HED Records Center Series 361 Science Reviews - File R060357 Rage 1

#### OPP OFFICIAL RECORD HEALTH EFFECTS DIVISION SCIENTIFIC DATA REVIEWS **EPA SERIES 361**



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

AUG | 6 1995

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

#### MEMORANDUM

PP#4F04321 Amended Petition: Request for Group Tolerance. SUBJECT:

Propiconazole in/on Stone Fruit. Crossover Studies for New Formulation. Chemical# 122101, DP Barcode: D217199,

CBTS#: 15866, MRID#:43655601 Vol: 1-2, 9-13.

FROM:

William D. Cutchin, Chemist William & Culchin

Chemistry Branch I: Tolerance Support

Health Effects Division (7509C)

Francis B. Suhre, Acting Section Head Chemistry Branch I: Tolerance Support THROUGH:

Health Effects Division (7509C)

TO: Connie Welch, PM Team 21

Fungicide/Herbicide Branch Registration Division (7505C)

Dr. Gregory R. Watson, Regulatory Manager, Plant Protection Division, Ciba-Geigy Corp., requests the establishment of a tolerance in or on cherries and a group tolerance for stone fruit at 1.5 ppm for the residues of the fungicide propiconazole (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4triazole), and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA) and expressed as parent compound. Tolerances have been established for residues at levels ranging from 5 ppm in/on celery to 0.05 ppm in milk (40 CFR §180.434).

Ciba also requests the registration of two new wettable powder formulations of propiconazole, Tilt® 45WP and Orbit® 45WP. addition to bridging studies between a registered product formulation and the new formulation, a volume of data regarding the product chemistry of the Tilt® 45WP formulation was also included in the submission.

Propiconazole is a FIFRA 88 List C chemical, for which a Phase 4 review was completed 6/30/92.

#### Background

Ciba-Geigy Corp. requested in PP#9F3758 (submitted to EPA on 3/3/89) a stone fruit crop group tolerance and tolerances on other RACs for propiconazole. Since no data were submitted for cherries, a representative crop for the stone fruit crop group, DEB denied the group tolerance. Ciba cited concerns over possible plant growth regulating activity resulting from the use of propiconazole on cherries as the reason for not submitting cherry residue data. Eventually, tolerances were established for the other crops addressed in the petition: wild rice, peaches, nectarines, apricots, plums, and prunes (final review 6/2/93).

In the original submission of PP#4F04321, Ciba-Geigy Corp. proposed to apply the data supplied with PP#9F3758 in support of a bloomonly use on cherries to establish a tolerance. The establishment of a tolerance on cherries, fulfilling the stone fruit crop group data requirements, would thereby establish a crop group tolerance. CBTS decided in favor of the petition and recommended the establishment of the tolerance on cherries and the stone fruit crop group at 1.0 ppm (PP#4F04321, 4/13/95). Ciba now submits data in support of a request for bloom and fruit applications of propiconazole on cherries and a tolerance on cherries and the stone fruit crop group at 1.5 ppm.

#### Conclusions

- 1. The product chemistry of the technical grade active ingredient (TGAI) propiconazole and its metabolite DCBA have been adequately described. A volume of product chemistry data on the new formulation Tilt® was included in the submission. Review of the product chemistry of formulations is not within the purview of CBTS. The data must be referred to RD for review.
- 2. The proposed use directions in Section B are adequate. No further changes are required for this proposed use.
- 3. The metabolism of propiconazole in plants has been described in detail. The residues of concern are propiconazole and its metabolites determined as DCBA and expressed as parent. No further data are required for this proposed use.
- 4. There are no significant animal feed stock uses for cherries or for other members of the stone fruit crop group. No animal metabolism data are necessary for this proposed use.
- 5. Adequate analytical methods have been approved for publication in PAM II for enforcement purposes, but has not as of this time appeared in PAM II. No further methodology is necessary for this proposed use.
- Propiconazole and DCBA are included in published multiresidue



methods. No further methodology is necessary for this proposed use.

- 7a. There are sufficient residue data submitted here to support the proposed use. However, the data indicate that the residues of propiconazole and its metabolites are not expected to exceed the recommended 1 ppm tolerance for cherries and the stone fruit crop group. Additional residue data are not required for this proposed use. The proposed establishment of the tolerance at 1.5 ppm is not necessary. A revised Section F proposing a stone fruit crop group tolerance at 1 ppm is required.
- 7b. The bridging studies for the new formulation are adequate to support the request for its registration on the stone fruit crop group as well as on all other crops with established propiconazole tolerances. The use of the new formulations are unlikely to exceed established tolerances. No further data are required for this proposed use.
- 7c. The geographic diversity of the studies submitted here are adequate to represent the cherry growing regions of the U.S.
- 7d. The studies submitted here fall under the scope of the GLPs in 40 CFR §160.
- 8. There were no storage stability data presented with this petition. The storage stability data in EPA files are sufficient to support the residue studies for stone fruit.
- 9. There are no significant animal feed stock uses for cherries or other members of the stone fruit crop group. Consequently, secondary residues in meat, milk, poultry, and eggs are not expected to be a problem.
- 10. Analytical standard materials for propiconazole and DCBA are available from RTP.
- 11. No Canadian or Mexican limits have been established for residues of propiconazole in or on stone fruit. A Codex tolerance of 1 ppm has been established for propiconazole in or on stone fruit. The recommended 1 ppm tolerance for propiconazole on stone fruit creates no compatibility problems.

#### Recommendations

CBTS recommends against establishment of the proposed propiconazole tolerance in or on cherries at 1.5 ppm and raising the proposed propiconazole tolerances on the stone fruit crop group to 1.5 ppm. The previously proposed tolerance for the stone fruit crop group at 1 ppm (PP#4F04321, 4/13/95) is adequate to support the fruit treatment of cherries with a 0 day PHI. The registrant should submit a revised Section F with a 1 ppm stone fruit crop group

tolerance. CBTS reiterates that a DRES run can be initiated using the 1 ppm residue level.

Provided RD clears the product chemistry of the new propiconazole product formulations, Tilt® 45WP and Orbit® 45WP, CBTS recommends in favor of their registration for use on all crops with established propiconazole tolerances.

#### Detailed Considerations

### Manufacture and Formulation

Propiconazole is a FIFRA 88 List C chemical, for which a Phase 4 review was completed 6/30/92. There are some data gaps still outstanding (DP Barcode: 198815, CBRS#13166, 4/26/94).

A volume of data regarding the product chemistry of the Tilt® 45WP formulation is included in the submission. Review of the product chemistry of formulations is not within the purview of CBTS. The data must be referred to RD for review.

Ciba-Geigy has submitted a request for the registration of two new wettable powder formulations of propiconazole, Tilt® 45WP and Orbit® 45WP. Although the accompanying transmittal letter states that completed EPA Forms 8570-4, Confidential Statement of Formula (CSF), are included in the submission for both formulations, neither are included in the package submitted to CBTS. A statement of formula, but not Form 8570-4, for Tilt® 45WP is included in a confidential appendix to the product chemistry data.

#### Proposed Use

The proposed use directions, Section B, are adequate. The proposed use directions state that the products, Orbit® 3.6EC, Orbit® 45WP, and Tilt® 45WP, are to be applied to cherries, apricots, nectarines, peaches, fresh prunes, and plums at the early bloom stage at a rate of 50 g ai/A (0.11 lb ai/A). For aerial applications a minimum spray volume of 5-10 gal/A is recommended. For ground applications a minimum of 50 gal/A spray volume is recommended. A second application is to be made at 50-75% bloom. A third application at petal fall may be made if disease conditions persist or blooming is prolonged.

Propiconazole may also be used on the fruits of apricots, cherries, nectarines, peaches, and plums. A maximum of 2 pre-harvest sprays at 50 g ai/A beginning 3 weeks before harvest through the day of harvest (0 day PHI). For aerial applications a minimum spray volume of 5-10 gal/A is recommended. For ground applications a minimum of 50 gal/A spray volume is recommended. The product is not to be applied to prunes.

## Nature of the Residue - Plants

The nature of the residue in plants is adequately understood. The metabolism of propiconazole has been studied in wheat, corn, peanuts, grapes, lettuce, carrots, and tomatoes. The residue to be regulated is propiconazole and its metabolites determined as DCBA (PP#8F3674, 12/14/88). No further data are required for this proposed use.

## Nature of the Residue - Animals

There are no significant animal feed stock uses for the members of the stone fruit crop group. Animals are not allowed to graze in stone fruit orchards nor are parts of the plants used as supplemental feeds after processing. Animal metabolism data are neither submitted nor necessary for this proposed use.

## Analytical Methods - Enforcement MRID#:43655601

The Ciba-Geigy Method AG-454A, the current enforcement method, is used in the submission for the analysis of all the crops in support of the tolerance and registration requests. The Ciba-Geigy Method AG-454A is described as follows. Samples are extracted by refluxing with 20% ammonium hydroxide/methanol for one hour. The mixture is then cooled and filtered and an aliquot is evaporated to dryness. The residue is dissolved in aqueous sodium hydroxide and heated for 1.25 hours with potassium permanganate. After dilution with water, the sample is partitioned with 10% diethyl ether/hexane and the organic solution containing DCBA collected. The sample solution is rotovaped to dryness in the presence of dodecane and methylated with diazomethane. The sample is cleaned-up on an acidic alumina Sep-Pak before being analyzed by capillary gas methylated with diazomethane. chromatography with electron capture (GC/EC) detection. The limit of detection (LOD) was reported by the performing laboratory, EPL Bio-Analytical Services, Inc. (EPL-BAS), as 0.05 ppm. Sample chromatograms and calibration curves are also included in the submission.

The method has been approved for publication in PAM II for enforcement purposes, but has not as of this time appeared in PAM II (PP#2F04086, 2/28/95). No further methodology is necessary for this proposed use.

#### Analytical Methods - Multiresidue

Multiresidue methods data indicate the recovery of propiconazole via FDA Multiresidue Protocol D (PAM II 232.4) is complete while recovery of propiconazole metabolites via this method is variable (Pestrak data base (11/6/90)). No further methodology is necessary for this proposed use.

#### Magnitude of Residue MRID#:43655601

#### Cherries

Residue studies were conducted on sweet cherries in California, Washington, Oregon, and Michigan and on tart cherries in Pennsylvania, New York, and Michigan. All seven sites contained plots which received the maximum number of applications and application rate (5 x 50 g ai/A). Five sites also had plots which received 2x the maximum application rates (5 x 100 g ai/A). Each plot was sampled the day of last application, 0 day PHI. The highest residue found at the 1x rate was 1.1 ppm on a single replicate sample from Pennsylvania. The other replicate of that sample was 0.88 ppm for an average of 0.99 ppm. The average residue for all 1x samples was 0.5 ppm. For the 2x studies the highest residue was 1.2 ppm and the average for all 2x samples was 0.97 ppm. This data show that expected residues in/on cherries are unlikely to exceed the 1 ppm tolerance previously recommended in PP#4F04321, 4/13/95. The residue data reflecting foliar use with a 0 day PHI support the previously recommended 1 ppm tolerance on cherries. The registrant should submit a revised Section F with a 1 ppm stone fruit crop group tolerance.

### Bridging Studies

Studies were conducted using the registered formulation Orbit® 3.6E (EPA Reg. No. 100-702) and the new 45WP formulation Orbit® 45W. The studies were conducted on crops from the stone fruit crop group, sweet and tart cherries, peaches, and plums, and selected crops with established tolerances, field and sweet corn, and celery. The results, listed in the table below, show no significant difference in residue levels using the two different formulations. The established and recommended tolerances are adequate to support the registration of Tilt® 45WP and Orbit® 45WP.

#### Geographic Representation

The data submitted in the petition PP#9F3758 reflect 17 field trials from the major stone fruit growing regions of the country, California (6), Georgia (1), Michigan (4), Pennsylvania (2), New York (1), Virginia (1), and Washington (2). No further data is necessary for this proposed use.

#### Storage Stability

There were no storage stability data submitted with this petition. Storage stability data for propiconazole on stone fruits were submitted with the PP#9F3758. Residues of propiconazole were found to be stable up to 25 months on stone fruits. Degradation of propiconazole residues on stone fruits is unlikely. No further data is necessary for this proposed use.

#### Meat, Milk, Poultry, and Eggs

Stone fruit or stone fruit by-products are not used for animal feed stock. No livestock residue data are necessary for this proposed use.

#### Other Considerations

No Canadian or Mexican limits have been established for residues of propiconazole in or on stone fruit. A Codex tolerance of 1 ppm has been established for propiconazole in or on stone fruit (PP#4F04321, 4/13/95). A 1 ppm tolerance for propiconazole on stone fruit will create no compatibility problems.

Comparison of Side-By-Side Residue Trials with Propiconazole 3.6EC and 45WP Formulations			
Commodity	Propiconazole 3.6EC Residues	Propiconazole 45WP Residues	Current Propiconazole Tolerances
Stone Fruit (sweet & tart cherries, peaches, plums)	Maximum: 0.8 ppm Range: <0.05-0.8 ppm Average: 0.28 ppm	Maximum: 0.67 ppm Range: <0.05-0.67 ppm Average: 0.23 ppm	1.0 ppm on stone fruit*
Corn Forage & Fodder	Maximum: 2.6 ppm Range: <0.05-2.6 ppm Average: 0.6 ppm	Maximum: 2.7 ppm Range: 0.05-2.7 ppm Average: 0.69 ppm	12.0 ppm in corn forage & fodder
Field and Sweet Corn Grain	Maximum: <0.05 ppm (all residues below LOD)	Maximum: <0.05 ppm (all residues below LOD)	0.1 ppm in corn grain (K+CWHR)
Celery	Maximum: 0.42 ppm Range: 0.27-0.42 ppm Average: 0.35 ppm	Maximum: 0.51 ppm Range: 0.45-0.51 ppm Average: 0.48 ppm	5.0 ppm in celery

<sup>\* =</sup> Recommended Tolerance (PP#4F04321, 4/13/95)

## Propiconazole

cc: RF, PP#4F04321, circ., Cutchin,
7509C: CBTS, Reviewer (WDC), CM#2, Rm 804P, 305-7990, WDC:8/16/95
R/I: Act. Sec. Head: B. Suhre, 8/14/95;
 Br. Sr. Sci.: R. Loranger, 8/14/95;
 Br. Chief: M. Metzger, 8/14/95

# END OF DOCUMENT

WPS MARKETING LABEL BOOKLET OPP OFFICIAL RECORD HEALTH EFFECTS DIVISION SCIENTIFIC DATA REVIEWS EPA SERIES 361

Tilt® 45W

FUNGICIDE

For control of certain diseases in celery, cereals, corn, grasses grown for seed, peanuts, pineapples, and sugarcane

KEEP OUT OF REACH OF CHILDREN.

#### CAUTION

See additional precautionary statements and directions for use inside booklet.

This outer protective container contains Tilt 45W in an inner water-soluble bag. Entire inner bag and contents dissolve in water. After opening outer container, immediately drop entire unopened inner bag into the partially filled sprayer or mix tank. Do not handle the soluble bag or expose it to moisture since this may cause rupturing.

EPA Reg. No. 100-EPA Est. 100-AL-1

20 oz. Net Weight

4 oz. Net Weight

CGA (20 oz.) CGA (4 oz.)

[GANNONC.LABELT\LBL-MS-T]TILT45W - 5/15/95

## DIRECTIONS FOR USE AND CONDITIONS OF SALE AND WARRANTY

IMPORTANT: Read the entire Directions for Use and the Conditions of Sale and Warranty before using this product. If terms are not acceptable, return the unopened product container at once.

#### Conditions of Sale and Warranty

The Directions for Use of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with 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 Ciba-Geigy or the Seller. All such risks shall be assumed by the Buyer.

Ciba-Geigy warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the Directions for Use subject to the inherent risks referred to above. Ciba-Geigy makes no other express or implied warranty of Fitness or Merchantability or any other express or implied warranty. In no case shall Ciba-Geigy or the Seller be liable for consequential, special, or indirect damages resulting from the use or handling of this product. Ciba-Geigy and the Seller offer this product, and the Buyer and user accept it, subject to the foregoing Conditions of Sale and Warranty, which may be varied only by agreement in writing signed by a duly authorized representative of Ciba-Geigy.

#### 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 the restricted entry interval (REI) of 24 hours.

Exception: If the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

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
- Waterproof gloves
- Shoes plus socks

#### General Information

Tilt 45W is a broad spectrum fungicide for the control of certain diseases in wheat, barley, rye, rice, wild rice, celery, corn, peanuts, pineapple, sugarcane, and in grasses grown for seed.

Important: Do not use in nurseries, on turf, landscape
plantings, or as a tree injection.

FAILURE TO FOLLOW DIRECTIONS AND PRECAUTIONS ON THIS LABEL MAY RESULT IN CROP INJURY, POOR DISEASE CONTROL, OR ILLEGAL RESUDUES.

#### Spray Equipment

Thorough coverage is necessary to provide good disease control.

To avoid spray drift, do not apply when conditions favor drift beyond the target area. Avoid spray overlap, as crop injury may occur.

Equip sprayers with nozzles that provide accurate and uniform application. Be certain that nozzles are the same size and uniformly spaced across the boom. Calibrate sprayer before use.

Use a pump with capacity to: (1) maintain 35-40 psi at nozzles, and (2) provide sufficient agitation in tank to keep mixture in suspension - this requires recirculation of 10 percent of tank volume per minute. Use a jet agitator or liquid sparge tube for agitation. Do not air sparge.

Use screens to protect the pump and to prevent nozzles from clogging. Screens placed on suction side of pump should be 16-mesh or coarser. Do not place a screen in the recirculation line. Use 50-mesh or coarser screens between the pump and boom, and where required, at the nozzles. Check nozzle manufacturer's recommendations.

For more information on spray equipment and calibration, consult sprayer manufacturers and state recommendations. For specific local directions and spray schedules, consult the current state agricultural experiment station recommendations.

### Application Instructions

Aerial Application: For those crops where aerial applications are indicated, apply in a minimum of 5 gals. of water per acre unless specified otherwise. Avoid application under conditions when uniform coverage cannot be obtained or when excessive spray drift may occur. Do not apply directly to humans or animals.

Ground Application: Apply Tilt 45W by ground equipment in a minimum of 15 gals. of water per acre.

## Application Through Irrigation Systems - For Southern Stem Rot Control in Peanuts

Tilt 45W, alone or in combination with other pesticides which are registered for application through irrigation systems, may be applied through irrigation systems. Apply this product only through center pivot, solid set, hand move, or moving wheel, irrigation systems. Do not apply this product through any other type of irrigation system. Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from nonuniform distribution of treated water. If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts. Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place. A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Note: Do not inject Tilt 45W at full strength or deterioration of valves and seals may occur. Use a dilution ratio of at least 10 parts water to 1 part Tilt 45W. Tilt 45W is corrosive to many seal materials. Leather seals are best. EPDM or silicone rubber seals can be used, but should be replaced once a year. Do not use Viton, Buna-N, Neoprene or PVC seals.

#### Operating Instructions

- 1. The system must contain a functional check-valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water-source contamination from backflow.
- 2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check-valve to prevent the flow of fluid back toward the injection pump.
- 3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- 4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- 5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the

water pressure decreases to the point where pesticide distribution is adversely affected.

- 6. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
- 7. Do not apply when wind speed favors drift beyond the area intended.

### Center Pivot Irrigation Equipment

Notes: (1) Use only with drive systems which provide uniform water distribution. (2) Do not use end guns when chemigating Tilt 45W through center pivot systems because of non-uniform application.

- Determine the size of the area to be treated.
- Determine the time required to apply 1/4-1/2 inch of water over the area to be treated when the system and injection equipment are operated at normal pressures as recommended by the equipment manufacturer. Run the system at 80-95% of the manufacturer's rated capacity.
- Using water, determine the injection pump output when operated at normal line pressure.
- Determine the amount of Tilt 45W required to treat the area covered by the irrigation system.
- Add the required amount of Tilt 45W and sufficient water to meet the injection time requirements to the solution tank.
- Make sure the system is fully charged with water before starting injection of the Tilt 45W solution. Time the injection to last at least as long as it takes to bring the system to full pressure.
- Maintain constant solution tank agitation during the injection period.
- Continue to operate the system until the Tilt 45W solution has cleared the sprinkler head.

Solid Set, Hand Move and Moving Wheel Irrigation Equipment

- · Determine the acreage covered by the sprinklers.
- Fill injector solution tank with water and adjust flow rate to use the contents over a 20 to 30-minute interval.
- Determine the amount of Tilt 45W required to treat the area covered by the irrigation system.
- Add the required amount of Tilt 45W into the same quantity of water used to calibrate the injection period.
- Operate the system at the same pressure and time interval established during the calibration.
- Stop injection equipment after treatment is completed. Continue to operate the system until the Tilt 45W solution has cleared the last sprinkler head.

## Application Notes for Southern Stem Rot Control on Peanuts:

Irrigation: When applying Tilt 45W in irrigatioin water for Southern Stem Rot Control of Peanuts, use a minimum of 0.25-0.5 inches of irrigation water per acre. Use enough water so that the fungicide penetrates the peanut canopy and reaches the crown of the plant where Sclerotium rolfsii is most active.

Ground Application: When applying Tilt 45W by ground equipment, use a minimum of 20-60 GPA directed to the crown of the plant where Sclerotium rolfsii is most active. For best disease control, the higher carrier volume is recommended. Canopy openers also may be used to improve fungicide placement.

When applying Tilt 45W via irrigation or as a directed ground application, additional methods should be employed for leaf spot control.

Banded Application: For banded applications, the treated area is the area covered by the band, not total cropland planted. The following formula can be used to calculate the amount of Tilt 45W needed per acre of crop when banded applications are made.

### Mixing Instructions

Prepare no more spray mixture than is needed for the immediate operation. Thoroughly clean spray equipment before using this product. Vigorous agitation is necessary to maintain uniformity of the spray mixture. Maintain maximum agitation throughout the spraying operation. Do not let the spray mixture stand overnight



in the spray tank. Flush the spray equipment thoroughly following each use and apply the rinsate to a previously treated area.

Precaution: Water-soluble bags of Tilt 45W must be completely dissolved and dispersed in plain water before any other tank mix partner, including micronutrients or other liquid or dry fertilizers, are added to the spray solution. Boron, especially in the form of a micronutrient additive, such as Solubor®, etc., or as a natural component of the mix water, may prevent water soluble bags from dissolving.

Tilt 45W Alone: Add 1/3 of the required amount of plain water to the spray or mixing tank. With the agitator running, drop the required number of unopened soluble bags of Tilt 45W into the tank all at once. Continue agitation while adding the remainder of the water. Begin application of the spray solution after the soluble bags have dissolved, and the material has completely dispersed into the mix water. Maintain agitation until all of the mixture has been applied.

Tilt 45W + Tank Mixtures: Tilt 45W is usually compatible with all tank mix partners listed on this label. Add 1/3 of the required amount of plain water to the spray or mixing tank. With the agitator running, drop the required number of unopened soluble bags of Tilt 45W into the tank all at once. Continue agitation while adding the remainder of the water. Allow the soluble bags of Tilt 45W to dissolve and the desired amount of other products recommended for tank mixture and allow them to become completely dispersed. Continue agitation to maintain a uniform suspension until all of the spray solution has been applied.

If using Tilt 45W in a tank mixture, observe all directions for use, crops/sites, use rates, dilution ratios, precautions, and limitations which appear on the tank mix product label. No label dosage rate should be exceeded, and the most restrictive label precautions and limitations should be followed. This product should not be mixed with any product which prohibits such mixing. Tank mixtures or other applications of products referenced on this label are permitted only in those states in which the referenced products are registered.

#### Rotational Crops

Soybeans may be planted as a double crop following a cereal crop which has been treated with Tilt 45W. Do not use hay, forage, or fodder from the soybean crop as any component of animal feed or bedding.

To avoid possible illegal residues, do not plant any other crop intended for food, grazing, or any component of animal feed or

bedding within 105 days of Tilt 45W application to the preceding crop, unless the second crop appears on this label.

#### Celery

For control of early blight (Cercospora) and late blight (Septoria), apply 0.25 lb. of Tilt 45W per acre on a 7-day schedule either by ground or aerial application. If desired, Tilt 45W may be tank-mixed with an appropriate spreader-sticker.

Notes: To avoid possible illegal residues, (1) Do not apply more than 1.0 lb. of Tilt 45W per crop (4 applications), and (2) Do not apply during the last 14 days before harvest.

#### Cereals

#### Wheat, Barley, Rye

In wheat, barley, and rye, Tilt 45W controls rusts (Puccinia spp.), powdery mildew (Erysiphe spp.), leaf blight and glume blotch (Septoria spp.), tan spot (Pyrenophora triticirepentis), Helminthosporium leaf blight, barley scald (Rhynchosporium secalis), and net blotch (Pyrenophora teres). Apply 0.25 lb. of Tilt 45W per acre by ground or aerial application. Highest yields are normally obtained when Tilt 45W is applied to the emerging flag leaf. Tilt 45W can be applied until the ligule of the flag leaf emerges. (Feekes growth stage 8). Do not apply after this growth stage to avoid possible illegal residues. Tilt 45W may be applied earlier if disease symptoms appear (especially applicable to barley).

For control of foot rot (Pseudocercosporella spp.), apply 0.25 lb. of Tilt 45W per acre plus half rates of other EPA-registered fungicides such as Benlate®, Mertect®, and Topsin® M. Apply at tillering, but before elongation has occurred.

Note: Apply Mertect and Topsin M to wheat only.

Do not graze or feed livestock treated forage or cut the green crop for hay or silage. After harvest, the straw may be used for bedding or feed.

#### Rice

In rice, Tilt 45W controls sheath blight (Rhizoctonia solani), brown leaf spot (Helminthosporium oryzae), narrow brown leaf spot and brown blotch (Cercospora oryzae), leaf smut (Entylona oryzae), sheath spot (Rhizoctonia oryzae), and black sneath rot (Gaeumannomyces graminis). Tilt 45W also suppresses stem rot (Sclerotium oryzae). Apply Tilt 45W on either of the following schedules as an aerial spray in 5-10 gals. of water per acre:

- A. 0.375 lb./A at first internode elongation (up to 2-inch panicle) and repeat at swollen boot. Make the second application 10-14 days after the first application, but before the boot splits and head emerges. Tilt 45W provides best control of sheath blight when the first application is applied at disease appearance in the field. The first application is recommended when 5 percent or fewer of the tillers are infected.
- B. 0.625 lb./A at first internode elongation (up to 2-inch panicle). The 0.625 lb. rate is recommended if greater than 10 percent of the tillers are infected with sheath blight. If disease reappears, use another registered fungicide for the second application.

Important: To avoid possible illegal residues: (1) Do not apply to stubble or ration crop rice; (2) Do not use in rice fields where commercial farming of crayfish will be practiced; (3) Do not drain water from treated rice fields into ponds used for commercial catfish farming; (4) Do not use water drained from treated fields to irrigate other crops; and (5) Do not use in CA.

Endangered Species Restrictions: The use of Tilt 45W (propiconazole) on rice is restricted to protect the endangered fat pocketbook pearly mussel (*Potamilus capax*) and its habitat. Use is prohibited in the following areas of AR:

Mississippi County - Within the basin that drains directly into the Right Hand Chute of Little River, south of Big Lake National Wildlife Refuge.

Poinsett County - Between Crowley's Ridge and the levee east of the Right Hand Chute of Little River and the St. Francis Floodway. Use is also prohibited west of Rt. 140 and north of Rt. 63 at the siphon near Marked Tree. Except that the prohibited area does not include the area bounded by Arkansas highway 373 on the west, highway 63 on the east, and highway 14 on the south.

Cross, St. Francis, and Lee Counties: Between Crowley's Ridge and the levee east of the Right Hand Chute of Little River, and the St. Francis Floodway as far south as the confluence of L'Anguille River (Lee County).

#### Wild Rice (MN only)

For control of Helminthosporium leaf blight and brown spot: . . (Bipolaris spp.), apply 0.375 lb. of Tilt 45W per activate both booting and heading, or make a single application of 0.5 lb./A booting. For aerial applications, apply in a spray volume of 5-10 gals./A.

Important: Do not use water drained from treated fields to irrigate other crops.

## Corn (Field Corn, Field Corn Grown for Seed, Sweet Corn, and Popcorn)

For control of Helminthosporium leaf blights (Helminthosporium maydis, H. turcicum, and H. carbonum), rusts (Puccinia spp.), gray leaf spot (Cercospora zeae-maydis), and eye spot (Kabatiella zeae), apply Tilt 45W according to the following schedule:

Helminthosporium Leaf Blights: Apply 0.125-0.25 lb. of Tilt 45W per acre when disease first appears and continue on a 7 to 14-day schedule.

Rusts: Apply 0.25 lb. of Tilt 45W per acre when rust pustules first appear and continue on a 7-14 day schedule.

Gray Leaf Spot and Eye Spot: Apply 0.25 lb. of Tilt 45W per acre when disease first appears. If conditions favorable for disease persist, continue to apply on a 14-day schedule.

Important: To avoid possible illegal residues: (1) Do not apply Tilt 45W to field and field corn grown for seed after silking. (2) Do not apply more than 1 lb. of Tilt 45W per acre per season. (3) Do not apply to sweet corn within 14 days of harvest. (4) Do not harvest field corn, field corn grown for seed, or popcorn for forage within 30 days of application. (5) Do not harvest sweet corn for forage within 14 days of application.

## Grasses Grown for Seed (Nebraska, Oregon, Washington, Idaho, and Minnesota only)

Tilt 45W controls rusts (*Puccinia* spp.), powdery mildew (*Erysiphe* spp.), and Selenophoma stem eyespot (*Selenophoma*) in perennial ryegrass, fescues, bluegrass, orchardgrass, and/or wheatgrasses.

Mix 0.25-0.5 lb. of Tilt 45W (maximum 0.25 lb. on bluegrass) in a minimum of 20 gals. of water per acre for ground application, or in a minimum of 10 gals. of water per acre for aerial application. Apply when powdery mildew and Selenophoma infections or rust pustules are noticeable and increasing in number, in late spring or early summer. Repeat at 14-21 day intervals. To maximize control under severe rust pressure, use the higher rate of 0.5 lb./A (except on bluegrass), and make applications at 14-day intervals until the seed is mature. Do not apply more than 2 lb. of Tilt 45W per acre per growing cycle. Make the last application at least 20 days before seed matures. For bluegrass, it is important to begin application early in the growing season.



Important: To avoid possible illegal residues, do not: (1) feed hay cut within 20 days of the last application, or (2) graze treated areas within 140 days of the last application.

#### Peanuts

#### Peanuts - Tilt 45W Alone For Foliar Disease Control

Late Leaf Spot (Cercosporidium) - Apply 0.25 lb. of Tilt 45W per acre beginning applications 35-40 days after planting or at the first appearance of disease. Continue applications on a 10-14 day schedule. Tilt 45W also may be used in State Agricultural Extension advisory (disease forecasting) programs which recommend application timing based on environmental factors favorable for disease development.

Early Leaf Spot (Cercospora) - Apply 0.16-0.25 lb. of Tilt 45W per acre beginning applications 35-40 days after planting or at the first appearance of disease. Continue applications on a 14-day schedule. Under heavy disease pressure use higher recommended application rates. Tilt 45W also may be used in State Agricultural Extension advisory (disease forecasting) programs which recommend application timing based on environmental factors favorable for disease development.

Important: To avoid possible illegal residues: (1) Do not apply
more than 1 lb. Tilt 45W per acre per season. (2) Do not feed
green vines to livestock or graze livestock in treated area. (3)
Do not apply within 14 days of harvest.

Peanuts - Tilt 45W Plus Chlorothalonil For Foliar Disease Control

Early and Late Leafspot - Combinations of Tilt 45W with products containing chlorothalonil may be used for early and late leaf spot control. Apply 0.125 lb. of Tilt 45W as a tank mixture with 0.75 lb. active ingredient chlorothalonil per acre. Use the following table as a guide to determine the appropriate amount of chlorothalonil to use in the tank mixture. Begin applications 35-40 days after planting or at the first appearance of disease and continue applications on a 10-14 day schedule. Tilt 45W plus chlorothalonil also may be used in State Agricultural Extension advisory (disease forecasting) programs which recommend application timing based on environmental factors favorable for disease development.

Important: Use the following table as a guide to determine the amount of product needed for the recommended tank mix ratios of Tilt 45W with various chlorothalonil formulations. To avoid possible illegal residues: (1) Do not apply more than 1 lb. of Tilt 45W per acre per season. (2) Do not apply within 14 days of harvest. (3) Do not graze livestock in treated area. (4) Do not feed hay or threshings from treated fields to livestock.

		Amount of chlorothalonil product required for treated area by formulation type (total acres to be treated)	
Number of acres to be treated	Amount of Tilt 45W required for treated area (total acres to be treated)	6 lbs. ai per Gallon	4.17 lbs. ai per Gallon
10 50 100	1.25 lb. 6.25 lb. 12.5 lb.	10 pts. 50 pts. 100 pts.	15 pts. 75 pts. 150 pts.

## Peanuts - Tilt 45W Alone for Southern Stem Rot Control

For the control of Southern Stem Rot (Sclerotium rolfsii), apply Tilt 45W using one of the following schedules:

A. Apply 0.25 lb. of Tilt 45W per acre to the crown and pegging zones of the plant using chemigation or directed ground application. Begin applications 45 days after planting, or at the first appearance of disease, and repeat on a 14-day schedule.

Important: To avoid possible illegal residues: (1) Do not apply more than 1 lb. Tilt 45W per acre per season. (2) Do not feed green vines to livestock or graze livestock in treated area. (3) Do not apply within 14 days of harvest.

B. Apply 0.5 lb. Tilt 45W per acre to the crown and pegging zones of the plant using chemigation or directed ground application. Make two applications: the first at pegging (approximately 60 days after planting) or at the first appearance of disease, and the second application 3-4 weeks later.

Important: To avoid possible illegal residues: (1) Do not apply more than 1 lb. Tilt 45W per acre per season. (2) Do not graze livestock in treated area. (3) Do not feed hay or threshings from treated fields to livestock. (4) Do not apply within 21 days of harvest.

Pineapple (Hawaii only)



For control of butt rot disease of pineapple (Ceratocystis paradoxa), apply 0.25 lb. of Tilt 45W/500 gals. of water. Treatments can be made in either a cold or hot water dip.

Cold Water Dip: Immerse crowns to give thorough wetting, remove and allow to drain.

Hot Water Dip: Maintain water temperature at 125°F (52°C). Soak crowns for 20-30 minutes, remove and allow to drain.

Important: To avoid possible illegal residues: (1) Do not use treated crowns for food or feed. (2) Do not graze while plant is growing. (3) Do not graze tops until fruit is harvested. (4) Dispose of used dip solution according to local, state, and federal regulations.

#### Sugarcane (Hawaii only)

For control of pineapple disease of sugarcane (Ceratocystis paradoxa), apply Tilt 45W to cut seed pieces using 0.25 lb./500 gals. of water. Treatments can be applied in either a cold or hot water dip. Do not use treated seed pieces for food or feed purposes. Dispose of spent dip solution according to state and federal regulations.

Cold Water Dip - Immerse seed pieces to give thorough wetting, remove, and allow to drain.

Hot Water Dip - Maintain water temperature at 125°F (52°C). Soak the seed pieces for 20-30 minutes, remove, and allow to drain.

#### Storage and Disposal

#### Pesticide Disposal

Do not contaminate water, food, or feed by storage or disposal. Pesticide wastes may be toxic. Improper disposal of unused pesticide, 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

Do not reuse outer container. Dispose of empty container in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, keep out of smoke.

For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to



avoid contamination of equipment and facilities during cleanup and disposal of wastes. In the event of a major spill, fire, or other emergency, call 1-800-888-8372, day or night.

#### Precautionary Statements

#### Hazards to Humans and Domestic Animals

#### CAUTION

Causes eye irritation. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing.

#### Statement of Practical Treatment

If in eyes: Hold eyelids open and flush eyes with a steady,

gentle stream of water for 15 minutes. Get medical attention if irritation persists.

If swallowed: Immediately call a physician or Poison Control

Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with

finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If on skin: Wash with plenty of soap and water. Get

medical attention if irritation persists.

## Note to Physician:

If ingested, induce emesis or lavage stomach. Treat symptomatically.

#### Personal Protective Equipment

## 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 Control Statements

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.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

### Environmental Hazards

This pesticide is toxic to fish. 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 when disposing of equipment wash waters. Refer to product labeling for use restrictions to protect endangered species.

#### Physical or Chemical Hazards

Do not use, pour, spill, or store near heat or open flame.

Tilt® 45W trademark of Ciba-Geigy Corporation U.S. Patent No. 4,079,062

Benlate® trademark of E. I. duPont de Nemours and Company, Inc.

Mertect® trademark of Merck and Company, Inc.

Solubor® trademark of United States Borax and Chemical Corporation

Topsin® trademark of Pennwalt Corporation

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Ciba Crop Protection Ciba-Geigy Corporation Greensboro, North Carolina 27419

CGA (20 oz.) Product ID: CGA (4 oz.) Product ID:

Product ID. Product ID.

#### Back Page of Booklet

Tilt® 45W

FUNGICIDE

For control of certain diseases in celery, cereals, corn, grasses grown for seed, peanuts, pineapple, and sugarcane

See directions for use in attached booklet.

## AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. Refer to supplemental labeling under "Agricultural Use Requirements" in the Directions for Use section for information about this standard.

EPA Reg. No. 100-EPA Est. 100-AL-1

20 oz. Net Weight

4 oz. Net Weight

#### KEEP OUT OF REACH OF CHILDREN.

#### CAUTION

#### Precautionary Statements

#### Hazards to Humans and Domestic Animals

Causes eye irritation. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing.

#### Statement of Practical Treatment

If in eyes: Hold eyelids open and flush eyes with a steady,

gentle stream of water for 15 minutes. Get medical attention if irritation persists.

If swallowed: Immediately call a physician or Poison Control

Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with

finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If on skin: Wash with plenty of soap and water. Get

medical attention if irritation persists.

#### Note to Physician:

If ingested, induce emesis or lavage stomach. Treat symptomatically.

#### Environmental Hazards

This pesticide is toxic to fish. 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 when disposing of equipment wash waters. Refer to product labeling for use restrictions to protect endangered species.

#### Physical or Chemical Hazards

Do not use, pour, spill, or store near heat or open flame. In event of spill, fire, or other emergency, call 1-800-888-8372 day or night.

#### Chemigation

Refer to supplemental labeling in attached booklet for use directions on chemigation. Do not apply this product through any type of irrigation system unless the supplemental labeling on chemigation is followed.



Tilt® 45W trademark of Ciba-Geigy Corporation U.S. Patent No. 4,079,062

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Ciba Crop Protection Ciba-Geigy Corporation Greensboro, North Carolina 27419

CGA (20 oz.) CGA (4 oz.) PRODUCT ID.: PRODUCT ID.:

[GANNONC.LABELT\LBL-T-MS]TILT45W - 5/2/95

# END OF DOCUMENT



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#### Ciba Plant Protection

OPP OFFICIAL RECORD HEALTH EFFECTS DIVISION SCIENTIFIC DATA REVIEWS **EPA SERIES 361** 

Ciba-Geigy Corporation P.O. Box 18300 Greensboro, NC 27419-8300 Telephone 910 632 6000

436556- 00

To Bill Cutchin for review on 7/24/95

Gregory R. Watson, Ph.D. Ciba Crop Protection Ciba-Geigy Corporation PO Box 18300 Greensboro, NC 27419-8300 Telephone 910 632 2993 Facsimile 910 632 2510 or 910 292 6374

May 15, 1995

Document Processing Desk (PETN) Office of Pesticide Programs-H7504C U. S. Environmental Protection Agency 401 M Street, SW Washington, DC 20460-0001

Attention: Ms. Connie Welch, PM Team 21

Dear Ms. Welch:

SUBJECT: PROPICONAZOLE (EPA REG. NO. 100-618), ORBIT™ (EPA REG. NO. 100-702) AND ORBIT™ GEL (EPA REG. NO. 100-737); PP NO. 4F4321 REQUESTING A STONE FRUIT CROP GROUPING TOLERANCE FOR PROPICONAZOLE AND REGISTRATION OF ASSOCIATED LABELING FOR ORBIT AND ORBIT GEL; REQUESTING REGISTRATION OF THE NEW END-USE FORMULATED PRODUCTS TILT 45W FUNGICIDE (EPA FILE SYMBOL 100-TIN ) AND ORBIT 45W FUNGICIDE (EPA FILE SYMBOL 100- $\mathcal{I}\mathcal{I}\mathcal{R}$ )

With this submission Ciba Crop Protection officially amends PP No. 4F4321, petitioning EPA for a stone fruit crop grouping tolerance for propiconazole and approval of enclosed proposed labeling to allow applications of Orbit™ and Orbit™ Gel to cherries. Please note that the Orbit Gel directions for use reflect a 4 fl. oz. packet size; this package size was submitted as a notification to EPA on January 10, 1994. The addition of the proposed application to cherries is the only additional use proposed in the enclosed labeling when compared to the current EPAapproved Orbit and Orbit Gel labels. With this submission we are also requesting the registration of Orbit 45W Fungicide for use on members of the stone fruit crop grouping, along with the request for registration of Orbit 45W and Tilt 45W Fungicide on all othercrops with established propiconazole tolerances.

In the attached Section F, we have amended our Stone Fruit Crop Grouping tolerance request in PP No. 4F4321 to 1.5 ppm; note that our previous request was 1.0 ppm. This amendment is based on. the fact that a single value for one replicate cherry sample treated with the 3.6EC formulation was found to be just above the 1.0 ppm propiconazole tolerance established for other members of the Stone Fruit Crop Grouping. The other replicate for the sample was found to have a residue of 0.88 ppm, making the average residue level for this site 0.99 ppm. However, to account for the residue, found in this one replicate sample, Ciba Crop Protection has elected to request a 1.5 ppm tolerance for the Stone Fruit Crop Grouping. Ciba Crop Protection would not object to the establishment of

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Ms. Connie Welch / PP No. 4F4321 Requesting a Stone Fruit Crop Grouping Tolerance for Propiconazole May 15, 1995
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a 1.0 ppm tolerance for this crop grouping, given the abnormal nature of the residue level found in this one sample.

Please note that this is a follow-up submission to our January 14, 1994 submission that initiated this petition. Due to some personnel changes within Team 21, this petition was not routed for review until 12/8/94, almost a year after submission. We have yet to receive a review of this previous submission by HED. Given this long delay in the processing and review of this petition, we are requesting expeditious processing and review of the attached product chemistry, acute toxicology, and residue data; we are requesting registration of Tilt 45W and Orbit 45W and approval of this stone fruit crop grouping tolerance at the latest by the end of December, 1995. We believe our request is reasonable given the level of EPA understanding of the propiconazole data base and the previous delay in the processing and review of this petition. Approval of this registration according to this timeline is also important for a planned experimental use permit application for stone fruit involving a new active ingredient, CGA-219417; this product is assigned to Team 23 (Ms. Joanne Miller) and has attributes that will allow Ciba Crop Protection to request the "Reduced Risk" classification for this active ingredient. We appreciate your understanding and consideration of our request for registration prior to December, 1995.

#### **Stone Fruit Crop Grouping:**

Ciba Crop Protection has requested a Stone Fruit Crop Grouping tolerance for propiconazole in the past (PP No. 9F3758; approved as amended by EPA on May 18, 1993). This petition was amended on October 8, 1992 to request specific crop tolerances in lieu of the crop grouping to allow PP No. 9F3758 to move as quickly as possible toward approval. The review of field residue data in association with PP No. 9F3758 (MRID No. 41063802, ABR-89007; submitted to EPA March 3, 1989) by the Tolerance Petition Section, Dietary Exposure Branch dated November 28, 1989 stated that:

"For a crop group tolerance in/on stone fruit in accordance with 40 CFRS180.34(f) (9) (xii), additional residue data are needed on sour or sweet cherry." (page 3 of the review; a copy of this review is enclosed for your records)

On January 14, 1994 Ciba Crop Protection initiated PP No. 4F4321 requesting a 1.0 ppm Stone Fruit Crop Grouping tolerance for propiconazole based on the assertion that substitution of residue data on apricots, nectarines, and prunes for data on sweet or sour cherries was adequate. In this submission we are supplying the residue data on cherries (attached Volume 11) as requested in the November 28, 1989 EPA review and amending our tolerance request to 1.5 ppm.

The original rationale for not conducting field residue research on cherries was in the process of developing propiconazole for use on stone fruit, some plant growth regulating (PGR) activity was found with propiconazole on cherries (i.e., in some cases fruit applications altered the shape of the ripening fruit). Given this potential PGR effect, it was determined that commercial use of proposionazole on cherries was limited. However, with further efficacy research we have

<sup>1 -</sup> Please recall that the current representative crops requiring field residue data to support a the 3tone Fruit Crop. Grouping tolerance include sour or sweet cherry, peach, and plums or fresh prunes (Pruna; comestica). The referenced data volume (i.e., MRID No. 41063802) provided field residue data for propiconazole on apricots, nectarines, peaches, plums and prunes. The 40 § CFRS 180.34(f) (1) states that: "The Agency will' take 'a, flexible approach to allow for group tolerances when data on suitable substitutes for the representative crops are available (e.g., limes instead of lemons)." Therefore, the required data on peach and plums was provided plus; additional data on apricots, nectarines, and prunes as a substitute for the required data on cherry.



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determined that the proposed use program on cherries carries little risk for PGR activity in cherries.

#### Propiconazole (Tilt and Orbit) 45WP:

As noted above, we are adding to this petition a request for registration of a new 45WP formulation under the brand names Orbit 45W and Tilt 45W. These products are planned to be marketed in water soluble film to reduce worker exposure during product mixing; however, to retain marketing flexibility in the future we are requesting registration of a basic formula of each product formula that does not list the water soluble film packaging. Please note that the 45W formulation of propiconazole carries the "Caution" signal word; both the 3.6EC (i.e., EPA Reg. No. 100-702 and 100-617) and the gel (EPA Reg. No. 100-737) formulations carry a "Warning" signal word.

Side-by-side crossover residue trials with the 3.6EC (the registered commerical Orbit and Tilt formula) and 45WP formulation were performed on diverse crops and substrates (attached Volumes 12-15); these trials demonstrate no significant differences in the residues found regardless of the formulation. At no time was an established propiconazole tolerance exceeded in crops receiving applications of the 45WP formulation. Except for the requested 1.5 ppm tolerance in the Stone Fruit Crop Grouping, current propiconazole tolerances are adequate to support the requested registration of Tilt 45W Fungicide and Orbit 45W Fungicide. The attached table provides a summary of the results from this side-by-side crossover residue program:

Comparison of Side-by-Side Residue Trials with Propiconazole 3.6EC and Propiconazole 45WP			
Commodity	Propiconazole 3.6EC Residues	Propiconazole 45WP Residues	Current Propiconazole Tolerances
Stone Fruit (sweet cherries, tart cherries, peaches, plums)	Maximum: 0.8 ppm Range: <0.05 - 0.8 ppm Average: 0.28 ppm	Maximum: 0.67 ppm Range: <0.05 - 0.67 ppm Average: 0.23 ppm	1.0 ppm in apricots, nectarines, peaches, plums, fresh prunes
Com Forage & Fodder	Maximum: 2.6 ppm Range: <0.05 - 2.6 ppm Average: 0.6 ppm	Maximum: 2.7 ppm Range: 0.05 - 2.7 ppm Average: 0.69 ppm	12.0 ppm in com forage, com fodder
Field and Sweet Com Grain	Maximum: <0.05 ppm (all residues below limit of detection)	Maximum: <0.05 ppm (all residues below limit of detection)	0.1 ppm in com grain, sweet com (K+CWHR)
Celery	Maximum: 0.42 ppm Range: 0.27 - 0.42 ppm Average: 0.35 ppm	Maximum: 0.51 ppm Range: 0.45 - 0.51 ppm Average: 0.48 ppm	5.0 ppm in celery

Please find attached the following items:

○ 15 volumes (14 data volumes and a transmittal volume) providing residue data supporting our Stone Fruiting Crop Grouping tolerance request; and product chemistry, acute toxicology, and residue data supporting our request for registration of Orbit 45W and Tilt 45W (3 copies each).

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- required documentation for amending of PP No. 4F4321 can be found in the attached Sections A-G (1 volume, 3 copies).
- five (5) copies of typed supplemental labeling proposing registration of Orbit (EPA Reg. No. 100-702), Orbit Gel (EPA Reg. No. 100-737) for use on cherries. Please note that two copies of the Orbit and Orbit Gel labeling are highlighted to indicate proposed labeling changes in comparison to the current Orbit and Orbit Gel labels. Completed EPA Forms 8570-1 for each product also accompany this request.
- five (5) copies of typed labeling for Orbit 45W (EPA File Symbol not yet assigned) proposing use on various members of the stone fruit crop grouping, pecans, and non-bearing citrus and Tilt 45W (EPA File Symbol not yet assigned) requesting use on celery, cereals (barley, rye, wheat), corn, peanuts, pineapple, rice, sugar cane, and wild rice. Completed EPA Forms 8570-1 for each product also accompany this request.
- completed EPA Forms 8570-4 (Confidential Statement of Formula) for Tilt 45W and Orbit 45W. We have also attached two sets of copies of authorization letters for certain inert ingredients in the alternate formulations that contain water soluble film packaging.

Please note that in our January 14, 1994 submission a check in the amount of \$13,825 was forwarded to the EPA Accounting Office in Pittsburgh along with a copy of this letter to support the consideration of this petition by EPA. We also enclosed in this earlier submission a copy of a completed Certification with Respect to Citation of Data form that utilizes the selective method of citing data and a completed data matrix for technical propiconazole and Tilt 3.6EC (please note that Orbit 3.6EC is the same formula as Tilt 3.6EC). Please be aware that Ciba Crop Protection is the sole data generator for agricultural uses of propiconazole and all formulated products containing propiconazole.

The proposed supplemental Orbit and Orbit Gel labeling does not include the full language required by the Worker Protection Standard (PR Notice 93-7 and 93-11); labeling for Orbit and Orbit Gel (Tilt Gel) containing appropriate WPS language was approved by on EPA January 14, 1994. The Orbit 45W and Tilt 45W labeling carries the required appropriate WPS language.

Thank you for your consideration of this petition and the associated proposed labeling. Please contact me if there are any questions associated with the proposed labeling or any other topic concerning propiconazole currently pending at EPA.

Best Regards,

Gregory R. Watson

Senior Regulatory Manager

Ms. Kathryn Scanlon, Team 21 (H7505C)

Ms. Connie Welch, Courtesy Copy; PM Team 21 (H7505C)

## VOLUME 1 OF 15 OF SUBMISSION (TRANSMITTAL DOCUMENT)

## NAME AND ADDRESS OF SUMBITTER

CIBA CROP PROTECTION CIBA-GEIGY CORPORATION P. O. BOX 18300 GREENSBORO, NC 27419-8300

## 2. REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

PROPICONAZOLE (EPA REG. NO. 100-618), PP NO. 4F4321 REQUESTING A STONE FRUIT CROP GROUPING TOLERANCE; SUBMISSION OF FIELD RESIDUE DATA IN SUPPORT OF A STONE FRUIT CROP GROUPING TOLERANCE FOR PROPICONAZOLE SUBMISSION OF DATA IN SUPPORT OF REGISTRATION OF A 45WP FORMULATION OF TILT ANT ORBIT FOR USE ON STONE FRUIT AND ALL CROPS WITH ESTABLISHED PROPICONAZOLE TOLERANCES

#### 3. TRANSMITTAL DATE

MAY 15, 1995

#### 4. LIST OF SUBMITTED STUDIES

MRID NO.	VOLUME NUMBER	STUDY TITLE	GUIDELINE NO.
	1 OF 15	TRANSMITTAL DOCUMENT	NOT APPLICABLE
43655601	2 OF 15	TILT® 45WP: PRODUCT CHEMISTRY (STUDY NO.: PC-95-013; P. McCAIN)	61-1, 61-2, 61-3, 62-2, 62-3, 63, 63-2, 63-3, 63-4, 63-7, 63-12, 63-14, 63-16, 63-17, 63-20
43655602	3 OF 15	CHARACTERIZATION REPORTS OF TILT 45WP TEST SUBSTANCES USED IN TOXICOLOGICAL STUDIES CONTAINED IN THIS SUBMISSION (STUDY NO. NA; P. McCAIN, AUTHOR)	NOT APPLICABLE
ADMIN	4 OF 15	SUMMARY OF ACUTE TOXICOLOGY STUDIES WITH TILT 45WP (STUDY NO.: NA; JOAN SOVA, AUTHOR)	NOT APPLICABLE
43655603	5 OF 15	CGA 64250 45WP-B: FINAL REPORT, ACUTE ORAL TOXICITY STUDY IN RATS (STUDY NO.: STILLMEADOW, INC.: 1855-95)	81-1

## 4. LIST OF SUBMITTED STUDIES, CONTINUED

MRID NO.	VOLUME NUMBER	STUDY TITLE	GUIDELINE NO.
43655604	6 OF 15	CGA 64250 45WP-B: FINAL REPORT, ACUTE DERMAL TOXICITY STUDY IN RABBITS (STUDY NO.: STILLMEADOW, INC. 1856-95)	81-2
43655605	7 OF 15	CGA 64250 45WP-B: FINAL REPORT, ACUTE INHALATION TOXICITY STUDY IN RATS (STUDY NO.: STILLMEADOW, INC. 1868-95)	81-3
43655606	8 OF 15	CGA 64250 45WP-B FL-940165: FINAL REPORT, PRIMARY EYE IRRITATION STUDY IN RABBITS (STUDY NO.: STILLMEADOW, INC. 1072-94)	81-4
43655607	9 OF 15	CGA 64250 45WP-B: FINAL REPORT, PRIMARY DERMAL IRRITATION STUDY IN RABBITS (STUDY NO.: STILLMEADOW, INC. 1857-95)	81-5
43655608	10 OF 15	CGA 64250 45WP-B: FINAL REPORT, DERMAL SENSITIZATION STUDY IN GUINEA PIGS (STUDY NO.: STILLMEADOW, INC. 1858-95)	81-6
43655609	11 OF15	PROPICONAZOLE - MAGNITUDE OF THE RESIDUES IN OR ON CHERRIES FOLLOWING POST FOLIAR APPLICATIONS OF ORBIT® (STUDY NO.: ABR-95001; F. B. SELMAN)	171-4(k)
43655610	12 OF 15	PROPICONAZOLE - COMPARISON OF RESIDUES RESULTING FROM APPLICATIONS OF PROPICONAZOLE 3.6EC AND PROPICONAZOLE 45WP TO THREE REPRESENTATIVE CROP GROUPS (STUDY NO.: ABR-95010; F. B. SELMAN)	NOT APPLICABLE
43655611	13 OF 15	PROPICONAZOLE - MAGNITUDE OF THE RESIDUES IN OR ON REPRESENTATIVE COMMODITIES OF THE STONE FRUITS GROUP FOLLOWING APPLICATIONS OF ORBIT AND ORBIT 45WP (STUDY NO.: ABR- 95007; F. B. SELMAN)	171-4(k)

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#### 4. LIST OF SUBMITTED STUDIES, CONTINUED

MRID NO.	VOLUME	STUDY TITLE	GUIDELINE NO.
	NUMBER		
43655612	14 OF 15	PROPICONAZOLE - MAGNITUDE OF THE	171-4(k)
		RESIDUES IN OR ON FIELD AND SWEET	
		CORN FOLLOWING APPLICATIONS OF	
		TILT AND TILT 45WP (STUDY NO.: ABR-	
		95008, F. B. SELMAN)	
43655613	15 OF 15	PROPICONAZOLE - MAGNITUDE OF THE	171-4(k)
		RESIDUES IN OR ON CELERY	
		FOLLOWING APPLICATIONS OF TILT	
		AND TILT 45WP (STUDY NO.: ABR-95009;	
		F. B. SELMAN)	

COMPANY OFFICIAL: GREGORY R. WATSON NAME	SIGNATURE )
COMPANY NAME: CIBA CROP PROTECTION, CIBA-GE	IGY CORPORATION
COMPANY CONTACT: GREGORY R. WATSON	910-632-2993
COMPANY CONTACT TITLE: _SENIOR REGULATORY	MANAGER



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

APR 1 3 1995

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

#### MEMORANDUM

SUBJECT: PP#4F04321, Propiconazole in/on Stone Fruit. Request for

Group Tolerance. Chemical# 122101, DP Barcode: D210252,

CBTS#: 14858, MRID#:434774.

FROM: William D. Cutchin, Chemist

Chemistry Branch I: Tolerance Support

Health Effects Division (7509C)

THROUGH: Robert Quick, Section Head

Chemistry Branch I: Tolerance Support

Health Effects Division (7509C)

TO:

Connie Welch, PM Team 21 Fungicide/Herbicide Branch Registration Division (7505C)

and

Jane Smith, Acting Section Head Risk Coordination and Analysis Branch Health Effects Division (7509C)

Dr. Gregory R. Watson, Regulatory Manager, Plant Protection Division, Ciba-Geigy Corp., requests the establishment of a tolerance in or on cherries and a group tolerance for stone fruit at 1 ppm for the residues of the fungicide propiconazole (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole), and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA) and expressed as parent compound. Tolerances have been established for residues at levels ranging from 5 ppm in/on celery to 0.05 ppm in milk (40 CFR §180.434). Propiconazole is a FIFRA 88 List C chemical, for which a Phase 4 review was completed 6/30/92.

Ciba-Geigy Corp. requested in PP#9F3758 (submitted to EPA on 3/3/89) a stone fruit group tolerance for propiconazole. DEB denied the group tolerance since there was no data for cherries, a requirement for a stone fruit group tolerance. Eventually,

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tolerances were established for the other crops addressed in the petition: wild rice, peaches, nectarines, apricots, plums, and prunes (final review 6/2/93). Ciba-Geigy Corp. proposes to apply the data supplied with PP#9F3758 in support of a bloom-only use tolerance in/on cherries, fulfilling the stone fruit group data requirements, and thereby establish a group tolerance.

#### Conclusions

- 1. The product chemistry of propiconazole and its metabolite DCBA have been adequately described. No further data is required for this proposed use.
- 2. The proposed use directions in Section B are adequate. No further changes are required for this proposed use.
- 3. The metabolism of propiconazole in plants has been described in detail. No further data is required for this proposed use. The residues of concern are propiconazole and its metabolites determined as DCBA and expressed as parent.
- 4. There are no known animal feed stock uses for cherries. No animal metabolism data are necessary for this proposed use.
- 5. Adequate enforcement methods have been approved for publication in PAM II for enforcement purposes, but has not as of this time appeared in PAM II. No further methodology is necessary for this proposed use.
- 6. Propiconazole and DCBA are included in published multiresidue methods. No further methodology is necessary for this proposed use.
- 7a. There are sufficient residue data to support the proposed use. Residues of propiconazole and its metabolites are not expected to exceed the proposed 1 ppm tolerance for the stone fruit crop group. Additional residue data are not required for this proposed use.
- 7b. The geographic diversity of the studies in EPA files are adequate to represent the cherry growing regions requested by this petition.
- 8. There were no storage stability data presented with this petition. The storage stability data in EPA files are sufficient support the residue studies for stone fruit.
- 9. There are no known animal feed stock uses for cherries. Consequently, secondary residues in meat, milk, poultry, and eggs are not expected to be a problem.
- 10. Analytical standard materials for propiconazole and DCBA are available.

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11. No Canadian or Mexican limits have been established for residues of propiconazole in or on stone fruit. A Codex tolerance of 1 ppm has been established for propiconazole in or on stone fruit. The establishment of a 1 ppm tolerance for propiconazole on stone fruit will create no compatibility problems.

#### Recommendations

TOX considerations permitting, CBTS recommends the establishment of the proposed stone fruit crop group tolerance of 1 ppm. There were no residue data submitted with this petition. The data in EPA files are adequate to establish a permanent tolerance for propiconazole in/or on cherries and are therefore adequate to establish a stone fruit group tolerance. A DRES run can be initiated at this time.

#### Detailed Considerations

#### Manufacture and Formulation

Propiconazole is a FIFRA 88 List C chemical, for which a Phase 4 review was completed 6/30/92. There are some data gaps still outstanding (DP Barcode#198815, CBRS#13166, 4/26/94). This is not a deficiency for this petition. Ciba-Geigy has submitted a separate request to add the brand name Orbit<sup>™</sup> Gel under the current Tilt<sup>™</sup> Gel registration (EPA Reg. No. 100-737). This is in addition to the already registered Orbit<sup>™</sup> (EPA Reg. No. 100-702).

#### Proposed Use

The proposed use directions, Section B, are adequate. The proposed use directions state that the product is to be applied to cherries, apricots, nectarines, peaches, fresh prunes, and plums at the early bloom stage at a rate of 50 g ai/A (0.11 lb ai/A). For aerial applications a minimum spray volume of 5-10 gal/A is recommended. For ground applications a minimum of 50 gal/A spray volume is recommended. A second application is to be made at 50-75% bloom. A third application at petal fall may be made if disease conditions persist or blooming is prolonged.

Propiconazole may also be used on the fruits of apricots, nectarines, peaches, and plums. A maximum of 2 pre-harvest sprays at 50 g ai/A beginning 3 weeks before harvest through the day of harvest (0 day PHI). For aerial applications a minimum spray volume of 5-10 gal/A is recommended. For ground applications a minimum of 50 gal/A spray volume is recommended. The product is not to be applied to the fruit of cherries or prunes.

#### Nature of Residue - Plants

The nature of the residue in plants is adequately understood. The metabolism of propiconazole has been studied in wheat, corn,



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peanuts, grapes, lettuce, carrots, and tomatoes. The residue to be regulated is propiconazole, <u>per se</u>, and its metabolites determined as DCBA (PP#8F3674, 12/14/88).

## Nature of Residue - Animals

There are no known animal feed stock uses for cherries. Animals are not allowed to graze in cherry orchards nor are parts of the plant used as supplemental feeds after processing. Animal metabolism data are neither submitted nor necessary for this proposed use.

## Analytical Methods - Enforcement MRID#:434774

The Ciba-Geigy Method AG-454B is referenced in the petition as the enforcement method. The Ciba-Geigy Method AG-454B is described as follows. Samples are extracted by refluxing with 20% ammonium hydroxide/methanol for one hour. The mixture is then cooled and filtered and an aliquot is evaporated to dryness. The residue is dissolved in aqueous sodium hydroxide and heated for 1.25 hours with potassium permanganate. After dilution with water, the sample is partitioned with 10% diethyl ether/hexane and the organic solution containing DCBA collected. The sample solution is rotovaped to dryness in the presence of dodecane and methylated with diazomethane. The sample is cleaned-up on an acidic alumina Sep-Pak before being analyzed by capillary gas chromatography with electron capture (GC/EC) detection.

The method has been approved for publication in PAM II for enforcement purposes, but has not as of this time appeared in PAM II (PP#2F04086, 2/28/95). No further methodology is necessary for this proposed use.

## Analytical Methods - Multiresidue MRID#:434774

Multiresidue methods data indicate the recovery of propiconazole via FDA Multiresidue Protocol D (PAM II 232.4) is complete while recovery of propiconazole metabolites via this method is variable (Pestrak data base (11/6/90)). No further methodology is necessary for this proposed use.

#### Magnitude of Residue MRID#:434774

There are sufficient residue data to support the proposed use and the proposed group tolerance. No data was submitted with this petition. The residue data in EPA files supports the proposed use.

The product cannot be used post-blossom on cherries as it can cause plant growth regulating activity. The data in the original petition pertinent to the cherry part of this petition is the blossom-only use data on prunes. The maximum residues found in/on prunes were 0.07 ppm dried and 0.27 ppm fresh at 1 x and 2 x

maximum use rates respectively (PP#9F3758, 6/2/93). This data shows expected blossom-only residues in/on cherries are unlikely to exceed the proposed 1 ppm tolerance.

The original petition cited here, PP#9F3758, contained mostly postblossom residue data in/on stone fruit. With the exceptions of prunes and cherries, other members of the stone fruit group can be treated foliarly as well as blossom-only. The residue tolerance, 1 ppm, established for those stone fruits included in PP#9F3758 reflect primarily post-blossom use. The maximum residue for a 0 day PHI foliar use was 0.78 ppm found on peaches. This data shows expected residues in/on the stone fruit crop group are unlikely to exceed the proposed 1 ppm tolerance. The residue data reflecting foliar use with a 0 day PHI support the establishment of a 1 ppm tolerance on the stone fruit crop group.

#### Geographic Representation

The data submitted in the original petition, PP#9F3758, reflect 17 field trials from the major stone fruit growing regions of the country, California (6), Georgia (1), Michigan (4), Pennsylvania (2), New York (1), Virginia (1), and Washington (2). No further data is necessary for this proposed use.

#### Storage Stability

There were no storage stability data submitted with this petition. Storage stability data for propiconazole on stone fruits were submitted with the original petition, PP#9F3758. Residues of propiconazole were found to be stable up to 25 months on stone fruits. Degradation of propiconazole residues on stone fruits is unlikely. No further data is necessary for this proposed use.

#### Meat, Milk, Poultry, and Eggs

Stone fruit or stone fruit by-products are not used for animal feed stock. No food stock residue data are necessary for this proposed use.

#### Other Considerations

An International Residue Limit Sheet is attached to this review. (Attachment 1). No Canadian or Mexican limits have been established for residues of propiconazole in or on stone fruit. A Codex tolerance of 1 ppm has been established for propiconazole in or on stone fruit. The establishment of a 1 ppm tolerance for propiconazole on stone fruit will create no compatibility problems.



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#### Propiconazole

Attachment: International Residue Limit Sheet

cc: RF, PP#4F04321, circ., Cutchin, SAB (B. Doyle)
7509C: CBTS, Reviewer (WDC), CM#2, Rm 804J, 305-5351, WDC:4/13/95
R/I: Sec. Head: R. Quick, 4/12/95; Br. Sr. Sci.: R. Loranger, 4/12/95; Br. Chief: E. Zager, 4/13/95



# END OF DOCUMENT

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#### Label Master Booklet

Orbit™ 45W

**FUNGICIDE** 

OPP OFFICIAL RECORD HEALTH EFFECTS DIVISION SCIENTIFIC DATA REVIEWS EPA SERIES 361

For control of certain diseases in pecans, apricots, cherries, nectarines, peaches, plums, prunes, and nonbearing citrus

Active Ingredient: Propiconazole: 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-

EPA Reg. No. 100-

Est. 100-AL-1

#### KEEP OUT OF REACH OF CHILDREN.

#### CAUTION

See additional precautionary statements and directions for use inside booklet.

4 oz. Net Weight

**CGA** 

Ciba-Geigy



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## DIRECTIONS FOR USE AND CONDITIONS OF SALE AND WARRANTY

**IMPORTANT:** Read the entire **Directions for Use** and the **Conditions of Sale** and **Warranty** before using this product. If terms are unacceptable, return the unopened product container at once.

### Conditions of Sale and Warranty

The **Directions for Use** of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with 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 Ciba-Geigy or the Seller. All such risks shall be assumed by the Buyer.

Ciba-Geigy warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the Directions for Use subject to the inherent risks referred to above. Ciba-Geigy makes no other express or implied warranty of Fitness or Merchantability or any other express or implied warranty. In no case shall Ciba-Geigy or the Seller be liable for consequential, special, or indirect damages resulting from the use or handling of this product. Ciba-Geigy and the Seller offer this product, and the Buyer and user accept it, subject to the foregoing Conditions of Sale and Warranty, which may be varied only by agreement in writing signed by a duly authorized representative of Ciba-Geigy.



#### 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 the restricted entry interval (REI) of 24 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
- Waterproof gloves
- Shoes plus socks



#### General Information

Orbit 45W is a broad spectrum fungicide for the control of certain diseases in pecans, certain stone fruit, and nonbearing citrus.

**Important:** Do not use in nurseries, on turf, on landscape plantings, or as a tree injection.

FAILURE TO FOLLOW DIRECTIONS AND PRECAUTIONS ON THIS LABEL MAY RESULT IN CROP INJURY, POOR DISEASE CONTROL, OR ILLEGAL RESIDUES.

#### **Spray Equipment**

Thorough coverage is necessary to provide good disease control.

To avoid spray drift, do not apply when conditions favor drift beyond the target area. Avoid spray overlap, as crop injury may occur.

Equip sprayers with nozzles that provide accurate and uniform application. Be certain that nozzles are the same size and uniformly spaced across the boom. Calibrate sprayer before use.

Use a pump with capacity to: (1) maintain a minimum of 35 psi at nozzles, and (2) provide sufficient agitation in tank to keep mixture in suspension - this requires recirculation of 10% of tank volume per minute. Use a jet agitator or liquid sparge tube for agitation. Do not air sparge.

Use screens to protect the pump and to prevent nozzles from clogging. Screens placed on suction side of pump should be **16-mesh or coarser**. Do not place a screen in the recirculation line. Use 50-mesh or coarser screens between the pump and boom, and where required, at the nozzles. Check nozzle manufacturer's recommendations.

For more information on spray equipment and calibration, consult sprayer manufacturers and state recommendations. For specific local directions and spray schedules, consult the current state agricultural experiment station recommendations.

#### Mixing Procedures

Prepare no more spray mixture than is needed for the immediate operation. Thoroughly clean spray equipment before using this product. Vigorous agitation is necessary to maintain uniformity of the spray mixture. Maintain maximum agitation throughout the spraying operation. Do not let the spray mixture stand overnight in the spray tank. Flush the spray equipment theroughly following each use and apply the rinsate to a previously treated area.

Precaution: Water-soluble bags of Orbit 45W must be completely dissolved and dispersed in plain water before any other tank mix partner, including micronutrients or other liquid or dry fertilizers, are added to the spray solution. Boron, especially in the form of a micronutrient additive, such as Solubor®, etc., or as a natural component of the mix water, may prevent water soluble bags from dissolving.

Orbit 45W Alone: Add 1/3 of the required amount of plain water to the spray or mixing tank. With the agitator running, drop the required number of unopened soluble bags of Orbit 45W into the tank all at once. Continue agitation while adding the remainder of the water. Begin application of the spray solution after the soluble bags have dissolved, and the material has completely dispersed into the mix water. Maintain agitation until all of the mixture has been applied.

Orbit 45W + Tank Mixtures: Add 1/3 of the required amount of plain water to the spray or mixing tank. With the agitator running, drop the required number of unopened soluble bags of Orbit 45W into the tank all at once. Continue agitation while adding the remainder of the water. Allow the soluble bags of Orbit 45W to dissolve and the product to completely disperse into the mix water. Then add the desired amount of other products recommended for tank mixtue and allow them to become completely dispersed. Continue agitation to maintain a uniform suspension until all of the spray solution has been applied.

Do not mix Orbit 45W with Cyprex®, or crop injury may occur.

If using Orbit 45W in a tank mixture, observe all directions for use, crops/sites, use rates, dilution ratios, precautions, and limitations which appear on the tank mix product label. No label dosage rate should be exceeded, and the most restrictive label precautions and limitations should be followed. This product should not be mixed with any product which prohibits such mixing. Tank mixtures or other applications of products referenced on this label are permitted only in those states in which the referenced products are registered.

**Aerial Application:** Avoid application under conditions where uniform coverage cannot be obtained or where excessive spray drift may occur. Do not apply directly to humans or animals.

Chemigation: Do not apply this product through any type of irrigation system.

#### Nonbearing Citrus

For control of greasy spot (*Mycosphaerella citri*) in nonbearing citrus, apply 0.375 lb. - 0.5 lb. of Orbit 45W per acre during June-August.

**Note**: To avoid possible illegal residues, do not apply to citrus that will bear harvestable fruit within 12 months.

#### **Pecans**

#### Pecans (bearing)

Apply Orbit 45W for control of pecan scab, downy spot, liver spot, vein spot, Zonate leaf spot, and fungal leaf scorch in a regular spray program, beginning at bud break when young leaves are unfolding. Continue applications while small nuts are forming, repeating at 2-week intervals as needed, not exceeding 4 applications per growing season (2 lb./A). Do not apply after shuck-split. Do not graze livestock in treated areas or cut treated cover crops for feed.

Apply Orbit 45W at the following rates in sufficient water to obtain good coverage, using a minimum spray volume of 10 gals./A by air or 50 gals./A by

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ground. For ground applications, the applicator must be in a closed cab during application.

Pecan Scab - South (AL, AR, FL, GA, KY, LA, MO, MS, NC, SC and TN): Apply 0.25-0.5 lb./A on a 14-day schedule during bud break and pre-pollination sprays. Under severe disease conditions, use the highest rate. Apply 0.5 lb./A during nut formation and cover sprays.

Pecan Scab - Southwest (AZ, NM, OK and TX): Apply 0.25 lb./A on a 14-day schedule during bud break and pre-pollination sprays. Apply 0.375 lb./A in case bearer and cover sprays.

**Foliar Diseases:** Orbit 45W may be applied for control of mid- to late-season foliar diseases (such as Zonate leaf spot, fungal leaf scorch, vein spot, and downy spot) at 0.25 lb./A with the recommended rate of Super Tin® in the cover sprays. Observe all directions, precautions, and limitations on the labeling for this product.

Endangered Species Restrictions: The use of any pesticide in a manner that may kill or otherwise harm an endangered or threatened species, or adversely modify their habitat, is a violation of federal laws. The use of this product in pecans is controlled to prevent death or harm to endangered species. Do not use Orbit 45W in the following counties:



State		Counties	
Alabama	Colbert	Lauderdale	Morgan
	Greene	Limestone	Pickens
	Jackson	Madison	Sumter
	Lamar	Marshall	
Arkansas	Clark	Dallas	Sharp
	Clay	Hot Springs	St. Francis
	Cross	Randolph	
Kentucky	Ballard	Hart	Taylor
-	Butler	Livingston	Warren
·	Green	McCracken	
Tennessee	Bedford	Lincoln	Perry
	Decatur	Marshall	Sequatchie
	Hardin	Maury	
Missouri	Gasconade	Osage	Wayne
	Jefferson	Ripley	
	Miller	St. Louis	
Mississippi	Lowndes	Manrae	Noxubee

#### Pecans (nonbearing)

Apply 0.25-0.33 lb. of Orbit 45W per acre in sufficient water to obtain good coverage for control of pecan scab, downy spot, brown leaf spot, liver spot, vein spot, Zonate leaf spot, and fungal leaf scorch. Begin applications at bud break and repeat at 2 to 4-week intervals as needed, not exceeding 4 applications per growing season. For ground applications, the applicator must be in a closed cab during application. Do not graze livestock in treated areas. Observe endangered species restrictions noted in the bearing pecan section.

## Apricots, Cherries, Nectarines, Peaches, and Plums (East of the Focky Mountains)

See Next Section for Directions for Use West of the Rocky Mountains)

CAUTION: Do not apply Orbit 45W to prunes.

Orbit 45W can be applied by either ground or aerial equipment. For aerial applications, a minimum spray volume of 5-10 gals./A is recommended. For ground applications a minimum spray volume of 50 gals./A is recommended.



Brown rot blossom blight and fruit brown rot are most effectively controlled by ground application, using sufficient water volume to provide thorough and uniform coverage. Orbit 45W is most effective when applied before a rainfall and allowed to dry.

Brown Rot Blossom Blight: Apply 0.25 lb. of Orbit 45W per acre at early bloom stage (apricots at red bud, cherries at popcorn, peaches and nectarines at pink bud, Japanese plums at green tip). Make a second application of 0.25 lb./A at 50-75% bloom. If blossoming is prolonged or conditions favorable for disease persist, make a third application of 0.25 lb./A at petal fall.

Fruit Brown Rot: Apply a maximum of 2 pre-harvest sprays of Orbit 45W at 0.25 lb./A during the period beginning 3 weeks before harvest through the day of harvest (0 day PHI).

## Apricots, Cherries, Nectarines, Peaches, Plums and Prunes (West of the Rocky Mountains)

See Previous Section for Directions for Use East of the Rocky Mountains)

Orbit 45W can be applied by either ground or aerial equipment. For aerial applications, a minimum spray volume of 20 gals./A is recommended. For ground applications, a minimum spray volume of 50 gals./A is recommended. Brown rot blossom blight and fruit brown rot are most effectively controlled by ground application, using sufficient water volume to provide thorough and uniform coverage. Orbit 45W is most effective when applied before a rainfall and allowed to dry.

Brown Rot Blossom Blight: Apply 0.25 lb. of Orbit 45W per acre at 5-10% bloom. Make a second application of 0.25 lb./A at 80-100% bloom.

Fruit Brown Rot: Apply a maximum of 2 pre-harvest sprays of Orbit 45W at 0.25 lb./A during the period beginning 10-14 days before harvest through the day of harvest (0 day PHI).

#### **Prunes**

Orbit 45W can be applied by either ground or aerial equipment. For aerial applications, a minimum spray volume of 20 gals./A is recommended. For ground applications, a minimum spray volume of 50 gals./A is recommended. Brown rot blossom blight is most effectively controlled by ground application using sufficient water volume to provide thorough and uniform coverage. Orbit 45W is most effective when applied before a rainfall and allowed to dry.

Brown Rot Blossom Blight: Apply 0.25 lb. of Orbit 45W per acre at early bloom stage (5-10% bloom). Make a second application of 0.25 lb./A at 50-75% bloom. If blossoming is prolonged or conditions favorable for disease persist, make a third application of 0.25 lb./A at petal fall. Do not apply Orbit 45W to prunes for control of fruit brown rot.



#### Storage and Disposal

#### Pesticide Disposal

Do not contaminate water, food, or feed by storage or disposal. Pesticide wastes may be toxic. Improper disposal of unused pesticide, 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**

Do not reuse outer container. Dispose of empty container in a sanitary landfill, by incineration, or, if allowed by state and local authorities, by burning. If burned, keep out of smoke.

For minor spills, leaks, etc., 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 1-800-888-8372, day or night.

#### **Precautionary Statements**

#### Hazards to Humans and Domestic Animals

#### CAUTION

Causes eye irritation. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing.

#### Statement of Practical Treatment

If in eves:

Hold eyelids open and flush eyes with a steady, gentle stream of water for 15 minutes. Get medical attention if

irritation persists.

If swallowed:

Immediately call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious

person.

If on skin:

Wash with plenty of soap and water. Get medical

attention if irritation persists.

#### Note to Physician

If ingested, induce emesis or lavage stomach. Treat symptomatically.

#### Personal Protective Equipment



Applications 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 Control Statements:**

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.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

#### **Environmental Hazards**

This pesticide is toxic to fish. 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 when disposing of equipment wash waters. Refer to product labeling for use restrictions to protect endangered species.

#### Physical or Chemical Hazards

Do not use, pour, spill, or store near heat or open flame.



Orbit<sup>™</sup> 45W and Supracide trademarks of Ciba-Geigy Corporation U.S. Patent No. 4,079,062

Cyprex® trademark of American Cyanamid

Solubor® trademark of United States Borax and Chemical Corporation

Super Tin® trademark of Griffin Ag Products Co., Inc.

Zolone® trademark of Rhône-Poulenc Ag Company

©1995 Ciba-Geigy Corporation

Ciba Crop Protection Ciba-Geigy Corporation Greensboro, North Carolina 27419

**CGA** 



#### Back Page of Booklet

Orbit™ 45W

**FUNGICIDE** 

Total:

For control of certain diseases in pecans, apricots, nectarines, peaches, plums. prunes, and nonbearing citrus

Active Ingredient: Propiconazole: 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-45% triazole..... Inert Ingredients: 55% 100.0%

See directions for use in attached booklet.

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. Refer to supplemental labeling under "Agricultural Use Requirements" in the Directions for Use section for information about this standard.

EPA Reg. No. 100-EPA Est. 100-AL-1

Orbit™ 45W trademark of Ciba-Geigy Corporation U.S. Patent No. 4,079,062 ©1995 Ciba-Geigy Corporation 4 oz. Net Weight

KEEP OUT OF REACH OF CHILDREN.



#### CAUTION

#### **Precautionary Statements**

#### Hazards to Humans and Domestic Animals

Causes eye irritation. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing.

#### Statement of Practical Treatment

If in eyes: Hold eyelids open and flush eyes with a steady, gentle

stream of water for 15 minutes. Get medical attention if

irritation persists.

If swallowed: Immediately call a physician or Poison Control Center.

Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious

person.

If on skin: Wash with plenty of soap and water. Get medical

attention if irritation persists.

#### Note to Physician

If ingested, induce emesis or lavage stomach. Treat symptomatically.

#### **Environmental Hazards**

This pesticide is toxic to fish. 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 when disposing of equipment wash waters. Refer to product labeling for use restrictions to protect endangered species.

#### **Physical or Chemical Hazards**

Do not use, pour, spill, or store near heat or open flame. In the event of a major spill, fire, or other emergency, call 1-800-888-8372 day or night.

#### Chemigation

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

Ciba Crop Protection Ciba-Geigy Corporation Greensboro, North Carolina 27419

**CGA** 

PRODUCT ID.:

April 12, 1995

[GANNONC.LABELO\LBL-O-MS]ORBIT45W - 5/15/95





# R060357

Chemical:

Propiconazole

PC Code:

122101

HED File Code

11500 Petition Files Chemistry

Memo Date:

03/28/2003 12:00:00 AM

File ID:

DPD217199

Accession Number:

412-04-0142

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