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

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

APR 4 2005

Subject: Agency review of various petitions (3E6636, 3E6741, 3E6742, 0F6087, 4F6887, 4F6873 and 4F6887) requesting that 40 CFR 180.511 be amended by establishing tolerances for residues of buprofezin in or on the following agricultural commodities: Fruit, pome, group 11, except apple and apple, pomace at 4.0 ppm; apple at 1.2 ppm; apple, pomace at 2.5 ppm; peach, apricot, and nectarine at 3.0 ppm; avocado, papaya, star apple, black sapote, mango, sapodilla, canistel, mamey sapote, sugar apple, cherimoya, atemoya, custard apple, ilama, soursop, biriba, guava, feijoa, jaboticaba, wax jambu, starfruit, passionfruit, and acerola at 0.30 ppm; meat commodities for (cattle, goats, hogs, horse, and sheep) at 0.05 ppm; kidney commodities for (cattle, goats, hogs, horse, and sheep at 0.05 ppm); fruit, citrus, group 10 at 2.5 ppm; citrus, dried pulp at 7.5 ppm; citrus, oil at 80 ppm; Head lettuce at 5 ppm; leaf lettuce at 13 ppm; vegetables, cucurbits, group 9 at 0.5 ppm, and associated documentation and label amendments (supplemental for 71711-20).

EPA Reg. No.: 71711-15, 71711-16, 71711-20, and 71711-21.

Product Names: Applaud® 70 WP Insect Growth Regulator, Buprofezin Technical, & Buprofezin 40SC, and Applaud 70DF Insect Growth Regulator

Dates of submissions: July 28, 1998, May 19, 2003, June 30, 2003, July 7, 2003, July, 2003, November 2, 2004, December 13, 2004, and March 11, 2005.

The supplemental labels submitted to the Agency on March 11, 2005 in conjunction with Applaud 70WP and Applaud DF (EPA Reg. Nos. 71711-15, and 71711-21) for registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable subject to the comments listed below.

Nichino must provide a signed letter within 10 days of this approval, agreeing to satisfy all confirmatory data requirements as identified in Items #1 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.

Item #1: Almond, Banana, Citrus, Cotton, Grape, and Tomato Section 3 Registrations. Review of Amendments Dated 23-Sep-2002, 11-Jun-2002, 14-Mar-2003, and 17-Mar-2003 . Submitted in Response to Residue Chemistry Deficiencies Identified D273252 (T. Bloem, 20-Mar-2001). MRIDs 45694203, 45694204, and 45782401.[1]

[1] A copy of the data evaluation report (DER D273252) is enclosed for reference.

1. Based on the information provided by Nichino and subsequent Agency review for Item #1 above, the following issues must be addressed by Nichino:
   a. Submit a Revised Sections B[2] and F[3];
   b. submit a confirmatory method and specificity study for plant enforcement method (conclusion 2 as identified in the DER[1]);
   c. submit a radiovalidation of the livestock enforcement method (conclusion 3 as identified in the DER[1]);
   d. submit storage stability data (conclusion 4 as identified in the DER[1]);
   e. submit field trial data for almond hull, banana, lemon, cotton, and tomato (conclusions 5, 6, 7, 8a, 9a, and 9b[1]);
   f. and provide processing studies for orange, apple, and grape (conclusion 11a and 11b as identified in the DER[1])

Item #2: **Buprofezin (PC Code 275100). Section 3 Registration for Application of Buprofezin to Avocado, Sugar Apple, Guava, and Related Tropical Fruits (PP# - 3E6742); Pome Fruit (PP# - 3E6636); and Peach (PP# - 3E6741). Summary of Analytical and Residue Chemistry Data. DB #: D293230. Decision Number: 331662. MRID 46007201, 46007202, 46007203, 4602610l, and 46034101 and follow-up memorandum in response to the Nichino rebuttal submission dated April 13, 2004.[4]**

1. Based on the information provided by Nichino and subsequent Agency review for Item #2 above, the following issues must be addressed by Nichino:

   a. Submit a revised Section B as follows: Based on the currently-available field trial data, buprofezin may be applied to avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla, and star apple grown in Florida and Puerto Rico only. Information concerning the application equipment and spray volumes for pome fruit must also be added to the label. The currently available field trial data only supports foliar directed ground application with spray volumes >20 gallons/acre (GPA).[5] Submit a revised Section F.[6]

   b. Per Guidance outlined in OPPTS 860.1500 Residue Chemistry Test Guidelines, the Agency requires that Nichino submit four avocado field trials in Region 10 (two with spray volumes >100 GPA and two with spray volumes <100 GPA).

   c. The results of a lemon metabolism study, which resulted in significant BF4 conjugate residues, and the results of a grape processing study which indicated that BF9 and/or BF12 may possess processing factors leading to significant residues in processed commodities, The Agency is requiring that Nichino submit an apple processing study monitoring for residues of BF9, BF12, and BF4 conjugates. Based on the results of this study, the Agency may require additional apple field trial data in the absence of these data.

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[2] *Revisions to a supplemental label were provided by Nichino for the following products: Applaud 70WP Insect Growth Regulator, 71711-15; Applaud 70 DF Insect Growth Regulator, 71711-21.*

[3] *Revisions were provided by Nichino as a superseding tolerance Petition PP 4F6873.*

[4] A copy of the data evaluation report (DER D293230 reviews dated 1/7/2004 and 5/19/2004) are enclosed for reference.

[5] *Submitted by Nichino as part of the supplemental label for Applaud DF Insect Growth Regulator; 71711-21.*

[6] *Submitted by Nichino as part of the March 11, 2005 communications.*

Item #3: Buprofezin. Cucurbit Vegetables and Lettuce Section 3 Registrations. Review of Amendments Dated 11-June-2002, 23-Septeniber-2002, and 14-March-2003 Submitted in Response to Residue Chemistry Deficiencies Identified P261869 (T. Bloem, 24-Apr-2000).[7]

1. Based on the information provided by Nichino and subsequent Agency review for Item #2 above, the following issues must be addressed by Nichino:
   a. Nichino must submit a Revised Section B[8].
   b. Nichino must submit confirmatory methods and interference studies for the plant enforcement method BF102196. If Nichino proposes a confirmatory method which employ a mass spectrum detector (MS), then interference studies are unnecessary (chromatograms and spectra of fortified samples should be submitted; structurally significant ions should be chosen with a m/z> 91 and intensity> 3x noise at the limit of quantitation (LOQ) for the primary method).
   c. The Agency is requiring storage stability data. The adequacy of these data to validate the storage intervals for the samples collected from the field trial, processing, feeding and rotational crop studies will be determined upon submission and review.

If you have any questions, you may contact Richard Gebken at (703)-305-6701.

Sincerely,

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

Enclosures

[7] A copy of the data evaluation report (DER) dated December 17, 2003 is enclosed for reference.

[8] *Revisions were provided by Nichino with a superseding tolerance Petition PP 4F6877 .*

SUPPLEMENTAL LABEL

APPLAUD® 70DF Insect Growth Regulator

For Use on Citrus (Grapefruit, Lemons, Limes, Kumquats, Oranges)

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.

The revised preharvest interval on this labeling of 3 days supersedes the preharvest interval for citrus that appears 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.

GENERAL INFORMATION

APPLAUD® 70DF insect growth regulator contains the active ingredient, buprofezin. It is effective against the nymph stages of scales and immature stages of other molting insects by inhibiting chitin biosynthesis. Buprofezin also suppresses oviposition of adults and reduces 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 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.

Apply when economic infestations occur based on local information.

INSECTS CONTROLLED

California red scale, Citricola scale, Cottony cushion scale, Glassy-winged sharpshooter

RESISTANCE MANAGEMENT

APPLAUD 70DF belongs to a class of chemicals not previously used as pesticides and not known to be cross-resistant to other classes of insecticides. However, insect pests are known to develop resistance to products used repeatedly. Because resistance development cannot be predicted, the use of this product should conform to resistance management strategies established for the crop and use area. Such strategies may include rotating with insecticides with different modes of action. Consult your local pest control advisor or extension office for details. If resistance to this product develops in your area, it may not provide adequate control. If you experience difficulty with control, and resistance is a likely cause, consult your local state university horticultural specialist or local agricultural authorities for the best alternative method of control. To preserve the usefulness of APPLAUD 70DF, do not make consecutive applications. Prior to subsequent applications, use an alternative chemistry with a different mode of action. If a different crop in an adjacent field has been treated with buprofezin against silverleaf whitefly within the past 28 days, do not apply APPLAUD 70DF as the first silverleaf whitefly application. Always consult your local crop advisor for the most appropriate control decision for your area. Resistance management strategies advise against applying rates lower than those recommended on the label.

ACCEPTED
with COMMENTS
In EPA Letter Dated
APR 4 2005
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 71711-21

Nichino America, Inc.
4550 New Linden Hill Road, Suite 501
Wilmington, DE 19808

APPLICATION RATE CHART FOR APPLAUD 70DF INSECT GROWTH REGULATOR

Crop	Pest	Dosage Rate Formulated Product/A	Comments
Citrus	California red scale Citricola scale Cottony cushion scale Glassy-winged sharpshooter	35 to 46 oz	• 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.

USE PRECAUTIONS

- All crops listed on the package label may be replanted at any time. Small grain crops and leafy vegetables may be planted 30 days following application. All other crops may be planted 60 days following application.
- Do not apply this product through any type of irrigation system.

APP-SUP-001 3/05

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SUPPLEMENTAL LABEL

Applaud® 70DF Insect Growth Regulator

For Use on acerola, atemoya, avocado, biriba, black sapote, canistel, cherimoya, custard apple, feijoa, guava, ilama, jaboticaba, mamey sapote, mango, papaya, passion fruit, sapodilla, soursop, star apple, starfruit, sugar apple, and wax jambu
(Limited to State of Florida and Puerto Rico)

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.
New crops 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.

GENERAL INFORMATION

APPLAUD® 70DF Insect Growth Regulator contains the active ingredient, buprofezin. It is effective against the nymph stages of scales and immature stages of other molting insects by inhibiting chitin biosynthesis. Buprofezin also suppresses oviposition of adults and reduces 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 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.

Apply when economic infestations occur based on local information.

INSECTS CONTROLLED

Whiteflies, scales, leafhoppers, and mealybugs

RESISTANCE MANAGEMENT

APPLAUD 70DF belongs to a class of chemicals not previously used as pesticides and not known to be cross-resistant to other classes of insecticides. However, insect pests are known to develop resistance to products used repeatedly. Because resistance development cannot be predicted, the use of this product should conform to resistance management strategies established for the crop and use area. Such strategies may include rotating with insecticides with different modes of action. Consult your local pest control advisor or extension office for details. If resistance to this product develops in your area, it may not provide adequate control. If you experience difficulty with control, and resistance is a likely cause, consult your local state university horticultural specialist or local agricultural authorities for the best alternative method of control. To preserve the usefulness of APPLAUD 70DF, do not make consecutive applications. Prior to subsequent applications, use an alternative chemistry with a different mode of action. If a different crop in an adjacent field has been treated with buprofezin against silverleaf whitefly within the past 28 days, do not apply APPLAUD 70DF as the first silverleaf whitefly application. Always consult your local crop advisor for the most appropriate control decision for your area. Resistance management strategies advise against applying rates lower than those recommended on the label.

Nichino America, Inc.
4550 New Linden Hill Road, Suite 501
Wilmington, DE 19808

ACCEPTED
with COMMENTS
In EPA Letter Dated
APR 4 2005
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 71711-21

APPLICATION RATE CHART FOR APPLAUD 70DF GROWTH REGULATOR

Crops	Insects Controlled	Formulated Product/A	Comments
Acerola Atemoya Avocado Biriba Black sapote Canistel Cherimoya Custard apple Feijoa Guava Ilama Jaboticaba Mamey sapote Mango Papaya Passion fruit Sapodilla Soursop Star apple Starfruit Sugar apple Wax jambu	Whiteflies Scales Leafhoppers Mealybugs	34.5 oz	• 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. • Do not apply within 21 days of harvest. • Do not apply more than 69 oz per acre per season.

USE PRECAUTIONS

- All crops listed on the package label may be replanted at any time. Small grain crops and leafy vegetables may be planted 30 days following application. All other crops may be planted 60 days following application.
- Do not apply this product through any type of irrigation system.

APP-SUP-002 3/05

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