerely,



Richard J. Gebken
Product Manager 10
Insecticide Branch
Registration Division (7505C)

Enclosures

DERs, and stamped approved labels (accepted with comments).

NICHINO AMERICA, INC.

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ACCEPTED
with COMMENTS
in EPA Letter Board

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

71711-16

BUPROFEZIN TECHNICAL

For Manufacturing or Formulating Use Only

Active Ingredient:

Buprofezin: 2-tert-butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one 99.1%

Other Ingredients: 0.9 %

TOTAL 100.0%

Contains 0.70 lbs. buprofezin per pound of product

EPA Reg. No. 71711-16

EPA Est. No. 067017- JPN- 003

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

| | |
|------------------------|---|
| If inhaled | <ul style="list-style-type: none">• 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 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. |
| If in eyes | <ul style="list-style-type: none">• 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 eye.• Call a poison control center or doctor for treatment advice. |
| If swallowed | <ul style="list-style-type: none">• Call 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 the poison control center or doctor.• Do not give anything by mouth to an unconscious person. |

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 1-800-348-5832 for emergency medical treatment information. In case of fire or spills, information may be obtained by calling 1-800-424-9300.

NOTE TO PHYSICIAN: There is no specific antidote. All treatment should be based on observed signs and symptoms of distress in the patient. Overexposure to materials other than this product may have occurred. For product information use internet website www.nichino.net

Active Ingredient Made in Japan
Nichino America, Inc.
4550 New Linden Hill Road, Suite 501
Wilmington, DE 19808

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals
CAUTION

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

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

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 (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 sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

IMPORTANT-Read the entire Directions for Use and Disclaimer of Warranties before using this product.

DIRECTIONS FOR USE

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

Only for formulation into a insecticide, for:

- (1) Almonds, pistachios; Bananas, citrus (crop group 10), grapes, stone fruit (crop group 12), and pome fruit (crop group 11); Acerola, atemoya, avocado, biriba, black sapote, canistel, cherimoya, custard apple, feijoa, guava, ilama, jaboticaba, longan, lychee, mamey sapote, mango, papaya, passion fruit, pulasan, rambutan, sapodilla, soursop, Spanish lime star apple, starfruit, sugar apple, and wax jambu; Cotton, cucurbits (crop group 9), lettuce, snap beans, tomatoes, and ornamentals (greenhouse and outdoor)
- (2) This product may be used to formulate products for specific use(s) not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s).

STORAGE AND DISPOSAL

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

STORAGE: Store in original container, unopened, in a cool, dry place.

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: Completely empty liner by shaking and tapping sides and bottom to loosen particles. Then dispose of empty container in a sanitary landfill, or by incineration, or, if allowed by State or local authorities, by burning. If burned, stay out of smoke.

NICHINO AMERICA, INC.

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IMPORTANT: READ BEFORE USE

By using this product, user or buyer accepts the following conditions, warranty, disclaimer of warranties and limitations of liability.

CONDITIONS: The directions for use of this product are believed to be accurate and should be followed carefully. However, because of extreme weather and soil conditions, use methods and other factors beyond the control of Nichino America, Inc. (NAI), it is impossible for NAI to eliminate all risks associated with the use of this product. As a result, crop injury or ineffectiveness is always possible. All such risks are assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: THERE ARE NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, WHICH EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of NAI is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. NAI disclaims any liability whatsoever for incidental or consequential damages, including, but not limited to, liability arising out of breach of contract, express or implied warranty (including warranties of merchantability and fitness for a particular purpose), tort, negligence, strict liability or otherwise.

LIMITATIONS OF LIABILITY: 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 THE ELECTION OF NICHINO AMERICA, THE REPLACEMENT OF PRODUCT.

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