


264-677

9/8/2000

Page 1 of 7

 <p>U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (HT-355C) 401 M St. S.W. Washington, D.C. 20460</p> <p>NOTICE OF PESTICIDE Registration</p> <p>(under FIFRA, as amended)</p>	<p>EPA Reg. Number: 264-677</p>	<p>Date of Issuance: SEP -8 2000</p>
	<p>Term of Issuance: Conditional Registration</p>	
	<p>Name of Pesticide Product: Applaud® 70WP</p>	
<p>Name and Address of Registrant (include ZIP Code): Aventis CropScience USA LP 2 T.W. Alexander Dr. Research Triangle Park, NC 27709</p>		
<p>Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.</p>		
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered/re-registered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p>		

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(C). Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3)(c)(2)(B).

1. **Make the following label changes (Revision of Section B of the Tolerance Petition):**

- a. Revise the EPA Registration Number to read: EPA Reg. No. 264-677.
- b. Pending submission and evaluation of the requested storage stability data, the Agency concluded that a 120-day plant back interval for all non-labeled crops is necessary for the following reasons:
 - (1) buprofezin residues were declining with increasing plant back interval in the confined rotational study;
 - (2) a 30-day plant back interval in the field rotational study resulted in low buprofezin residues; and
 - (3) the soil was treated with a single application of buprofezin at 2x the maximum seasonal rate in the field rotational study.
- c. The label should also be amended to include a minimum application volume for both air and ground application.

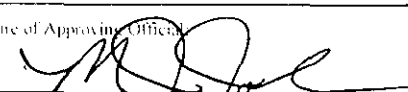
2. **Human Health Assessment data requirements:**

Additional data requirements are needed to upgrade and/or characterize the human health and/or environmental effects of buprofezin and are as follows:

- a. A developmental neurotoxicity study in rats (OPPTS 870.6300) [guideline requirement (40 CFR 158) for Food/Feed Use], based on thyroid effects observed in the dog and rat. Aventis CropScience should contact the Agency for specific details regarding this study, and present a protocol for Agency review prior to initiation of this study.

3. **Revision of Section F of the Tolerance Petition:**

- a. Aventis CropScience shall make any necessary modifications to the proposed

<p>Signature of Approving Official: </p>	<p>Date: SEP 8 2000</p>
---	------------------------------------

enforcement method resulting from petition method validation. A confirmatory method has not been proposed by Aventis, nor has an interference study been submitted. If Aventis proposes a confirmatory method which employs a mass spectrum detector (MS), then an interference study is not necessary (chromatograms and spectra of fortified lettuce and cucumbers must be submitted along with the limit of quantitation (LOQ)). In addition, Aventis Crop Science will be required to make any necessary modifications to the proposed enforcement method resulting from petition method validation.

b. Aventis Crop Science must submit storage stability data validating the following intervals for buprofezin, BF 9, and BF 12 (field trial data needs validation of buprofezin only):

- cucumber - 26 months (field trial);
- summer squash - 12 months (field trial);
- lettuce - 31 months (field trial and field rotational studies);
- wheat forage, hay, and straw - 29 months (confined and field rotational studies);
- wheat grain - 21 months (confined and field rotational studies);
- sugar beet top and root - 24 months (field rotational study);
- mustard greens - 28 months (field rotational study);
- turnip tops and roots - 29 months (field rotational study);
- and carrot - 26 months (field rotational study).

c. **Curcubits crop group:** The Agency concluded that the available field trial data are sufficient for establishment of **time-limited buprofezin tolerances in/on "vegetables, cucurbits, group" at 0.50 ppm**. Appropriate permanent tolerances will be assessed once Aventis CropScience submits the requested storage stability and field trial data. At that time, Aventis Crop Science should submit a revised Section F.

In addition the following additional data are required:

- (1) The frozen storage intervals for the cantaloupe (10 months), summer squash (12 months), and cucumber (26 months) samples should be validated.
- (2) Since the crops were treated with a 40% SC formulation at 2x the maximum seasonal rate (petitioner is requesting registration of a 70% WP formulation), HED requests the petitioner to conduct cantaloupe field trials in Regions 2 (n=1), 5 (n=1), 6 (n=1), and 10 (n=3). Three plots should be established at each of the field trial sites (1 control and 2 treated). One of the treated plots should receive application of the 40% SC formulation (application scenario equivalent to that in the submitted field trial studies) while the other treated plot should receive application of the 70% WP formulation (application scenario equivalent to label instructions). From this data, an adjustment factor will be calculated and applied to all the currently available cucurbit field trial data.

d. **Lettuce, leaf; lettuce, Head crop groups:** The Agency concluded that the available field trial data are sufficient for establishment of time-limited buprofezin tolerances in/on "lettuce, head" and "lettuce, leaf" at 5.0 ppm and 15 ppm, respectively. Appropriate permanent tolerances will be assessed once Aventis CropScience submits the requested storage stability and field trial data. At that time, Aventis Crop Science should submit a revised Section F.

- (1) The frozen storage interval for the lettuce samples (28 months) Should be validated.
- (2) Since the majority of the field trial data was performed with a 40% SC formulation at 2x the maximum seasonal rate, the Agency is requiring Aventis CropScience to conduct additional leaf lettuce field trials in Regions 1 (n=1), 3 (n=1), 6 (n=1), and 10 (n=6). Three plots should be established at each of the field trial sites (1 control and 2 treated). One of the treated plots should receive application of the 40% SC formulation

Signature of Applying Official	Date: SEP 8 2000
--------------------------------	------------------

(application scenario equivalent to that in the submitted field trial studies) while the other treated plot should receive application of the 70% WP formulation (application scenario equivalent to label instructions). From this data, an adjustment factor will be calculated and applied to all the currently available leaf and head lettuce field trial data.

4. **Environmental Effects data requirements:**

- a. Additional data are needed to upgrade the Terrestrial field study (164-1): storage stability data from "Upgradable" to "Acceptable" in accordance to the Subdivision N Guidelines for the fulfillment of EPA data requirements.
- b. An additional aquatic chronic toxicity test: Freshwater Fish Full Life-Cycle (72-5), is required since the TGAI is moderately persistent in the environment and shows some potential effects on growth and reproduction in fish and birds. In addition, the 56-day EEC of 3.71 ppb approaches one-tenth of the NOAEL of 52 ppb in the Fish Early Life Stage study and the peak EEC of 6.95 ppb is greater than one-tenth of the NOAEL.

5. You will submit production information (pounds or gallons produced) for this product for the fiscal year in which the subject use is now conditionally registered, in accordance with FIFRA section 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 should be submitted to:

**U.S. Environmental Protection Agency
Office of Pesticide Programs (7504C)
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460**

6. Submit two copies of the revised final printed label before you release the product for shipment.

If these conditions are not complied with on or before **December 31, 2003**, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,



Marion Johnson
Product Manager 10
Insecticide Branch
Registration Division (7505C)

enclosure

Signature of Approving Official:	Date: SEP 8 2000
----------------------------------	---------------------



AGREVO[®]

Applaud[®] 70WP

INSECT GROWTH REGULATOR

**ACCEPTED
with COMMENTS
In EPA Letter Dated**

SEP - 8 2000

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

264-677



For Lettuce, Melons, Cucumbers, Pumpkins, & Squash

Specimen Label

ACTIVE INGREDIENT:

Buprofezin: (2-*tert*-butylimino-
3-isopropyl-5-phenyl-1,3,5-
thiadiazinan-4-one) 70.00%

INERT INGREDIENTS: 30.00%

TOTAL: 100.00%

This product contains 0.70 lbs. of buprofezin per pound of product.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

**STATEMENT OF PRACTICAL
TREATMENT (FIRST AID)**

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger, or if available by administering syrup of ipecac. If person is unconscious, do not give anything by mouth and do not induce vomiting.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IN CASE OF MEDICAL EMERGENCIES OR HEALTH AND SAFETY INQUIRIES, OR IN CASE OF FIRE, LEAKING, OR DAMAGED CONTAINERS, INFORMATION MAY BE OBTAINED BY CALLING 800-228-5635, EXT. 202.

**PRECAUTIONARY STATEMENTS
HAZARD 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.

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.

USER SAFETY RECOMMENDATIONS

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

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.

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 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 the 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® 70WP Insect Growth Regulator contains the active ingredient, buprofezin. It is effective against the nymph stages of whitefly by inhibiting chitin biosynthesis. APPLAUD 70 WP 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.

Do not apply this product through and type of irrigation system.

**MIXING, LOADING, AND
HANDLING INSTRUCTIONS**

USE PRECAUTIONS

DO NOT use APPLAUD 70WP Insect Growth Regulator water soluble bags in a tank mix with products that contain boron, chromium, or other micronutrients.

GENERAL HANDLING INSTRUCTIONS

APPLAUD 70WP Insect Growth Regulator is sealed in 1.0 lb. water soluble bags. Do not open the foil-lined outer box until time of use. Do not use a knife or other sharp object to open the foil lined outer box. Once the outer protective box has been opened, the water soluble bag inside can be dropped into the spray tank at the appropriate time.

SPECIFIC MIXING INSTRUCTIONS

To ensure proper mixing of the soluble bags, follow the instructions below:

1. **APPLAUD 70WP ALONE:** Begin by filling the spray tank with clean water to prime the system (about 6-8 inches for most sprayers). Turn off the fill valve and drop the recommended number of soluble bags into the tank, distributing them across the bottom but not covering the circulation and outlet holes. After the bags have soaked for 2 minutes, start the agitation and agitate thoroughly for 2 minutes. With the agitation on, continue to fill the spray tank to the desired level. Agitate during spraying. If spraying must be stopped before emptying the sprayer, resume agitation before spraying the remainder of the load.
2. **APPLAUD 70WP TANK MIXTURES:** Follow all use directions

as listed above under **APPLAUD 70WP ALONE** with the following exception: After the APPLAUD 70WP bags are thoroughly mixed and the water is added to fill the tank 1/2 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 (except fertilizers containing boron, chromium or other micronutrients (see **USE PRECAUTIONS**), surfactant, or crop oil concentrate to the spray tank. Then continue adding water to the tank to achieve the desired level, while maintaining agitation.

3. **APPLAUD 70WP TANK MIXTURES WITH PRODUCTS IN WATER-SOLUBLE PACKAGING:** Follow all use directions as listed above under **APPLAUD 70WP ALONE** with the following exception: Add the desired number of other water-soluble bags to the tank (if allowed by their label instructions) at the same time the APPLAUD 70WP bags are added to the spray tank.

HANDLING PRECAUTIONS FOR WATER SOLUBLE BAGS

- Do not allow the foil lined outer box or portions thereof to fall into spray tank as they are not water soluble and may clog the sprayer.
- Do not handle the soluble bag with wet gloves as the bag will begin to dissolve on contact with even a small amount of water.
- Do not open the soluble bag or attempt to remove the APPLAUD 70WP Insect Growth Regulator from it. The product is not designed to be re-measured or subdivided; the entire contents of the water-soluble bag must be used.

Refer to the charts below for the proper application rate of APPLAUD 70WP Insect Growth Regulator.

APPLICATION RATE CHART FOR APPLAUD 70WP INSECT GROWTH REGULATOR

Crop	Pest	Rate/Acre	
		lb ai/A	lb formulated/A
Melons (cantaloupe, honeydew melons, watermelons, muskmelons)	Whitefly	0.25-0.38	0.36-0.54
Cucumbers			
Pumpkins			
Squash			
Lettuce (head and leaf)			

Treatment should be made when population level reaches economic threshold. Consult local or State agricultural authorities for details. Do not make more than two applications per season per crop. Allow at least 5 days between applications.

Do not apply within 7 days of harvest.

APPLICATION CHART FOR DETERMINING NUMBER OF WATER SOLUBLE BAGS OF APPLAUD 70WP INSECT GROWTH REGULATOR

lb ai/A	Rate	Number of 1.0 lb bags	Number of Acres Treated
	lb formulated/A		
0.25	0.36	1	2.8
0.25	0.36	3	8.4
0.25	0.36	5	14.0
0.38	0.54	1	1.8
0.38	0.54	3	5.5
0.38	0.54	5	9.2

RESISTANCE MANAGEMENT

Whiteflies are known to develop resistance to products used repeatedly for control. Because the development of resistance cannot be predicted, the use of this product should conform to resistance management strategies established for the use area. Consult your local or State agricultural authorities for details.

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: Remove inner water soluble bag from outer packaging and place inner bag into application equipment. Then dispose of empty outer 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 adequate and should be followed carefully. However, because of extreme weather and soil conditions, manner of use and other factors beyond AgrEvo USA Company's control, it is impossible for AgrEvo USA Company to eliminate all risks associated with the use of this product. As a result, crop injury or ineffectiveness is always possible. All such risks shall be 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 AgrEvo USA Company is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. AgrEvo USA Company 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 AGREVO USA COMPANY'S ELECTION, THE REPLACEMENT OF PRODUCT.

© AgrEvo USA Company, 1997

Regional Offices

NORTHERN

Bob Rose
Regional Manager
AgrEvo USA Company
14665 Galaxie Avenue, West
Suite #300
Apple Valley, MN 55124-8575
Phone: (612) 997-4500
FAX: (612) 997-4507

MIDWESTERN

Marc Olson
Regional Manager
AgrEvo USA Company
14665 Galaxie Avenue, West
Suite #300
Apple Valley, MN 55124-8575
Phone: (612) 997-4500
FAX: (612) 997-4507

SOUTHERN

Howard Corbett
Regional Manager
AgrEvo USA Company
311 Poplar View Lane West
Collierville, TN 38017
Phone: (901) 853-4188
FAX: (901) 853-4436

WESTERN

Mark Munger
Regional Manager
AgrEvo USA Company
5150 North Sixth Street
Suite 118
Fresno, CA 93710
Phone: (209) 224-6580
FAX: (209) 224-1758



AgrEvo USA Company
Little Falls Centre One
2711 Centerville Road
Wilmington, DE 19808

