

71711-21



02/29/2008
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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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/or 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
maney 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).

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ACCEPTED
with COMMENTS
in EPA Letter Dated

FEB 29 2008

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

71711-21

Nichino America, Inc.



APPLAUD® 70DF
INSECT GROWTH REGULATOR

ACTIVE INGREDIENT:

Buprofezin: (2-tert-butylimino-3-isopropyl-5-phenylperhydro-1,3,5-thiadiazin-4-one) 70.00%

OTHER INGREDIENTS: 30.00%

TOTAL 100.00%

Contains 0.70 lbs. buprofezin per pound of product.

EPA Reg. No. 71711-21

KEEP OUT OF REACH OF CHILDREN
CAUTION

Net Contents: 12 lb.

450510
040602 Rev. 10/07

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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.	

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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.

User Safety Recommendations

Users should: Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENGINEERING CONTROLS STATEMENT

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

ENVIRONMENTAL HAZARDS

For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters.

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

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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.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls over long-sleeved shirt and long pants
- Waterproof gloves
- Socks and chemical-resistant footwear

GENERAL INFORMATION

APPLAUD® 70DF insect growth regulator contains the active ingredient, buprofezin. It is effective against the nymph stages of whitefly, scales, mealybugs, planthoppers, and leafhoppers by inhibiting chitin biosynthesis, suppressing oviposition of adults, and reducing viability of eggs. Treated susceptible pests may remain alive on the plant for 3-7 days, but feeding damage during this time is typically very low. APPLAUD 70DF is not disruptive to beneficial insects and mites.

Good coverage is essential. Apply by ground or air in sufficient water volume. Orient nozzles to assure good coverage. Use of higher volume of water will assure better coverage, especially under adverse conditions such as hot, dry weather, and/or a dense canopy. The entire field should be treated.

Apply when economic infestations occur based on local information.

APPLAUD 70DF is not for sale, sale into, distribution, and or use in Nassau and Suffolk counties of New York state.

INSECTS CONTROLLED

Whiteflies: Ash whitefly; Greenhouse whitefly; Silverleaf whitefly; Sweet potato whitefly

Mealybugs: Citrus mealybug; Comstock mealybug; Gill's mealybug; Grape mealybug; Longtailed mealybug; Mexican mealybug; Obscure mealybug; Striped mealybug; Vine mealybug

Leafhoppers and Planthoppers: Brown planthopper; Cherry leafhopper; Eastern grape leafhopper; Glassy-winged sharpshooter; Potato leafhopper; Variegated leafhopper; Western grape leafhopper

Scales:

Soft Scales: Barnacle scale; Black scale; Brown soft scale; Citricola scale; False oleander scale; Hemispherical scale; Indian wax scale and other wax scales; Tessellated scale; White peach scale

Armored Scales: Boissduval scale; Cactus scale; California red scale; Coconut scale; Fern scale; Florida red scale; Oystershell scale; San Jose scale

Margarodid Scale: Cottony cushion scale

MIXING, LOADING, AND HANDLING INSTRUCTIONS

SPECIFIC MIXING INSTRUCTIONS

APPLAUD 70DF ALONE: Fill spray tank with 3/4 of the amount of water needed for the intended application and then turn on agitation. Pour recommended amount of product on the surface of water in the spray tank. Add the balance of the water to the spray tank with agitation running. Keep agitation running during filling and spraying operations. If spraying must be stopped before emptying the sprayer, resume agitation before spraying the remainder of the load.

APPLAUD 70DF TANK MIXTURES: Follow all use directions as listed above under **APPLAUD 70DF ALONE** with the following exception: after the APPLAUD 70DF is thoroughly mixed and the tank is 3/4 full, add the recommended amount of wettable powder, soluble powder, flowable, emulsifiable concentrate, or soluble liquid product, while maintaining agitation. If a spray additive is needed, add a liquid fertilizer, surfactant, or crop oil concentrate to the spray tank at this time. Then continue adding water to the tank to achieve the desired level, while maintaining agitation.

APPLAUD 70DF TANK MIXTURES WITH PRODUCTS IN WATER-SOLUBLE PACKAGING: Follow all use directions as listed above under **APPLAUD 70DF ALONE** with the following exception: add the desired number of water-soluble bags to the tank (if allowed by their label instructions) at the same time the APPLAUD 70DF is added. **Note:** If using products in water soluble packaging, do not tank mix with products that contain boron, chromium, or other micronutrients.

**APPLICATION RATE CHART FOR
APPLAUD 70DF INSECT GROWTH REGULATOR**

Crop	Pest	Dosage Rate Formulated Product/A	Application Directions And Restrictions
Acerola Atemoya Avocado Biriba Cherimoya Custard apple Feijoa Guava Ilama Jaboticaba Passion fruit Soursop Star apple Sugar apple Wax jambu	Scales	34.5 oz	Limited to Florida, Hawaii, and Puerto Rico <ul style="list-style-type: none"> • Treatment should be made when peak crawler emergence occurs. Consult local and State agricultural authorities for details. • Good coverage is essential. Apply by ground application using at least 20 gallons of water per acre. • Apply no more than two applications per season. • Allow at least 14 days between applications. • Do not apply more than 69 oz per acre per season. • Do not apply within 21 days of harvest.
	Leafhoppers Mealybugs Whiteflies	9 to 12 oz	
Black sapote Canistel Mamey sapote Mango Papaya Sapodilla Star apple	Leafhoppers Mealybugs Scales Whiteflies	9 to 12 oz	Limited to Florida, Hawaii, and Puerto Rico <ul style="list-style-type: none"> • Treatment should be made when peak crawler emergence occurs. Consult local and State agricultural authorities for details. • Good coverage is essential. Apply by ground application using at least 20 gallons of water per acre. • Apply no more than five applications per season. • Allow at least 14 days between applications. • Do not apply more than 45 oz per acre per season. • Do not apply within 3 days of harvest.

**APPLICATION RATE CHART FOR
APPLAUD 70DF INSECT GROWTH REGULATOR**

Crop	Pest	Dosage Rate Formulated Product/A	Application Directions And Restrictions
Bananas	Leafhoppers Mealybugs Scales Whiteflies	7 oz	<ul style="list-style-type: none"> • Treatment should be applied when population level reaches economic threshold. Consult local or State agricultural authorities for details. • Good coverage is essential. Apply by ground in a minimum of 15 gallons of water per acre. Use of a higher volume of water will assure better coverage, especially under adverse conditions, such as hot, dry weather and/or a dense canopy. • Apply no more than four applications per season. • Allow at least 14 days between applications. • Do not apply within one day of harvest.
Citrus Crop Group	California red scale Citricola scale Cottony cushion scale Glassy-winged sharpshooter Mealybugs	34.5 to 46 oz	<ul style="list-style-type: none"> • Treatment should be made when peak crawler emergence occurs. Consult local and State agricultural authorities for details. • Good coverage is essential. Apply by ground application using 750 to 2000 gallons of water per acre. • Apply no more than two applications per season. • Allow at least 60 days between applications. • Do not apply within 3 days of harvest.

**APPLICATION RATE CHART FOR
APPLAUD 70DF INSECT GROWTH REGULATOR**

Crop	Pest	Dosage Rate Formulated Product/A	Application Directions And Restrictions
Grapes	Leafhoppers	9 to 12 oz	<ul style="list-style-type: none"> • Treatment should be applied when population level reaches economic threshold. Consult local and State agricultural authorities for details. • Good coverage is essential. Apply by ground application using 50 to 200 gallons of water per acre, depending on the size of the grapes. Orient nozzles to assure good coverage. Use of a higher volume of water will assure better coverage, especially under adverse conditions, such as hot, dry weather and/or a dense canopy. • Apply no more than two applications per crop cycle. • Allow at least 14 days between applications. • Do not exceed 24 oz/A per crop cycle. • Do not apply within 7 days of harvest.
	Mealybugs	12 to 24 oz	
Longan Lychee Pulasan Rambutan Spanish Lime	Scales	34.5 oz	<ul style="list-style-type: none"> • Apply by ground in a minimum of 75 gallons per acre spray volume. • Do not make more than 2 applications per year. • Allow at least 14 days between applications. • Do not exceed 72 oz/A (3.16 lb ai/A) per year. • Do not apply within 21 days of harvest.

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 container into application equipment. Then dispose of empty packaging in a sanitary landfill, or by incineration, or, if allowed by State or local authorities, by burning. If burned, stay out of smoke.

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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Active Ingredient Made in China; Formulated and Packaged in U.S.A.

Nichino America, Inc.

4550 New Linden Hill Road, Suite 501
Wilmington, DE 19808

www.nichino.net

450510
040602 Rev. 10/07

SUPPLEMENTAL LABEL

Applaud® 70DF Insect Growth Regulator

For Use on Grapes

EPA Reg. No. 71711-21

ACCEPTED
with COMMENTS
in EPA Letter Dated

FEB 29 2008

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

71711-21

DIRECTIONS FOR USE

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

This supplemental labeling must be in the possession of the user at the time of application. A revised preharvest interval, revised rates, and revised rotational restrictions appear on this supplemental labeling that do not appear on the Section 3 container label.

NOTICE: Before using this product, read the First Aid, Precautionary Statements, Conditions of Sale and Warranty, and complete Directions for Use found on the container labeling.

APPLICATION RATE CHART FOR APPLAUD 70DF GROWTH REGULATOR

Crop	Insects Controlled	Formulated Product/A	Preharvest Interval (PHI)	Application Directions And Restrictions
Grapes	Leafhoppers	9 to 12 oz	7 days	<ul style="list-style-type: none"> Treatment should be applied when population level reaches economic threshold. Consult local and State agricultural authorities for details. Good coverage is essential. Apply by ground application using 60 to 200 gallons of water per acre, depending on the size of the grapes. Orient nozzles to assure good coverage. Use of a higher volume of water will assure better coverage, especially under adverse conditions, such as hot, dry weather and/or a dense canopy. Apply no more than two applications per crop cycle. Allow at least 14 days between applications. Do not apply more than 7 days before harvest.
	Mealybugs	12 to 24 oz		

USE PRECAUTIONS

- Crop Rotational Restrictions: All crops listed on this label may be planted at any time. Leafy vegetables may be planted 30 days following application. Root and tuber vegetables may be planted 60 days following application. All other crops may be planted 365 days following application.
- Do not apply this product through any type of irrigation system.

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