

US EPA ARCHIVE DOCUMENT

①

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



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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

06/15/06

**MEMORANDUM:**

**SUBJECT: Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Revised Residue Chemistry Considerations**  
DP Barcode: D329394  
Reregistration Case: 3125

**FROM:** Yan Donovan, Chemist *Yan Donovan*  
Reregistration Branch 4  
Health Effects Division (7509C)

**THROUGH:** Susan V. Hummel, Branch Senior Scientist *Susan V. Hummel*  
Reregistration Branch 4  
Health Effects Division (7509C)

**TO:** Michael Goodis/Christina Scheltema  
Reregistration Branch III  
Special Review & Reregistration Division (7508W)

Attached please find the revised Residue Chemistry Chapter for the Propiconazole RED. This document was originally prepared under contract by Dynamac Corporation (20440 Century Boulevard, Suite 100; Germantown, MD 20874; submitted 02/16/2000). The document has been reviewed by the Health Effects Division (HED) to ensure that it reflects current Office of Pesticide Programs (OPP) policies, and updated to add new information available since 2000. The product Chemistry chapter was reviewed separately.

JUL 07 2006

HED has been requested to reassess tolerances for propiconazole uses on a variety of crops (Use Closure Memos from SRRD, dated on 01/28/02 and 04/22/05). Syngenta (previously Novartis) recently submitted new petitions to the Registration Division (RD) for its product Tilt™ (EPA Registration No. 100-617). The petitions propose tolerances on alfalfa, almond, beans (dry), berry crop group, carrot, cranberry, corn, leafy petiole, mint, onion, soybean, etc.). Section B of the petition (proposed use patterns) includes revised use patterns on existing crops, such as an increase in application rate on barley, wheat, oats, rye, and triticale. The data package for the new uses and revisions to the existing uses has not been reviewed, and are not included in this assessment of the existing uses for Reregistration Eligibility Decision (RED), due to the fact that RD is scheduled to complete its assessment of the revised labels after the RED signature date, July 2006, the data package has yet to be reviewed. Therefore, both the new uses and revised use patterns will be assessed separately from this RED. Syngenta recently combined PP# 4F3007, 4G3075, 5F4498, PP#9F3740, 5F4424, 5F4591, into a single petition, PP#2F6371. IR-4 is still supporting PP# 5E4437 on mushrooms and 8E4931 on mint (now part of 2F6371). Below are list of the pending petitions which are not included in this RED chapter.

|        |   |
|--------|---|
| 4F3007 | Pecans  |
| 4G3075 | Rice, wheat   |
| 9F3740 | Almonds, tree nuts (now part of 2F6371)   |
| 5F4424 | Dried beans, soybeans (now part of 2F6371)  |
| 5F4498 | Alfalfa, sorghum (rotational crops)   |
| 5F4591 | Berry crop group, carrots, onions (green & dry bulb) (now part of 2F6371)   |
| 6E4788 | Celery  |
| 7E4860 | Cranberries   |
| 8E4931 | Mint  |
| 2F6371 | combines PP# 4F3007, 4G3075, 5F4498, 9F3740, 5F4424, and 5F4591.  |
| 2F6371 | strawberries, sugar beets, wheat, corn, rice, sorghum, carrots, onions, berry group, dry beans, soybeans, almonds, tree nuts. |

Propiconazole is among the group of chemicals which generates a common metabolite called 1,2,4-Triazole. A separate document has addressed this issue (see reference, D284131). 1,2,4-Triazole and conjugates will not be further discussed in this chemistry chapter.

## Executive Summary

Propiconazole [1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole] is a systemic broad-spectrum fungicide registered for treatment of disease in/on a variety of crops. Propiconazole end-use products are marketed in the United States under the trade names Tilt®, Alamo®, Banner®, and Orbit®. Recently, propiconazole is also registered for use on a variety of crops under the trade names of Stratego™ Twin-Pak™ and Stratego™, which are end-use products containing a mixture of trifloxystrobin and propiconazole. The amount of active ingredient range from 11.4% to 45%. The propiconazole formulations registered for food/feed uses include emulsifiable concentrate (EC) and flowable concentrate (FIC) formulations. Except for pineapple and sugarcane (seed pieces), all uses are pre-harvest foliar application, ground or air. Pineapple and sugarcane uses are postharvest uses. The application rates range from 0.081 lbs ai/A/season (such as wheat) to 0.90 lbs ai/A/season (grass grown for seed).

Available plant metabolism data (primary and rotated crops) show that plants absorb, metabolize and translocate propiconazole throughout the plant. A major metabolic pathway in plants appears to be hydroxylation (primarily of the beta-carbon) of the n-propyl group on the dioxolane ring of the cis/trans isomers of propiconazole. These metabolites appear to readily form sugar conjugates. The majority of TRR was found in the stalks, such as peanut stalk, wheat forage and straw, grape leaves, and celery stalks. The HED MARC concluded that for plants and animals, residues of propiconazole and all its metabolites containing the 2,4-dichlorophenyl moiety (2,4-DCBA), including conjugates, are of concern and should be included in the dietary (food) risk assessments, propiconazole *per se* should be included in the dietary (water) risk assessments. For tolerance expression, MARC concluded that the current tolerance expression for propiconazole should be amended to include residues of propiconazole *per se* only. For enforcement purpose, the Multiresidue Methods Section 302 (Luke Method; Protocol D) picks up parent propiconazole.

Tolerances are established for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in/on various plant and animal commodities [40 CFR §180.434]. The reassessed tolerances will be expressed as propiconazole *per se*. As a result, in some cases the tolerance levels will be over estimated, due to the fact that the analytical data collection method is a moiety method that detects all residues convertible to 2,4-dichlorobenzoic acid (DCBA), and the field data were reported as propiconazole and all its metabolites containing the 2,4-DCBA, as a result, HED is unable to separate out the parent residue from the metabolites at this time. HED recommends that the registrant analyze parent and metabolites separately in all future field trials, so that more realistic tolerances can be set in the future.

With the exception of sunflower, the reregistration requirements for magnitude of the residue in/on all the raw agricultural commodities (RACs), based on the currently registered use patterns, will be fulfilled pending label revisions and/or tolerance adjustments: barley, rye, rice, wheat, sweet corn; field and pop corn, oat, peanut, pineapple, stone fruits, and aspirated grain fractions. As a result of this review, new tolerances are being proposed on several commodities. The reregistration requirements for magnitude of the residue in the processed commodities have been

fulfilled, except for pineapple (juice). A rice processing study has been submitted and reviewed by the Agency as acceptable. The reregistration requirements for data depicting the magnitude of propiconazole residues of concern in meat, milk, poultry, and eggs have been fulfilled. The maximum theoretical dietary burden to livestock has been recalculated due to added new uses. Tolerances in ruminant commodities were reassessed at the existing level, while tolerances for poultry commodities are not required. Plantback restrictions have been established for propiconazole products registered for use on rotatable crops based on the confined rotational crop studies.

### **Regulatory Recommendations and Residue Chemistry Deficiencies**

- Amend the product labels for the 41.8% EC formulations to indicate the propiconazole concentration in terms of lb ai/gal. In addition, the following products have label restrictions prohibiting the feeding of treated forage and/or hay of cereals and corn to livestock: the 41.8% EC (100-617 and 100-737) and the 45% WP (100-780) formulations. Such restrictions are no longer permitted and must be removed.
- The maximum number of applications for peanuts on Stratego™ label is not very clear. After discussing with RD and the registrant, it is understood that the maximum number of six applications is intended only for the 7.0 oz ai/A rate, while the restricted number of application at 14 oz ai/A is only two. HED recommends that the registrant to amend the Stratego™ label to specify these instructions.
- HED is translating the wheat grain, wheat straw, wheat hay and forage data to barley and rye grain, straw, hay and forage. The product labels for the 41.8% EC (EPA Reg. Nos. 100-617 and 100-737) and the 45% WP (EPA Reg. No. 100-780) formulations must be modified to make the use patterns for barley and rye identical to wheat.
- The use directions for rice on all labels should be amended to specify a 45-day PHI .
- HED recommends increasing the wheat grain tolerance to 0.3 ppm, wheat straw to 15.0 ppm, and to propose new tolerances on wheat hay and forage at 2.0 ppm, and on wheat bran at 1.0 ppm.
- A more appropriate level for the oat hay tolerance at 2.0 ppm should be established using data translated from wheat. The reassessed tolerances for barley grain and rye grain should be 0.3 ppm, for barley and rye straw should be 15.0 ppm. New tolerances for barley hay and rye forage should be established at 2.0 ppm.
- The available rice residue data support the established 3.0 ppm tolerance for propiconazole residues in/on rice straw; however, the data also indicate that the registrant should propose increasing the tolerance for residues in/on rice grain. An appropriate level for residues in/on rice grain would be 0.3 ppm. The registrant needs to propose new tolerances on rice grain at 0.3 ppm, rice bran at 1.0 ppm, and rice hulls at 1.2 ppm.

- HED recommends a 5.0 ppm tolerance on aspirated grain fractions for propiconazole.
- The use on sunflower for seeds can not be considered non-food use, and therefore, no tolerance can be established on sunflower until field trial data are submitted.
- Pineapple processing study is required to determine the potential for concentration in pineapple juice, unless field trials conducted at 5x the maximum application rate indicated that all residues are less than LOQ.
- The registrant has generated virtually all its residue data using a common moiety method that converts the parent and all of the metabolites of concern to 2,4-dichlorobenzoic acid. HED recommends that the registrant analyze parent and metabolites separately in all future field trials, so that more realistic tolerances can be set in the future.

**PROPICONAZOLE**  
**PC Code No. 122101; Case 3125**

**Reregistration Eligibility Decision (RED) Document;**  
**Residue Chemistry Considerations**

**Updated by EPA**  
**June 15, 2006**

**Contract No. 68-D4-0010**

**Submitted to:**  
**U.S. Environmental Protection Agency**  
**Arlington, VA**

**Submitted by:**  
**Dynamac Corporation**  
**The Dynamac Building**  
**2275 Research Boulevard**  
**Rockville, MD 20850-3268**

# PROPICONAZOLE

## REREGISTRATION ELIGIBILITY DECISION

### RESIDUE CHEMISTRY CONSIDERATIONS

PC Code No. 122101; Case 3125

#### TABLE OF CONTENTS

page

---

|  |           |
|--|-----------|
| INTRODUCTION.....  | <u>2</u>  |
| REGULATORY BACKGROUND.....   | <u>2</u>  |
| SUMMARY OF SCIENCE FINDINGS.....   | <u>3</u>  |
| GLN 860.1200: Directions for Use.....  | <u>3</u>  |
| GLN 860.1300: Nature of the Residue - Plants.....                                | <u>17</u> |
| GLN 860.1300: Nature of the Residue - Animals.....                               | <u>18</u> |
| GLN 860.1340: Residue Analytical Methods.....                                    | <u>22</u> |
| GLN 860.1360: Multiresidue Methods.....  | <u>22</u> |
| GLN 860.1380: Storage Stability Data.....  | <u>22</u> |
| GLN 860.1500: Crop Field Trials.....   | <u>23</u> |
| GLN 860.1520: Processed Food/Feed.....   | <u>25</u> |
| GLN 860.1480: Meat, Milk, Poultry, Eggs.....                                     | <u>26</u> |
| GLN 860.1400: Water, Fish, and Irrigated Crops.....                              | <u>28</u> |
| GLN 860.1460: Food Handling.....   | <u>29</u> |
| GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops.....  | <u>29</u> |
| TOLERANCE REASSESSMENT SUMMARY.....  | <u>41</u> |
| Tolerances Established Under 40 CFR §180.434.....                                | <u>41</u> |
| Tolerances To Be Proposed Under 40 CFR §180.434.....                             | <u>42</u> |
| Time-Limited Tolerances Established Under 40 CFR §180.434(b).....                | <u>43</u> |
| Tolerances with Regional Registrations Established Under 40 CFR §180.434(c)..... | <u>43</u> |
| Pending Tolerance Petitions.....   | <u>44</u> |
| CODEX HARMONIZATION.....   | <u>51</u> |
| .....  | <u>52</u> |
| AGENCY MEMORANDA RELEVANT TO REREGISTRATION.....                                 | <u>53</u> |
| MASTER RECORD IDENTIFICATION NUMBERS.....  | <u>67</u> |



# PROPICONAZOLE

## REREGISTRATION ELIGIBILITY DECISION

### RESIDUE CHEMISTRY CONSIDERATIONS

PC Code No. 122101; Case 3125

#### INTRODUCTION

Propiconazole [1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole] is a systemic broad-spectrum fungicide registered for treatment of disease in bananas (including plantains), barley, celery, corn (field, pop, and sweet), grasses grown for seed, mint, oats, peanuts, pineapple, rice and wild rice, rye, stone fruits, sugarcane, and wheat. Propiconazole end-use products are marketed in the United States under the trade names Tilt®, Alamo®, Banner®, and Orbit®. Recently, propiconazole is also registered for use on a variety of crops under the trade names of Stratego™ Twin-Pak™ and Stratego™, which are end-use products containing a mixture of trifloxystrobin and propiconazole. The reregistration of propiconazole is being supported by Syngenta (previously Novartis Crop Protection, Inc.), the basic producer. Uses on mint and mushrooms are being supported by IR-4. The propiconazole formulations registered for food/feed uses include emulsifiable concentrate (EC) and flowable concentrate (FIC) formulations.

#### REGULATORY BACKGROUND

The Propiconazole Phase 4 Review dated 6/25/92 by B. Cropp-Kohlligian, F. Fort, and F. Toghrol and the subsequent Propiconazole Data-Call-In (DCI) Notice dated 10/6/93 summarized the status of available residue chemistry data for the reregistration of propiconazole. The Phase 4 Review identified several data deficiencies including plant and animal metabolism, residue analytical methods, storage stability, and magnitude of the residue in plants. Several studies have been submitted and evaluated in response to the Propiconazole DCI; in addition, uses on a number of crops have been registered since the issuance of the Phase 4 Review. This document presents an overall and up-to-date Residue Chemistry Science Assessment with respect to the reregistration of propiconazole.

Tolerances are established for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in/on various plant and animal commodities [40 CFR §180.434]. The established permanent tolerances for plant and animal commodities [40 CFR §180.434(a)] range from 0.05 ppm (milk) to 40 ppm (grass hay). Time-limited tolerances, due to expire 12/31/05, are established for cranberry, dry bean forage, dry bean hay, and dry beans. In addition, time-limited tolerances, due to expire 06/30/05, are established for aspirated grain fractions (20 ppm), sorghum grain, and stover [40 CFR §180.434(b)]. Time-limited tolerances are being recommended to be established in/on soybeans

at 0.5 ppm, in/on soybean forage at 8 ppm, and in soybean hay at 25 ppm. And in/on blueberry at 1.0 ppm. Tolerances with regional registration are also established for mint at 0.3 ppm and wild rice at 0.5 ppm [40 CFR §180.434(c)]. No tolerances are established for rotational crops [40 CFR §180.434(d)]. This document does not include recently submitted petitions.

## SUMMARY OF SCIENCE FINDINGS

### GLN 860.1200: Directions for Use

According to an OPPIN search, there are 228 active registrations for propiconazole, and a total of six active Syngenta end-use products (see Table A1) containing the active ingredient propiconazole which are registered for use on domestically grown food/feed crops. In addition, there are 36 SLN registrations for use of propiconazole on food/feed crops.

A comprehensive summary of propiconazole food/feed use patterns, based on the product labels registered to Syngenta, is presented in Table A2. A tabular summary of the residue chemistry science assessments for the reregistration of propiconazole is presented in Table B. The status of reregistration requirements for each guideline topic listed in Table B is based on the use patterns registered by the basic producer, Syngenta Crop Protection, Inc.

Table A1. Propiconazole End-Use Products with Food/Feed Uses Registered to Syngenta Crop Protection.

| EPA Reg. No.          | Label Acceptance Date <sup>1</sup> | Formulation <sup>2</sup> | Product Name                  |
|-----------------------|------------------------------------|--------------------------|-------------------------------|
| 100-617 <sup>3</sup>  | 3/99 (10/16/97)                    | 41.8% (3.6 lb/gal) EC    | Tilt® Fungicide               |
| 100-702               | 9/96                               | 41.8% (3.6 lb/gal) EC    | Break™ EC Fungicide           |
| 100-737 <sup>4</sup>  | 11/95                              | 41.8% (3.6 lb/gal) EC    | Tilt® 428C or 428GS Fungicide |
| 100-780               | 8/99                               | 45% WP                   | Tilt® 45W                     |
| 100-781               | 9/96                               | 45% WP                   | Break™ Fungicide              |
| 3125-562 <sup>5</sup> | 6/01                               | 11.4% EC                 | Stratego                      |

<sup>1</sup> Date of the most recently EPA-approved label found by reviewer in the product jacket or Pesticide Product Label System (PPLS).

<sup>2</sup> None of the labels for the 41.8% EC formulations specify concentration in terms of lb ai/gal; the value in parentheses is based on historical data.

<sup>3</sup> Including SLN Nos. AL980003, AR980001, AR990002, DE980002, FL880016, GA980003, IA990002, ID950012, ID980004, IL980001, IL990006, IL990008, IN980003, IN990003, KS980002, KS990008, KY980002, MI980001, MI990003, MN980003, MN990014, MO980003, MS980004, NE990006, ND980002, OH980002, TN980004, TX980001, VA980003, WA950033, WA980018, and WI990015.

<sup>4</sup> Also packaged as Tilt® Gel in water-soluble packets. Including SLN Nos. OR960013 and OR960007.

<sup>5</sup> Including ND-010009, MN-010007, OH-02001, WA-030015, KS-010002, VA-100002, TX010009, AR-010005, GA-010002, IN-020001, AL-000003

In addition to the products listed above, SLN products HI910009 and PR930001, registered for use on bananas, are formulated from an unregistered source product, Tilt® 250 EC Fungicide.

Included in the product jackets for these products are Confidential Statements of Formula for the source product. We note that information reflecting the active ingredient content in terms of lb ai/gal is not presented on either label.

The above labels specify a re-entry interval (REI) of 24 hours, except for the 45% WP (EPA Reg. Nos. 100-780 and 100-781) formulations which specify an REI of 12 hours.

The 41.8% EC (EPA Reg. Nos. 100-617 and 100-737) and the 45% WP (EPA Reg. No. 100-780) are the only products currently registered for use on rotatable crops. Labels for these formulations specify that soybeans may be planted as a double crop following a cereal crop which has been treated with the product, but soybean hay, forage, and fodder may not be used as any component of animal feed or bedding. The labels specify that any food/feed crops not listed on the label should not be planted within 105 days of treatment.

Syngenta is required to amend the product labels for the 41.8% EC formulations to indicate the propiconazole concentration in terms of lb ai/gal. In addition, the following products have label restrictions prohibiting the feeding of treated forage and/or hay of cereals and corn to livestock: the 41.8% EC (100-617 and 100-737) and the 45% WP (100-780) formulations. Such restrictions are no longer permitted and must be removed. Label amendments are also required to incorporate the parameters of use patterns reflected in the submitted field trials; details of the crop-specific label amendments are presented in the respective endnotes for each crop (GLN 860.1500: Crop Field Trials) in Table B.

Propiconazole can be mixed with other fungicides. Formulations which contain both propiconazole and trifloxystrobin (e.g. Stratego™ Twin-Pak™ and Stratego™ Fungicide, EPA Reg. Nos. 264-779 ) have been registered for uses on corn, peanuts, pecans, rice, and wheat. The use patterns are shown in Table A2. These uses were registered based on reviews of trifloxystrobin. Residue data for trifloxystrobin were reviewed in PP#9F5070 (DP Barcodes D254213, D254217, D254218, and D254221, 4/6/00, L. Cheng). After comparing the use rates of Stratego™ Twin-Pak™ and Stratego™ on corn, peanuts, pecans and rice to the use rates which current tolerances on corn, peanuts, pecans and rice are based on, **HED concludes that the Stratego™ use rates on these crops are below the use rates which tolerances are based on, except for wheat.** Residue data for propiconazole on wheat have been recently reviewed by Y. Donovan (HED memo of 02/02/05, Y. Donovan, D271790). Since there are adequate field trial data to support Section 3 registration of propiconazole uses on wheat at the rate of 0.08 - 0.11 lbs ai/A/application, maximum 2 applications, and 35 day PHI (HED memo of 02/02/05, Y. Donovan, D271790), **HED can support the label use direction changes provided that the existing tolerances on wheat RAC are raised.** These new reassessed tolerances will cover all 24C uses on wheat as well. HED recommends canceling all 24C uses while revising the Section 3 label to include these 24C uses.

HED notice that **the maximum number of applications for peanuts on Stratego™ label is not very clear. After discussing with RD and the registrant, it is understood that the maximum number of six applications is intended only for the 7.0 oz ai/A rate, where the**

**restricted number of application at 14 oz ai/A is only two. HED recommends that the registrant to amend the Stratego™ label to specify these instructions.**

**HED is translating the wheat grain, wheat straw, wheat hay and forage data to barley and rye grain, straw, hay and forage. The product labels for the 41.8% EC (EPA Reg. Nos. 100-617 and 100-737) and the 45% WP (EPA Reg. No. 100-780) formulations must be modified to make the use patterns for barley and rye identical to wheat.**

For the purpose of generating this Residue Chemistry Science Chapter, HED examined the registered food/feed use patterns of the basic producer and reevaluated the available residue chemistry database for adequacy in supporting these use patterns. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer labels.

The use directions for rice on all labels should be amended to specify a 45-day PHI (HED memo of 02/23/05, T. Morton, D240856).

Table A2 Food/Feed Use Patterns on EP Labels Subject to Reregistration for Propiconazole (Case 3125)

| Site   | Application Type<br>Application Equipment | Formulation<br>[EPA Reg.<br>No.]   | Maximum Single<br>Application Rate<br>(lb ai/A) | Maximum<br>Number of<br>Applications<br>Per Season | Maximum<br>Seasonal<br>Rate<br>(lb ai/A) | Preharvest<br>interval<br>(days) | Use Directions and Limitations   |
|--|---|--|---|--|--|----------------------------------|--|
| <b>Bananas and Plantains</b>                                 |   |  |   |  |  |                                  |  |
| Preharvest foliar<br>Ground                                  |   | 41.8% EC<br>[PR40005]  | 0.086   | 8  | NS                                       | NS                               | Apply before disease symptoms appear at the onset of the rainy season. Apply 3 fl. oz. per acre. Apply no more than 2 consecutive applications on a 21-25 day. Apply up to 8 applications. Applications should be made using an orchard oil and an emulsifier. Applications within 100 yards of non-bagged bananas or directly to non-bagged bananas are prohibited. |
| <b>celery</b>  |   |  |   |  |  |                                  |  |
| Preharvest foliar<br>or aerial                               | Ground                                    | 41.8% EC<br>(3.6 lb ai/gal)<br>[100-617]<br>[100-737]<br>45% WP<br>[100-780] | 0.1125  | 4  | 0.45                                     | 14                               | Apply multiple treatments on a 7-day schedule. May be tank-mixed with a spreader-sticker. Applications should be made using a minimum of 10 (ground) or 5 (aerial) gal of water/A.   |
| Foliar   |   | Quilt<br>[100-1178]  | 0.1138  | NS   | 0.45                                     | 7                                | Aerial, ground, and sprinkler irrigation   |
| <b>Cereals (Including Wheat, Barley, Triticale, and Rye)</b> |   |  |   |  |  |                                  |  |

|                                       |  |        |    |       |    |   |
|---------------------------------------|--|--------|----|-------|----|---|
| Preharvest foliar<br>Ground or aerial | 41.8% EC<br>(3.6 lb ai/gal)<br>[100-617]<br>[100-737]<br>45% WP<br>[100-780] | 0.1125 | NS | 0.167 | NS | Highest yields when applied to the emerging flag leaf; do not apply after the ligule of the flag leaf emerges (Feekes growth stage 9) on barley, rye, oats and triticale. For wheat only. Tilt can be applied until full head emergence (Feekes growth stage 10.5). Grazing or feeding livestock treated forage or cutting the green crop for hay or silage is prohibited; following harvest, straw may be used for bedding or feed. Applications should be made in a minimum of 10 (ground) or 5 (aerial) gal. of water/A. |
|---------------------------------------|--|--------|----|-------|----|---|

|   |  |        |    |      |                       |  |
|---|--|--------|----|------|-----------------------|--|
| Corn (Including Field Corn, Field Corn Grown for Seed, Sweet Corn, and Popcorn) |  |        |    |      |                       |  |
| Preharvest foliar<br>Ground or aerial   | 41.8% EC<br>(3.6 lb ai/gal)<br>[100-617]<br>[100-737]<br>45% WP<br>[100-780] | 0.1125 | NS | 0.45 | 14<br>(sweet<br>corn) | Treatment should be started when disease appears and repeated on a 7- to 14-day schedule. Application to field corn and field corn grown for seed after silking is prohibited. Harvest of forage from field corn, field corn grown for seed, and popcorn within 30 days of application and of sweet corn forage within 14 days of application is prohibited. Applications should be made in a minimum of 10 (ground) or 5 (aerial) gal of water/A. |

|  |   |        |    |      |   |   |
|--|---|--------|----|------|---|---|
| Preharvest foliar<br>Ground or aerial<br>(post silk)               | 41.8% EC<br>(3.6 lb ai/gal)<br>[LA990002]<br>[KS030002]<br>[MN990014]<br>[NE990006]<br>[IL040004] | 0.1125 | NS | 0.45 | 14<br>(sweet<br>corn)<br><br>30<br>(seed,<br>field, and<br>popcorn) | Treatment should be started when disease<br>appears and repeated on a 7- to 14-day<br>schedule. Feeding livestock treated forage<br>or fodder and harvest of sweet corn forage<br>within 14 days of application are prohibited.<br>Applications should be made in a minimum<br>of 10 (ground) or 5 (aerial) gal of water/A. |
| Between V4 to after silking  | Stratego <sup>R</sup><br>[264-779]  | 0.1125 | NS | 0.29 | 30 (forage<br>)<br>before<br>silking                                |   |
| Corn Grown for Seed (See Also "Corn")                              |   |        |    |      |   |   |
| Preharvest foliar<br>Ground or aerial, and<br>sprinkler irrigation | 41.8% EC<br>(3.6 lb ai/gal)<br>[IN990003]   | 0.1125 | NS | 0.45 | 30  | Treatment should be started when disease<br>appears and repeated on a 7- to 14-day<br>schedule. Making more than two<br>applications after 50% silk and feeding<br>livestock treated forage or fodder are<br>prohibited. Applications should be made in<br>a minimum of 10 (ground) or 5 (aerial) gal<br>of water/A.        |
| Preharvest foliar?   | Tilt  | 0.1125 | NS | 0.45 | 7   | When disease first appears. Aerial, ground,<br>and sprinkler irrigation.  |
| Grasses Grown for Seed   |   |        |    |      |   |   |

|  |   |                                 |    |        |    |   |
|--|---|---------------------------------|----|--------|----|---|
| Preharvest foliar<br>Ground or aerial  | 41.8% EC<br>(3.6 lb ai/gal)<br>[100-617]<br>[100-737]<br>45% WP<br>[100-780]                                    | 0.225<br>(0.1125-<br>bluegrass) | NS | 0.9    | 20 | Use is limited to ID, MN, NE, OR, and WA.<br>Apply multiple treatments on a 14- to 21-<br>day schedule. The feeding of treated hay is<br>prohibited within 20 days of the last<br>application, and the grazing of treated areas<br>is prohibited within 140 days. Applications<br>should be made in a minimum of 20<br>(ground) or 10 (aerial) gal of water/A.                              |
| Preharvest foliar<br>Ground or aerial  | 41.8% EC<br>(3.6 lb ai/gal)<br>[ID950012]<br>[OR050012]<br>[WA950033]<br>[IN990003]<br>[NV010004]<br>[MT030004] | 0.225                           | 2  | 0.45   | 20 | Apply just prior to anthesis. Make second<br>application 7-10 days later. Should be tank<br>mixed with an appropriate surfactant. The<br>feeding of treated hay is prohibited within<br>20 days of the last application, and the<br>grazing of treated areas is prohibited within<br>140 days. Applications should be made in a<br>minimum of 20 (ground) or 10 (aerial) gal<br>of water/A. |
| <b>Mint</b>                            |   |                                 |    |        |    |   |
| Preharvest foliar<br>Ground            | 41.8% EC<br>(3.6 lb ai/gal)<br>[OR050011]   | 0.1125                          | NS | 0.225  | 90 | Apply when plants are 2-4" high. Make<br>second application 10-14 days later.<br>Applications should be made in a minimum<br>of 20 gal of water/A.  |
| <b>Nectarines (See "Stone fruits")</b> |   |                                 |    |        |    |   |
| <b>Oats</b>                            |   |                                 |    |        |    |   |
| Preharvest foliar<br>Ground or aerial  | 41.8% EC<br>(3.6 lb ai/gal)<br>[100-617]  | 0.1125                          | NS | 0.1125 | 40 | Highest yields when applied to the emerging<br>flag leaf; do not apply after the ligule of the<br>flag leaf emerges (Feekes growth stage 8).<br>Applications should be made in a minimum<br>of 10 (ground) or 5 (aerial) gal of water/A.  |
| <b>Peaches (See "Stone fruits")</b>    |   |                                 |    |        |    |   |



|  |  |        |    |      |    |   |
|--|--|--------|----|------|----|---|
| Peanuts  |  |        |    |      |    |   |
| Preharvest foliar<br>Chemigation or directed<br>ground | 41.8% EC<br>(3.6 lb ai/gal)<br>[100-617]<br><br>45% WP<br>[100-780]              | 0.225  | 2  | 0.45 | 21 | Apply to crown and pegging zones. Begin applications 45 or 60 days after planting or at the first appearance of disease; make second application 14 days or 3-4 weeks later. Grazing livestock or feeding hay or threshings to livestock are prohibited. Applications should be made in a minimum of 20 (ground) gal of water/A.                                |
| Preharvest foliar<br>Ground or aerial                  | 41.8% EC<br>(3.6 lb ai/gal)<br>[100-617]<br>[100-737]<br><br>45% WP<br>[100-780] | 0.1125 | NS | 0.45 | 14 | Begin applications 35-40 days after planting and repeat on a 10- to 14-day schedule. Grazing of livestock or feeding green vines to livestock is prohibited. Applications should be made in a minimum of 10-20 (ground) or 5 (aerial) gal of water/A.   |
| Preharvest foliar<br>Ground or aerial                  | Stratego <sup>R</sup><br>[264-779]   | 0.1134 | 6  | 0.68 | 14 |   |
| Pecans   |  |        |    |      |    |   |
| Preharvest foliar<br>Ground or aerial                  | Stratego <sup>R</sup><br>[264-779]<br>Tilt [100-617]<br>Quilt [100-1192]         | 0.081  | NS | 0.24 | 30 | Apply on a 14-day schedule during bud break, prepollination sprays, or during nut formation and cover sprays. Use higher rates when disease pressure is heavier. Do not apply after shuck split. Grazing of livestock in treated areas or cutting treated cover crops for feed is prohibited. Application should be made using a minimum of 20 gal. of water/A. |
| Pineapple  |  |        |    |      |    |   |

|  |   |                               |  |      |     |   |
|--|---|-------------------------------|--|------|-----|---|
| Postharvest<br>Cold or hot water dip<br>(Seed treatment) | 45% WP<br>[100-780]                                   | 0.1125 lb ai/500<br>gal water | N/A  | N/A  | N/A | Use is limited to HI; immerse or soak crowns for control of disease. Feeding livestock treated crowns or grazing livestock on growing plants or tops before fruit is harvested is prohibited.   |
| Plantains (See "Bananas and Plantains")                  |   |                               |  |      |     |   |
| Plums (See "Stone fruits")                               |   |                               |  |      |     |   |
| Rice   |   |                               |  |      |     |   |
| Preharvest foliar<br>Aerial                              | 41.8% EC<br>(3.6 lb ai/gal)<br>[100-617]<br>[100-737] | 0.2813                        | 2@ 0.1688 lb<br>ai/A<br>or<br>1@ 0.2813 lb<br>ai/A | NS   | NS  | If 5% of tillers are infected, two applications should be made, the first application at first internode elongation (up to 2-inch panicle) and the second at swollen boot (10-14 days following the first but before the boot splits and head emerges). If greater than 10% of the tillers are infected, the higher single application rate should be made at first internode elongation. Use is prohibited in CA and areas of the following AR counties: Mississippi, Poinsett, Cross, St. Francis, and Lee. The following are prohibited: use in rice fields where commercial farming of crayfish is practiced; draining water from treated rice fields into ponds used for commercial catfish farming; application to stubble or ratoon crop rice; and use of water drained from treated fields to irrigate other crops. Applications should be made in a minimum of 5 gal of water/A. |
|  | Stratego <sup>R</sup><br>[264-779]                    | 0.16                          | NS   | 0.31 | 35  |   |

| Rye (See "Cereals")  |  |                            |      |                    |     |   |
|--|--|----------------------------|------|--------------------|-----|---|
| Stone Fruits (Sweet or tart Cherry, Apricots, Nectarines, Peaches, and Plums or Prune) |  |                            |      |                    |     |   |
| Preharvest foliar (ground or aerial)   | 41.8% EC (3.6 lb ai/gal) [100-702]<br><br>45% WP [100-781] | 0.1125                     | 2    | Not Specified (NS) | 0   | Use is restricted to West of the Rocky Mountains for EPA reg# 100-781. Two applications may be made during the period beginning 10-14 days before harvest through the day of harvest; or the first application may be made at early bloom stage. A second application may be made as needed through petal fall. Applications should be made using a minimum of 50 (ground) or 20 (aerial) gal of water/A. |
| Sugarcane  |  |                            |      |                    |     |   |
| Postharvest Cold or hot water dip  | 45% WP [100-780]   | 0.1125 lb ai/500 gal water | N/A  | N/A                | N/A | Use of the federal label is limited to HI. Immerse or soak cut seed pieces for control of disease. Use of treated seed pieces for food or feed is prohibited.   |
| Sunflower (Breeder's seed)   |  |                            |      |                    |     |   |
| Foliar spray   | Tilt [IL050002] [TX000006]                                 | 0.1125                     | 0.45 | N/A                | N/A | Foliar spray. When disease first appears. 7-day retreatment interval.   |
| Wheat (See also "Cereals")   |  |                            |      |                    |     |   |

|                                       |   |        |    |        |    |  |
|---------------------------------------|---|--------|----|--------|----|--|
| Preharvest foliar<br>Ground or aerial | 41.8% EC<br>(3.6 lb ai/gal)<br>[AR990002]<br>[GA980003]<br>[ID980004]<br>[IN980003]<br>[MI980001]<br>[MN980003]<br>[MS980004]<br>[VA980003]<br>[WA980018] | 0.1125 | NS | 0.1125 | 40 | Highest yields when applied to the emerging flag leaf; do not apply after full head emergence (Feekes growth stage 10.5). Grazing or feeding livestock treated forage is prohibited; following harvest, straw may be used for bedding or feed. Applications should be made in a minimum of 15 (ground) or 5 (aerial) gal of water/A. |
| Tilt                                  | [100-617]<br>[AR030008]<br>[MO980003]<br>[KS030001]<br>[OK010002]<br>[TN030002]<br>[OH040002]<br>[DE030003]<br>[KY050002]                                 |        |    |        |    |  |

| Wheat (cont'd.)  |   |        |    |        |  |  |
|--|---|--------|----|--------|--|--|
| Preharvest foliar<br>(Ground or aerial)                                  | Quilt [100-1178]<br>[AR050001]<br>[W/A040026]<br>[MS040011]<br>[AL040002]<br>[OK040001]<br>[GA040003]<br>[TN040004]<br>[MO040006]<br>[TX040022]<br>[ID050007] | 0.1125 | NS | 0.1125 | 40   | Highest yields when applied to the emerging (flag leaf); do not apply after late boot, sheath split stage (Feekes growth stage 10.0). Grazing or feeding livestock treated forage or cutting the green crop for hay or silage is prohibited; following harvest, straw may be used for bedding or feed. Applications should be made in a minimum of 15 (ground) or 5 (aerial) gal of water/A. |
| Trifloxystrobin registration<br>(coactive ingredient with propiconazole) | Stratego <sup>R</sup><br>[264-779]  | 0.081  | 2  | 0.162  | 35 (grain)<br>30<br>(forage)<br>45 (hay)<br>35 (straw) |  |

|  |   |       |   |       |  |   |
|--|---|-------|---|-------|--|---|
| Preharvest foliar<br>Ground or aerial (Section<br>24C) | Stratego<br>[3125-562]<br>ND-010009<br>MN-010007<br>OH-02001<br>WA-030015<br>KS-010002<br>VA-100002<br>TX010009<br>AR-010005<br>GA-010002<br>IN-020001<br>AL-000003 | 0.081 | 1   | 0.081 | 35 (grain)<br>30<br>(forage)<br>45 (hay)<br>35 (straw) |   |
|  | Wild Rice   |       |   |       |  |   |
| Preharvest foliar<br>Aerial                            | 41.8% EC<br>(3.6 lb ai/gal)<br>[100-617]<br>[100-737]<br>45% WP<br>[100-780]  | 0.225 | 2@ 0.1688 lb<br>ai/A<br>or<br>1@ 0.225 lb<br>ai/A | NS    | NS   | Use is limited to MN. Applications should be made at booting and heading, or a single application may be made at the higher rate at booting. Use of water drained from treated rice fields to irrigate other crops is prohibited. Applications should be made in a minimum of 5 gal of water/A. |

**Note:**

<sup>1</sup> The 41.8% EC formulations have been determined to contain 3.6 lb ai/gal of propiconazole based on historical data.

<sup>2</sup> Product labels specify a re-entry interval (REI) of 24 hours, except for the 45% WP (EPA Reg. Nos. 100-780 and 100-781) formulations which specify an REI of 12 hours. Propiconazole may be tank mixed with other fungicides; however labels for EPA Reg. Nos. 100-702 and 100-781 state that tank mixing with Cyprex® may cause crop injury.

<sup>3</sup> The 41.8% EC (EPA Reg. Nos. 100-617 and 100-737) and the 45% WP (EPA Reg. No. 100-780) are the only products currently registered for use on rotatable crops. The labels for these formulations state that soybeans may be planted as a double crop following a cereal crop which has been treated with the product, but soybean hay, forage, and fodder may not be used as any component of animal feed or bedding. The labels specify that any food/feed crops not listed on the label should not be planted within 105 days of treatment.

## GLN 860.1300: Nature of the Residue - Plants

Previous metabolism studies on peanuts, wheat, grapes, and rice demonstrated that similar metabolites were present in both the primary and rotational crops; however, quantitative information was not provided to calculate the percentage of uncharacterized residues. The Propiconazole Phase 4 Review required that additional metabolism studies be conducted on wheat, bananas, and pecans; however, on further consideration of the original data for peanuts, wheat, grapes, and rice, the Agency concluded (DP Barcode D198815, 4/26/94, F. Fort) that an additional celery metabolism study would be adequate to determine the metabolic pathway in plants. Because only a small amount of propiconazole was metabolized in celery, the registrant submitted an additional wheat metabolism study to further delineate the nature of the residue of propiconazole in plants. The reregistration requirements for plant metabolism are fulfilled based on acceptable metabolism studies reflecting foliar treatment of propiconazole on celery and wheat.

Available plant metabolism data (primary and rotated crops) show that plants absorb, metabolize and translocate propiconazole throughout the plant. A major metabolic pathway in plants appears to be hydroxylation (primarily of the beta-carbon) of the n-propyl group on the dioxolane ring of the cis/trans isomers of propiconazole. These metabolites appear to readily form sugar conjugates. The majority of TRR was found in the stalks, such as peanut stalk, wheat forage and straw, grape leaves, and celery stalks. A possible alternative pathway involves reductive deketalization of the dioxolane ring and sugar conjugation of the resulting metabolite. The alkyl bridge between the phenyl and triazole rings is metabolized and free triazole, as 1H-1,2,4-triazole, is released. The free triazole is readily conjugated with the amino acid, serine/alanine, forming triazole aniline which is further metabolized to triazole acetic acid possibly through the intermediate formation of triazole lactic acid. As mentioned earlier, the triazole issue will be addressed separately. The HED MARC concluded that residues of propiconazole and all its metabolites containing the 2,4-dichlorophenyl moiety (2,4-DCBA), including conjugates, are of concern and should be included in the dietary (food) risk assessments for propiconazole, due to the fact that the registrant has generated virtually all its residue data using a method that converts the parent and all of the metabolites of concern to a common moiety, 2,4-DCBA. MARC was in agreement that the metabolites that have the basic structure of propiconazole (e.g. alkanol, beta-hydroxy and conjugates) would likely exhibit some of the same toxicity as the parent compound, but would not likely be more toxic than the parent compound. For the purposes of risk assessment HED would assume these metabolites would have equal toxicity as the parent compound. (The conjugates are included because of the possibility they could be hydrolyzed in the stomach to the unconjugated form). Only residues of propiconazole *per se* should be included in the dietary (water) risk assessments (HED memo of 04/04/02, B. Cropp-Kohlligian, D279299). **For tolerance expression, MARC concluded that the current tolerance expression for propiconazole should be amended to include residues of propiconazole *per se* only** for the following reasons: 1) there are a number of pesticides that have 2,4-DCBA as common metabolite. An enforcement agency may not be able to determine if residues are due to misuse of propiconazole or the proper use of other pesticides containing 2,4-

DCBA; 2) the FDA multiresidue method detects parent only; 3) to harmonize with the Codex MRI which includes parent only. In rotational crops, the most blatant misuse of propiconazole would be application to unlabeled crops. If rotational crop tolerances are expressed in terms of parent, then any residues of propiconazole on rotated crops would likely be due to direct application to these crops.

#### GLN 860.1300: Nature of the Residue - Animals

The reregistration requirements for animal metabolism are fulfilled based on acceptable goat and poultry metabolism studies. These studies were initially reviewed in conjunction with the following tolerance petitions: PP#4F3007, PP#1F3974, and PP#8F3674 (poultry), and were summarized in the Propiconazole Phase 4 Review. For one ruminant study, three lactating goats received [phenyl-<sup>14</sup>C]propiconazole at 67-92 ppm for four consecutive days in feed. The dosing levels correspond to 2.5-3.3x the maximum theoretical dietary burden to dairy cattle (see "Meat, Milk, Poultry, Eggs"). The parent (1.7-13.9% TRR), and metabolites CGA-118244 (9.4-34% TRR), and CGA-91305 (15.9-31.3% TRR) were identified in the organic extract of tissues; metabolites CGA-118244 (23% TRR) and CGA-91305 (24% TRR) were also identified in milk.

In addition, an unknown was quantitated (6.2-31.1% TRR) in goat tissues. In a second ruminant study, a single goat was fed [triazole-<sup>14</sup>C]propiconazole at 4.53 ppm (0.2x) for 10 days. The TRR in tissues and milk ranged from 0.01 ppm in muscle to 0.96 ppm in liver; TRR in milk were 0.015 ppm. On further analysis of subsamples of milk and liver, sulfate and glucuronide conjugates were found in milk, and conjugation with amino acids was suggested in liver; propiconazole *per se* was not identified in milk or liver.

For the poultry study, four laying hens received [phenyl-<sup>14</sup>C]propiconazole at 67 ppm for eight consecutive days in feed. The dosing level corresponds to 560x the maximum theoretical dietary burden to poultry. The parent (1.4-39.0% TRR), and metabolites CGA-118244 (1.5-50.0% TRR), and CGA-91305 (17.7-78.6% TRR) were identified in the organic extracts of tissues and eggs.

MARC concluded that parent and all metabolites convertible to 2,4-DCBA are residues of concern for risk assessment, since the analytical method is a moiety method that detects all residues convertible to 2,4-dichlorobenzoic acid (DCBA). **For tolerance expression, MARC concluded that the current tolerance expression for propiconazole should be amended to include residues of propiconazole *per se* only** for the same reasons as described above in plants. In addition, if only propiconazole *per se* is regulated, there will not likely be a need for meat and milk tolerances; only meat by-products would likely require a tolerance. Should there be detectable residues of the parent compound in meat and milk, it would most certainly be as a result of a misuse.

The chemical names and structures of propiconazole and its metabolites in animal commodities are depicted in Figure A.

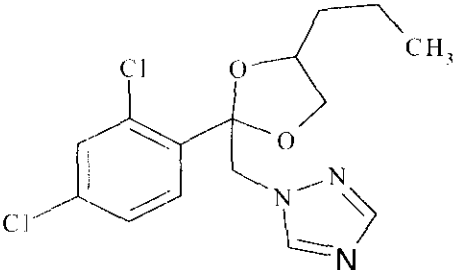
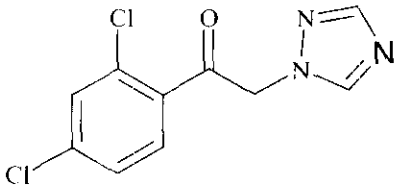
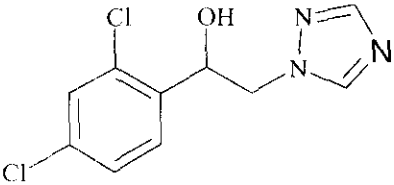
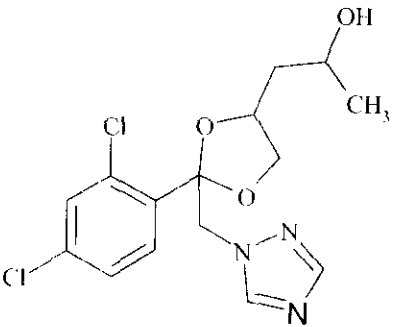


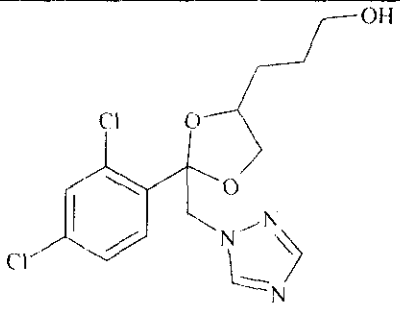
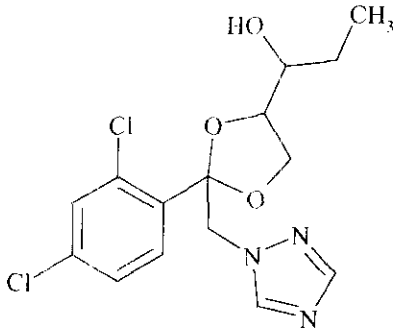
## HED MARC Meeting Summary Chart

| Chemical: Propiconazole            |   |                          |
|------------------------------------|---|--------------------------|
| Date: 18-Dec-2001, and 08-Jan-2002 |   |                          |
| Residues of Concern                |   |                          |
| Matrix                             | For Risk Assessment*                                | For Tolerance Expression |
| Plants                             | Parent plus all metabolites convertible to 2,4-DCBA | Parent only              |
| Rotational crop                    | Parent plus all metabolites convertible to 2,4-DCBA | Parent only              |
| Livestock:                         | Parent plus all metabolites convertible to 2,4-DCBA | Parent only              |
| Water                              | Parent only   | N/A                      |

\* Triazole is also residue of concern, but it will be addressed separately.

Figure A. Chemical Names/Codes and Structures of Propiconazole Residues of Concern in Plant and Animal Commodities.

| Common Name/Code<br>Chemical Name  | Chemical Structure  | Matrices   |
|--|---|--|
| <b>Propiconazole;<br/>CGA-64250</b><br><br>1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole |   | Celery<br>Wheat forage, straw, chaff and grain<br>Goat liver, kidney, muscle, and fat<br>Poultry eggs, liver, kidney, muscle, and fat        |
| <b>CGA-91304</b>   |   | Celery<br>Wheat forage, straw, chaff, and grain  |
| <b>CGA-91305</b>   |  | Celery<br>Wheat forage, straw and chaff<br>Goat milk, liver, kidney, muscle, and fat<br>Poultry eggs, liver, kidney, muscle, and fat         |
| <b>CGA-118244</b>  |  | Celery<br>Wheat forage, straw, chaff, and grain<br>Goat milk, liver, kidney, muscle, and fat<br>Poultry eggs, liver, kidney, muscle, and fat |
| <b>CGA-118245</b>  |   | Wheat forage, straw, chaff, and grain  |

| Common Name/Code<br>Chemical Name | Chemical Structure   | Matrices               |
|-----------------------------------|--|------------------------|
|                                   |   |                        |
| CGA-136735                        |  | Wheat straw            |
| GB-XLIII-42-1                     |  | Wheat forage and straw |

#### GLN 860.1340: Residue Analytical Methods

*Plant commodities:* Residue methods AG-454, AG-454B and AG-626 (both are modification of method AG-454) were used to determination residues of propiconazole and its metabolites on samples of raw agricultural and processed commodities from field trials and processing studies. The methods use a single moiety detection in which residues are converted to 2,4-DCBA, determined as the 2,4-DCBA methyl ester, and reported as propiconazole equivalents using a conversion factor of 1.79. The reported method LOQ is 0.05 ppm. Concurrent method recoveries were acceptable.

In the Phase 4 Review, the registrant was required to conduct enforcement method validation for Method AG-454A using bananas. These data are no longer needed.

**For enforcement purposes, residue method AG-354 is available for the determination of propiconazole *per se* in/on plant commodities using gas chromatography and flame ionization detection, and the reported LOQ is 0.05 ppm. The Multiresidue Methods Section 302 (Luke Method; Protocol D) picks up parent propiconazole as well.**

*Animal commodities:* Residue methods AG-517 and AG-629 (a modification of method AG-517) were used for determination of propiconazole and its metabolites in animal commodities. The methods use a single moiety detection in which residues are converted to 2,4-DCBA, determined as the 2,4-DCBA methyl ester, and reported as propiconazole equivalents using a conversion factor of 1.79. The method LOQ is 0.05 ppm for residues in meat, poultry, and eggs and 0.02 ppm for residues in milk. Samples from the ruminant and poultry feeding studies were analyzed using method AG-359 (an early version of method AG-517) and method AG-517. **For enforcement purpose, the Multiresidue Methods Section 302 (Luke Method; Protocol D) picks up parent propiconazole.**

#### GLN 860.1360: Multiresidue Methods

The reregistration requirements for multiresidue method testing for residues of propiconazole and its metabolites are satisfied. The 10/99 FDA PESTDATA database (PAM Volume I, Appendix I) indicates that propiconazole is completely recovered (>80%) using Multiresidue Methods Section 302 (Luke Method; Protocol D). The recovery of propiconazole metabolites CGA-91305, CGA-118244, and 1,2,4-triazole is variable using Section 302. Propiconazole and metabolites CGA-91305, CGA-118244, and 1,2,4-triazole are not recovered using Multiresidue Methods Sections 303 (Mills, Onley, and Gaither; Protocol E, nonfatty) and 304 (Mills, fatty food).

#### GLN 860.1380: Storage Stability Data

The reregistration requirements for storage stability data are satisfied. Adequate storage stability data for plant and animal commodities have been submitted and evaluated.

*Plant commodities:* Several storage stability studies have been submitted and evaluated. These studies showed that fortified residues of propiconazole and its metabolites determined as 2,4-DCBA are stable under frozen storage conditions in/on: (i) peaches, bananas, corn meal, wheat grain, celery, corn oil, and peanut nutmeat, hay, and hulls for up to 36 months at -20°C; (ii) carrots for up to 10 months at -20 °C; and (iii) soybeans and soybean fodder for up to 4 and 6 months, respectively, at -15 °C. Weathered residues of propiconazole and metabolites were found to be stable under frozen storage conditions in/on: (i) grass forage, straw, and seed for up to 39 months at -20 °C; (ii) wild rice and stone fruits for up to 25 months frozen (temperature unspecified); (iii) peanut shells and fodder for 25 months at -15 °C; and (iv) extracts of silage-stage corn forage and soybeans for 3 and 8 months, respectively, at 4 C. These storage stability data are adequate to validate the storage intervals and conditions of samples collected from field and processing studies.

*Animal commodities:* In response to the Propiconazole Phase 4 Review, data were submitted showing no degradation of residues in propiconazole in animal commodities following storage for four years. Data submitted in support of the goat and hen metabolism studies demonstrated that residues of propiconazole were stable in the following frozen matrices: goat urine for ~7 months, goat tissues for up to 11 months, and extracts of egg whites, yolks, and poultry muscle for up to 6 months. These data are adequate to validate the storage intervals of animal commodity samples collected from the feeding studies.

#### GLN 860.1500: Crop Field Trials

The reregistration requirements for magnitude of the residue in/on the following raw agricultural commodities (RACs), based on the currently registered use patterns, will be fulfilled pending label revisions and/or tolerance adjustments: barley, rye, rice, wheat, sweet corn; field and pop corn, oat, peanut, pineapple, stone fruits, and aspirated grain fractions. We note that the submitted field trial data for sugarcane indicate that treatment of sugarcane seed pieces according to the currently registered use pattern can be considered a non-food use.

Overall, adequate field trial data depicting propiconazole residues of concern following treatments according to the maximum registered use patterns of the representative formulations that are being supported have been submitted for the RACs listed above, or have been translated where appropriate. The available crop field trials reflecting use of registered formulations at 1x the maximum label rate showed finite residues of propiconazole and its metabolites determined as 2,4-DCBA and expressed as parent in/on the RACs of all crops for which registration exists except for mushrooms, pecans, and sugarcane; residues concentrated 10.4x in wheat aspirated grain fractions. Details of any required label amendments are presented in the endnotes for GLN 860.1200 (Directions for Use) and respective crop sections for GLN 860.1500 (Crop Field Trials) of Table B. Refer to “Tolerance Reassessment Summary” section for recommendations with respect to established tolerance levels.

Residue data for uses of Stratego™ Twin-Pak™ and Stratego™ Fungicide formulations on wheat have been submitted and reviewed (HED memo of 02/02/05, Y. Donovan, D271790). These data support Section 3 registration of propiconazole use on wheat with the use pattern of 0.08 lbs - 0.11 lbs ai/A/application, maximum of two applications per growing season, and with 35- day PHI (covers Stratego™ Twin-Pak™ and Stratego™ Fungicide formulations on wheat). The residue data also covers all 24 C wheat use patterns. These uses have higher maximum seasonal rate compared to currently registered propiconazole formulations (maximum single application of 0.11 lb ai/A, maximum of one application per growing season, PHI 40 days). Therefore, for the purpose of reregistration, the wheat RAC tolerances should be reassessed using data from the current submission. **Based on the cited field trials associated with Stratego™ Twin-Pak™ and Stratego™ uses, HED recommends increasing the wheat grain tolerance to 0.3 ppm, wheat straw to 15.0 ppm, and to propose new tolerances on wheat hay and forage at 2.0 ppm.**

As mentioned under Directions for Use, Stratego™ Twin-Pak™ and Stratego™ Fungicide (EPA Reg. Nos. 264-779 ) have been registered for uses on corn, peanuts, pecans, rice, and wheat based on reviews of trifloxystrobin. After comparing the use rates of Stratego™ Twin-Pak™ and Stratego™ on corn, peanuts, pecans and rice to the use rates which current tolerances on corn, peanuts, pecans and rice are based on, **HED concludes that except for wheat, the rest of crops have lower use rates on Stratego™ label than the propiconazole application rates used in the crop field trials used to set the original tolerances. HED concludes that the current tolerances support the Stratego™ label.**

**The Agency now recommends that wheat hay data be translated to oats to establish a more appropriate level for the oat hay tolerance at 2.0 ppm.**

**HED is translating the wheat grain, wheat straw, wheat hay and forage data to barley and rye grain, straw, hay and forage.** Therefore, no further data requirements are needed. The reassessed tolerances for barley grain and rye grain should be 0.3 ppm, for barley and rye straw should be 15.0 ppm. New tolerances for barley hay and rye forage should be established at 2.0 ppm.

The available rice residue data support the established 3.0 ppm tolerance for propiconazole residues in/on rice straw; however, the data also indicate that the registrant should propose new tolerance for residues in/on rice grain. An appropriate level for residues in/on rice grain would be 0.3 ppm (HED memo of 02/23/05, T. Morton, D240856).

A Section 18 risk assessment has been conducted by RD (S18 request from the States of Minnesota and South Dakota for use of propiconazole on soybeans to control soybean rust). It was recommended that **time-limited tolerances of 0.5 ppm in/on soybeans, 8 ppm in/on soybean forage, and 25 ppm in soybean hay be established** (Agency memo of 04/14/04, J. R. Tomerlin, D262299).

A Section 18 risk assessment has been conducted by RD (S18 request from the States of Maine for use of propiconazole on blueberry). It was recommended that **time-limited tolerances of 1.0 ppm in/on blueberry be established.** (Agency memo of 02/22/05, D. Rate, D313289).

Among all the 24C requested uses, the only tolerances required to be reassessed are mint, corn, sunflower, and banana. The rest can be considered non-food uses. The use on sugarcane seed pieces is considered non-food due to the fact that it takes 18 months from planting to harvesting of sugar canes (conversation with Bernie Schneider, 02/03/05). The use on sunflower for seeds can not be considered non-food use, and therefore, no tolerance can be established on sunflower until field trial data are submitted. Field trial data for bananas were generated in Honduras, Republic of Ivory Coast, Martinique, and Belize. With one exception, residues did not exceed the tolerance following 1-13 aerial or ground applications of a 250EC formulation at 41 g ai/A/application (= 0.90 lbs ai/A/application). The only registered uses are in Hawaii and Puerto Rico(24C), with the rate of 0.084 lbs ai/A/application and maximum 8 applications. HED concludes that the existing tolerance on banana is adequate

#### GLN 860.1520: Processed Food/Feed

The reregistration requirements for magnitude of the residue in the processed commodities of the following crops have been fulfilled: barley, corn, mint, oats, peanut, plums, rye, and wheat. The available data indicate that residues do not concentrate significantly in corn wet-milled and dry-milled processed fractions; mint oil; rolled oats, hulls, groats, oat flour, fines, light impurities, bran, and feed oats; peanut meal, soapstock, crude and refined oil, and peanut presscake; dried prunes; and wheat flour, middlings, shorts, and germ.

The most recent wheat processing study (HED memo of 02/02/05, Y. Donovan, D271790) indicated that total propiconazole residues do not concentrate in germ, middlings, low grade flour, and patent flour processed from whole wheat grains bearing either nondetectable (<0.05 ppm) or measurable residues, and therefore, no tolerances are needed on these commodities. The average concentration factor of residues in wheat bran is 3.3x. The maximum expected residues of total propiconazole in wheat bran is 0.99 ppm which is determined by multiplying the average concentration factor of 3.3x with the highest average field trial (HAFT) residue value of 0.3 ppm. **A tolerance for wheat bran at 1.0 ppm is needed.**

A new rice processing study has been submitted and reviewed as acceptable by the Agency (MRID 45080811.DER2), the review indicated that the concentration factor for rice bran is 2.9x, for rice hulls is 3.8x, and for polished rice is 0.12x. The registrant needs to propose new tolerances for rice bran at 1.0 ppm and for rice hulls at 1.2 ppm.

#### Aspirated wheat grain fractions

Composition of AGF: Corn 46%, wheat 32%, soybean 16%, sorghum 6% (reference from ChemSAC minute 05/01/02).

The average concentration factor of residues in aspirated wheat grain fraction is 13.7x from the new submitted processing study (HED memo of 02/02/05, Y. Donovan, D271790). Based on the field trials, the proposed tolerance on wheat grain is 0.3 ppm, and therefore, the maximum AGF residue would be 4.3 ppm. The maximum expected propiconazole residues in soybean aspirated grain fractions would be 3.5 ppm (memo of 03/10/05, T. Morton, D246884). A 20 ppm AFG tolerance was established on barley based on a Section 18 use on barley, which is based on the tolerance level for grain sorghum grain (0.2 ppm), and the maximum concentration factor of 100x. This Section 18 tolerance will expire on 06/30/05. No data are yet available on aspirated grain fractions derived from corn (A 0.1 ppm tolerance on corn grain has been established). However, HED believes that residues from corn AGF will not likely to be higher than that from wheat based on the fact that wheat grain has higher residues than corn grain, therefore, **HED recommends a 5.0 ppm tolerance on aspirated grain fractions for propiconazole.**

The reregistration requirements for magnitude of the residue in the processed commodities of pineapple have not been fulfilled. For pineapple, data are required reflecting the potential for concentration in pineapple juice. Although processing data are now required for pineapple process residue instead of pineapple fodder, data provided with the original tolerance petition confirmed that residues were non detectable (<0.05 ppm) in pineapple shells, cores, bran, and fodder.

Based on the available field trial data for sugarcane, treatment of sugarcane seed pieces according to the currently registered use pattern can be considered a non-food use; therefore, there are no requirements for magnitude of the residue in processed sugarcane commodities.

GLN 860,1480): Meat, Milk, Poultry, Eggs

The reregistration requirements for data depicting the magnitude of propiconazole residues of concern in meat, milk, poultry, and eggs have been fulfilled. Acceptable ruminant and poultry feeding studies were submitted and evaluated in conjunction with previous propiconazole petitions (PP#4F3074 and PP#1F3974). Because of the addition of a number of registered uses and corresponding tolerances for crops with animal feed items since the Phase 4 Review, including grasses grown for seed, peanuts, and wheat (increased use rate), the maximum theoretical dietary burden to livestock has been recalculated and is presented below.



Calculation of maximum livestock dietary burden for propiconazole.

| Feed Commodity           | Reassessed Tolerance (ppm) | % Dry Matter | % of Diet | Burden (ppm) |
|--------------------------|----------------------------|--------------|-----------|--------------|
| <b>Beef cattle</b>       |                            |              |           |              |
| Grass, hay               | 40                         | 88           | 60        | 27.3         |
| Aspirated grain fraction | 5.0                        | 85           | 20        | 1.2          |
| Corn, field, grain       | 0.1                        | 88           | 20        | 0.03         |
| TOTAL                    |                            |              | 100       | <b>28.53</b> |
| <b>Dairy cattle</b>      |                            |              |           |              |
| Grass, hay               | 40                         | 88           | 60        | 27.3         |
| Aspirated grain fraction | 5.0                        | 85           | 20        | 1.2          |
| Corn, field, grain       | 0.1                        | 88           | 20        | 0.03         |
| TOTAL                    |                            |              | 100       | <b>28.53</b> |
| <b>Poultry</b>           |                            |              |           |              |
| Corn, field, grain       | 0.1                        | 88           | 80        | 0.08         |
| Peanut, meal             | 0.2                        | 89           | 20        | 0.04         |
| TOTAL                    |                            |              | 80        | <b>0.12</b>  |
| <b>Swine</b>             |                            |              |           |              |
| Peanut, meal             | 0.2                        | 85           | 15        | 0.03         |
| Wheat, grain             | 0.1                        | 89           | 80        | 0.08         |
| TOTAL                    |                            |              | 95        | <b>0.11</b>  |

The results of the livestock feeding studies are summarized below.

In the ruminant feeding study, cattle were fed propiconazole at dose levels of 15, 75, and 150 ppm for periods of 14, 21, or 28 days. These dose levels represent 0.54x, 2.6x, and 5.2x the maximum theoretical dietary burden to dairy cattle. Milk samples were collected daily. The results of the study are summarized in the table below.

Residues of propiconazole and metabolites in tissues of dairy cows fed propiconazole at dose levels of 15, 75, and 150 ppm.

| Matrix | Feeding level (ppm) |      |      |         |      |      |         |      |      |
|--------|---------------------|------|------|---------|------|------|---------|------|------|
|        | 14 days             |      |      | 21 days |      |      | 28 days |      |      |
|        | 15                  | 75   | 150  | 15      | 75   | 150  | 15      | 75   | 150  |
| Muscle | <0.05               | 0.11 | 0.18 | <0.05   | 0.08 | 0.13 | <0.05   | 0.05 | 0.11 |
| Kidney | 0.61                | 3.04 | 6.48 | 0.56    | 4.68 | 5.0  | 0.63    | 3.68 | 5.5  |
| Liver  | 0.5                 | 4.0  | 4.6  | 0.81    | 4.3  | 5.3  | 0.57    | 2.7  | 5.6  |

|     |       |      |      |       |      |      |       |      |      |
|-----|-------|------|------|-------|------|------|-------|------|------|
| Fat | <0.05 | 0.23 | 0.26 | <0.05 | 0.15 | 0.19 | <0.05 | 0.08 | 0.17 |
|-----|-------|------|------|-------|------|------|-------|------|------|

In milk, residues were nondetectable (<0.01 ppm) at the 15-ppm feeding level, and maximum residues of 0.1 ppm and 0.11 ppm were detected at the 75- and 150-ppm feeding levels, respectively. These results indicate that tolerances for propiconazole residues of concern in ruminant commodities are necessary. The appropriate levels for these tolerances are addressed in the Tolerance Reassessment Summary.

In the poultry feeding study, laying hens were fed propiconazole at dose levels of 7.5, 37.5, and 75 ppm for periods of 14, 21, or 28 days. These dose levels represent 63x, 310x, and 630x the maximum theoretical dietary burden to dairy cattle. Egg samples were collected daily. The results of the study are summarized in the table below.

Residues of propiconazole and metabolites in tissues of laying hens fed propiconazole at dose levels of 7.5, 37.5, and 75 ppm.

| Matrix | Feeding level (ppm) |       |      |         |       |      |         |       |      |
|--------|---------------------|-------|------|---------|-------|------|---------|-------|------|
|        | 14 days             |       |      | 21 days |       |      | 28 days |       |      |
|        | 7.5                 | 37.5  | 75   | 7.5     | 37.5  | 75   | 7.5     | 37.5  | 75   |
| Muscle | <0.05               | --    | --   | <0.05   | <0.05 | 0.07 | <0.05   | <0.05 | 0.06 |
| Liver  | <0.1                | 0.1   | 0.47 | --      | 0.08  | 0.39 | <0.1    | 0.16  | 0.3  |
| Fat    | --                  | <0.05 | 0.11 | --      | <0.05 | 0.06 | --      | <0.05 | 0.05 |

In eggs, residues were nondetectable (<0.05 ppm) at the 7.5-ppm feeding level, and maximum residues of 0.18 ppm and 0.37 ppm were detected at the 37.5- and 75-ppm feeding levels, respectively. These results indicate that propiconazole residues of concern are nondetectable in eggs, muscle, and liver at a feeding level corresponding to 63x the maximum dietary burden, and in fat at a feeding level corresponding to 310x the maximum dietary burden. Therefore, propiconazole can be classified as Category 3 of 180.6(a) with respect to the need for tolerances in eggs and poultry tissues. Tolerances for poultry commodities are not required. (Also see HED memo of 03/06/02, Bonnie Cropp-Kohlligian, D281520).

#### GLN 860.1400: Water, Fish, and Irrigated Crops

Propiconazole is presently not registered for direct use on water and aquatic food and feed crops. Although propiconazole is registered for use on rice, current label restrictions prohibit the use on rice in CA (where typical agricultural practices for rice field irrigation entail a "flow-through" system); typical agricultural practices concerning rice field irrigation in all other areas allow for the on-site evaporation of waters used in rice fields. Label restrictions preclude the use of water drained from treated rice fields to irrigate other crops. Label restrictions also preclude use where catfish and crayfish are produced. Therefore, no residue chemistry data are required under these guideline topics.

#### GLN 860.1460: Food Handling

Propiconazole is presently not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

#### GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

The nature of the residue in confined rotational crops is understood, and no additional confined rotational crop data are required for the purpose of reregistration. Based on acceptable studies reviewed by EFED, the metabolism of propiconazole in rotational crops is similar to that in primary crops.

Plantback restrictions have been established for propiconazole products registered for use on rotatable crops based on the confined rotational crop studies. Labels for these formulations specify that soybeans may be planted as a double crop following a cereal crop which has been treated with the product, but soybean hay, forage, and fodder may not be used as any component of animal feed or bedding. The labels specify that any food/feed crops not listed on the label should not be planted within 105 days of treatment.

Recent data are also available depicting propiconazole residue in rotational lentils and peas to satisfy requirements for field rotational crop trial data for potential uses in the Pacific Northwest. Residues of propiconazole were <LOQ (0.05 ppm) in/on all matrices harvested from rotational legume crops planted 329-376 days posttreatment. Additional field rotational crop data would be required to revise the established plantback intervals.

A petition is pending for tolerances on the rotational crops alfalfa and sorghum (PP# 5F4498). This petition has not been reviewed.

Table B (continued).

Table B. Residue Chemistry Science Assessments for Reregistration of Propiconazole.

| GLN: Data Requirements               | Current Tolerances, ppm [40 CFR] | Must Additional Data Be Submitted? | References <sup>1</sup>   |
|--------------------------------------|----------------------------------|------------------------------------|---|
| 860.1200: Directions for Use         | Not applicable (N/A)             | Yes <sup>2</sup>                   | See Tables A1 and A2  |
| 860.1300: Plant Metabolism           | N/A                              | No                                 | 00074496 <sup>3</sup> , 00074498, 00074499, <b>00074500</b> , <b>00074501</b> , <b>00074502</b> , 00129915, 00155645, 44049601 <sup>4</sup> , 44381402 <sup>5</sup> , <b>93194062</b>   |
| 860.1300: Animal Metabolism          | N/A                              | No <sup>b</sup>                    | PP#8F3674 <sup>7</sup> , <b>00067905</b> , <b>00074503</b> , <b>00074504</b> , <b>41823301</b> <sup>8</sup> , <b>41823302</b> , <b>41823304</b> , 42564006 <sup>9</sup> , 42983001 <sup>10</sup> , <b>93194085</b>  |
| 860.1340: Residue Analytical Methods |                                  |                                    |   |
| - Plant commodities                  | N/A                              | No <sup>11</sup>                   | 00137150 <sup>12</sup> , 40154501 <sup>13</sup> , <b>40180701</b> <sup>14</sup> , 40692203 <sup>15</sup> , 40692204, 40692206, 40783306 <sup>16</sup> , 41063801 <sup>17</sup> , 41063802, 41486801 <sup>18</sup> , 41823305, 42061301 <sup>19</sup> , 42182901 <sup>20</sup> , 42564005, 42605801 <sup>21</sup> , 42634101 <sup>22</sup> , 43424601 <sup>23</sup> , 43434201 <sup>24</sup> , 43825401 <sup>25</sup> , 44411201 <sup>26</sup> , 44411206, 44411207, 44411208, <b>93194064</b> |
| - Animal commodities                 | N/A                              | No                                 | 40150701 <sup>27</sup> , <b>40154501</b> , <b>40180702</b> , 41823304, 44411204, <b>93194067</b>  |
| 860.1360: Multiresidue Methods       | N/A                              | No                                 | <b>40100101</b> <sup>28</sup> , <b>93194066</b>   |
| 860.1380: Storage Stability Data     |                                  |                                    |   |
| - Plant/processed commodities        | N/A                              | No                                 | <b>00074510</b> , <b>00074511</b> , <b>00133385</b> , 40692201, 41063801, 41063802, 41486802, 42605801, 43314201 <sup>29</sup> , 43825402, 44411205, <b>93194068</b>  |

Table B (continued).

| GLN: Data Requirements                                     | Current Tolerances, ppm [40 CFR]                    | Must Additional Data Be Submitted? | References <sup>1</sup> |
|--|---|------------------------------------|-------------------------|
| - Animal commodities<br>860.1500: Crop Field Trials        | N/A   | No <sup>30</sup>                   | 40150701 , 42983001     |
| <u>Leafy Vegetables (Except Brassica Vegetables) Group</u> |   |                                    |                         |
| - Celery   | 5.0<br>[§180.434(a)]                                | No                                 | 40783301 , 41486801     |
| <u>Legume Vegetables Group</u>                             |   |                                    |                         |
| - Bean, dry  | 0.5<br>[§180.434(b)]                                | No <sup>31</sup>                   |                         |
| <u>Foliage of Legume Vegetables Group</u>                  |   |                                    |                         |
| - Bean, dry, forage and hay                                | 8.0, forage<br>8.0, hay<br>[§180.434(b)]            | No                                 |                         |
| <u>Stone Fruits Group</u>                                  |   |                                    |                         |
| - Apricots   | 1.0<br>[§180.434(a)]                                | No <sup>32</sup>                   |                         |
| - Cherries   | 1.0<br>[§180.434(a)]                                | No                                 | 41063802                |
| - Nectarines   | Group tolerance established<br>1.0<br>[§180.434(a)] | No                                 | 43655609<br>41063802    |
| - Peaches  | 1.0<br>[§180.434(a)]                                | No                                 | 41063802                |
| - Plums  | 1.0<br>[§180.434(a)]                                | No                                 | 41063802                |
| - Prunes, fresh  | 1.0<br>[§180.434(a)]                                | No                                 | 41063802                |
| <u>Berries Group</u>                                       |   |                                    |                         |
| - Blueberries  | 1.0<br>[§180.434(b)]                                | No <sup>33</sup>                   |                         |
| - Raspberries  | 1.0<br>[§180.434(b)]                                | No                                 |                         |
| <u>Tree Nuts Group</u>                                     |   |                                    |                         |

Table B (continued).

| GLN: Data Requirements                                       | Current Tolerances, ppm [40 CFR]            | Must Additional Data Be Submitted? | References <sup>1</sup>   |
|--|---|------------------------------------|---|
| - Almonds, nutmeat and hulls                                 | 0.1, nutmeat<br>2.5, hulls<br>[§180.434(b)] | No <sup>34</sup>                   |   |
| - Pecans   | 0.1<br>[§180.434(a)]                        | No <sup>35</sup>                   | <b>00074495 , 00074508 ,<br/>00074509 , 00153327</b>              |
| <u>Cereal Grains Group</u>                                   |   |                                    |   |
| - Barley, grain  | 0.1<br>[§180.434(a)]                        | No <sup>36</sup>                   | PP#4F3074 <sup>37</sup> , <b>93194072</b>                         |
| - Corn, field, grain and aspirated grain fractions           | 0.1, grain<br>[§180.434(a)]                 | No <sup>38</sup>                   | 40783303 , 42564004 ,<br>42564005                                 |
| - Corn, pop  | 0.1, grain<br>[§180.434(a)]                 | No <sup>39</sup>                   |   |
| - Corn, sweet (kernels plus cobs with husks removed)         | 0.1<br>[§180.434(a)]                        | No                                 | 40783303 , 42564004 ,<br>42564005                                 |
| - Oats, grain  | 0.1<br>[§180.434(a)]                        | No                                 | 42182901 , 43314202   |
| - Rice, grain  | 0.1<br>[§180.434(a)]                        | No <sup>40</sup>                   | 00137861 , 42915601 <sup>41</sup> ,<br>44411208 , <b>93194075</b> |
| - Rye, grain   | 0.1<br>[§180.434(a)]                        | No                                 |   |
| - Sorghum, grain and aspirated grain fractions               | 0.2, grain<br>20, AGF<br>[§180.434(b)]      | No <sup>42</sup>                   |   |
| - Wheat, grain and aspirated grain fractions                 | 0.1, grain<br>[§180.434(a)]                 | No <sup>43</sup>                   | PP#4F3074 , 44411206 ,<br>44411207 , <b>93194072</b>              |
| - Wild rice  | 0.5<br>[§180.434(c)]                        | No                                 | 41063801 , 42511401 <sup>44</sup>                                 |
| <u>Fodder, Forage, Hay, and Straw of Cereal Grains Group</u> |   |                                    |   |

Table B (continued).

| GLN: Data Requirements                           | Current Tolerances, ppm [40 CFR]                                       | Must Additional Data Be Submitted? | References <sup>1</sup>  |
|--|--|------------------------------------|--|
| - Barley, hay and straw                          | 1.5, straw<br>[§180.434(a)]  | No <sup>45</sup>                   | PP#4F3074 , <b>93194072</b>  |
| - Corn, field, forage and stover                 | 12, fodder and forage<br>[§180.434(a)]                                 | No                                 | 40783303 , 42564004 , 42564005                                     |
| - Corn, pop, stover                              | 12, fodder<br>[§180.434(a)]  | No                                 |  |
| - Corn, sweet, forage and stover                 | 12, fodder and forage<br>[§180.434(a)]                                 | No                                 | 40783303 , 42564004 , 42564005                                     |
| - Oats, forage, hay, and straw                   | 10.0, forage<br>30.0, hay<br>1.0, straw<br>[§180.434(a)]               | No <sup>46</sup>                   | 42182901 , 43314202  |
| - Rice, straw                                    | 3.0<br>[§180.434(a)]   | No                                 | 00137861 , 44411208 , <b>93194075</b>                              |
| - Rye, forage and straw                          | 1.5, straw<br>[§180.434(a)]  | No                                 |  |
| - Sorghum, stover                                | 1.5<br>[§180.434(b)]   | No                                 |  |
| - Wheat, forage, hay, and straw                  | 1.5, straw<br>[§180.434(a)]  | No <sup>47</sup>                   | PP#4F3074 , 44411206 , 4441207 , <b>93194072</b>                   |
| <u>Grass Forage, Fodder, and Hay Group</u>       |  |                                    |  |
| - Grass, seed screenings, forage, hay, and straw | 60, seed screenings<br>0.5, forage<br>40, hay (straw)<br>[§180.434(a)] | No <sup>48</sup>                   | <b>40890701</b> , 41823305 , 42634101 , 42634102 , <b>93194073</b> |
| <u>Miscellaneous Commodities</u>                 |  |                                    |  |
| - Bananas  | 0.2<br>[§180.434(a)]   | No <sup>49</sup>                   | <b>00137150 , 93194071</b>   |

Table B (continued).

|                               |                          |   |                   |   |
|-------------------------------|--------------------------|---|-------------------|---|
| -                             | Cranberries              | 1.0<br>[§180.434(b)]                          | No                |   |
| -                             | Mint                     | 0.3<br>[§180.434(c)]                          | No <sup>50</sup>  | 42061301 , 43424601                     |
| -                             | Mushrooms                | 0.1<br>[§180.434(a)]                          | No <sup>51</sup>  | 43434201                                |
| -                             | Peanut, nutmeat and hay  | 0.2, peanut<br>20.0, hay<br>[§180.434(a)]     | No <sup>52</sup>  | 40692201                                |
| -                             | Pineapple                | 0.1, pineapple<br>and fodder<br>[§180.434(a)] | No                | 40783305                                |
| -                             | Sugarcane                | None<br>established                           | No <sup>53</sup>  | 44142401 , <b>93194077</b>              |
| -                             | Sunflower Breeder's Seed | None<br>established                           | Yes <sup>54</sup> |   |
| 860.1520: Processed Food/Feed |                          |   |                   |   |
| -                             | Barley                   | None<br>established                           | No <sup>55</sup>  |   |
| -                             | Corn, field              | None<br>established                           | No                | 40783303 , 42564005                     |
| -                             | Mint                     | None<br>established                           | No                | 42061301 , 43424601                     |
| -                             | Oat                      | None<br>established                           | No                | 42182901                                |
| -                             | Peanut                   | None<br>established                           | No                | 40692201 , 42605801                     |
| -                             | Pineapple                | None<br>established                           | Yes <sup>56</sup> | 40783305                                |
| -                             | Plum                     | None<br>established                           | No                | 41063802                                |
| -                             | Rice                     | None<br>established                           | No <sup>57</sup>  | 00137861 , 42915601,<br><b>93194079</b> |



Table B (continued).

|  |   |   |                  |  |
|--|---|---|------------------|--|
| -  | Rye   | None established  | No               |  |
| -  | Sorghum   | None established  | No <sup>58</sup> |  |
| -  | Sugarcane   | None established  | No               |  |
| -  | Wheat   | None established  | No               | PP#4F3074 , 44411206 ,<br>44411207 , 44757208,<br><b>93194080</b>  |
| 860.1480: Meat, Milk, Poultry, Eggs                  |   |   |                  |  |
| -  | Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep | 0.05, milk;<br>0.1, fat, meat,<br>and mby; 2.0, kidney and liver<br>[§180.434(a)] | No               | <b>00137861</b> , 40150701 ,<br><b>93194070</b>  |
| -  | Eggs and the Fat, Meat, and Meat Byproducts of Poultry                                | 0.1, eggs, fat, meat, and mby; 0.2, kidney and liver<br>[§180.434(a)]             | No               | <b>00137861</b> , 40150701 ,<br><b>93194070</b>  |
| 860.1400: Water, Fish, and Irrigated Crops           |   | N/A   | N/A              |  |
| 860.1460: Food Handling                              |   | N/A   | N/A              |  |
| 860.1650 Submittal of Analytical Reference Standards |   |   | Yes              | See foot note <sup>64</sup>  |
| 860.1850: Confined Rotational Crops                  |   | N/A   | No <sup>59</sup> | 00074498, 00129915 <sup>60</sup> ,<br>00138266, 00155644 <sup>61</sup> ,<br>00155645, 00164802 <sup>62</sup> ,<br>41102001 <sup>63</sup> |
| 860.1900: Field Rotational Crops                     |   | None established  | No <sup>64</sup> | 44411206   |

Table B (continued).

1. Bolded references were evaluated in the Propiconazole Phase 4 Review dated 6/25/92, by B. Cropp-Kohlhligian, F. Fort, and F. Toghrol; because a number of the references cited in the Phase 4 Review were reviewed in connection with petitions for uses which have since been registered, in some cases the original review documents are noted as well. All other references were reviewed as noted.
2. Syngenta is required to amend the product labels for the 41.8% EC formulations (100-617 and 100-737) to indicate the propiconazole concentration in terms of lb ai/gal. In addition, label restrictions which prohibit the feeding of treated forage and/or hay of cereals and corn to livestock must be removed from the 41.8% EC (100-617 and 100-737) and the 45% WP (100-780) formulations. The use directions for rice on all labels should be amended to specify a 45-day PHI. HED notice that the maximum number of applications for peanuts on Stratego™ label is not very clear. After discussing with RD and the registrant, it is understood that the maximum number of six applications is intended only for the 7.0 oz ai/A rate, where the restricted number of application at 14 oz ai/A is only two. HED recommends that the petitioner to amend the Stratego™ label to specify these instructions. Since there are adequate field trial data to support Section 3 registration of propiconazole uses on wheat at the rate of 0.08 - 0.11 lbs ai/A/application, maximum 2 applications, and 35 day PHI (HED memo of 02/02/05, Y. Donovan, D271790), HED recommends increasing the existing tolerances on wheat RAC to cover Stratego Fungicide (EPA Reg. No. 264-779) uses on wheat. These new reassessed tolerances will cover all 24C uses on wheat as well. HED recommends canceling all 24C uses while revising the Section 3 label to include these 24C uses.
3. PP#4F3007 on pecans, RCB#711, 5/15/84, A. Smith.
4. DP Barcode D233755, 9/14/99, T. Morton.
5. DP Barcode D245249, 12/14/99, T. Morton.
6. Although the Phase 4 Review concluded that additional animal metabolism data were required, the Agency concluded, based on the registrant's 90-day response to the DCI, that the available data were adequate to satisfy data requirements (CB#13166, DP Barcode D198815, 4/26/94, F. Fort).
7. PP#8F3674, CB#11976, DP Barcode D191918, 9/20/93, M. Flood.
8. PP#1F3974 on grass seed screenings, CB No. 7822, 6/11/91, S. Willett.
9. PP#8F3674 on corn and pineapple, CB#10974, D185251, 5/6/93, M. Flood.
10. PP#8F3674 on corn and pineapple, CB#12839, DP Barcode D196789, 3/28/94, M. Flood.
11. In the Phase 4 Review, the registrant was required to conduct enforcement method validation for Method AG-454A using bananas. This requirement is no longer needed.
12. PP#4F3026, RCB#826, 6/20/84, K. Arne.
13. PP#4F3074 on small grains, CB No. 2174, 5/7/87, S. Malak.
14. PP#4F3074 on small grains, CB No. 2262, 5/15/87, S. Malak.
15. PP#8F3654 on peanuts, CB No. 4108, 11/22/88, H. Fonouni.
16. PP#8F3674 on legumes, CB No. 4279, 12/14/88, C. Deyrup.
17. PP#9F3758 on rice, wild rice, stone fruits, CB Nos. 5226-5228, 11/28/89, S. Malak.
18. PP#0F3869 on cherry, CB No. 6724, 8/15/90, W. Chin.
19. PP#2F4027 on mint, DP Barcode D170759, 2/14/92, W. Wassell.
20. PP#2F4086 on oats, CB#9325, DP Barcodes D174248 and D175989, 7/20/93, R. Lascola.

Table B (continued).

21. PP#8F3674 on peanuts, CB#12638, DP Barcodes D186202, D186203, D186205, D186206, and D195499, 11/8/93, M. Flood.
22. PP#1F3979 on grass grown for seed, CB# 11304, DP Barcodes D187417, D190147, and D190263, 5/12/93, M. Flood.
23. PP#2F4037 on mint hay, CB#14711, DP Barcode D209458, 4/25/95, W. Wassell.
24. PP#5F4437 on mushroom, CB#14693, DP Barcode D209195, 3/29/95, W. Cutchin.
25. DP Barcode D220935, 3/25/99, T. Morton.
26. DP Barcode D240856, 02/23/05, T. Morton.
27. PP#4F3074 on small grain/pecans, CB No. 2172, 5/14/87, S. Malak.
28. PP#4F3074 on small grain/pecans CB No. 2108, 4/28/87, S. Malak.
29. PP#2F4086 on rice, CB# 14941, DP Barcode D210742, 3/15/95, M. Rodriguez.
30. The Phase 4 Review concluded that additional storage stability data were required to support the livestock feeding studies. In their 90-day response to the DCI, the registrant presented data to satisfy this data requirement (DP Barcode D198815, 4/26/94, F. Fort).
31. Section 18 Exemption with associated time-limited tolerance on dry beans. Use of propiconazole on dry beans has been proposed under pending petition PP#5F4424 (now incorporated into PP#2F6371).
32. Establishment of a stone fruit group tolerance was approved on further consideration of new and available data for cherries (PP# 4F4321, DP Barcode D217199, 8/14/95, W. Cutchin and DP Barcode D210252, 4/25/95, W. Cutchin).
33. Section 18 Exemption with associated time-limited tolerance on blueberry in Maine (Agency memo of 02/22/05, D. Rate, D313289). Use of propiconazole on the berries group has been proposed under pending petition PP#5F4591, now incorporated into PP#2F6371.
34. Section 18 Exemption with associated time-limited tolerance on tree nuts. Use of propiconazole on tree nuts has been proposed under pending petition PP#9F3470, now incorporated into PP#2F6371.
35. The existing tolerance covers the registered uses of propiconazole on pecans. Syngenta is petitioning for a tree nut group tolerance (PP#9F3740, now incorporated into PP#2F6371), which will be handled by registration.
36. The available data pertaining to propiconazole residues of concern in/on wheat grain and straw supporting the currently registered maximum use pattern (D271790) can be translated to barley grain and straw and rye grain and straw.
37. PP#4F3074, RCB#898, 7/12/84, A. Smith.
38. PP#8F3674 on corn and pineapple, 03/28/94, D196789, M. Flood. The new submitted storage stability data are adequate and indicate that propiconazole is stable at -20°C for up to 36 months in the following commodities: peaches, bananas, corn meal, wheat grain, celery, corn oil, and peanut nutmeat, hay, and hulls. Propiconazole is also stable in carrots for up to 10 months at -20°C (Barcode D240856). Time-limited tolerances have been extended to 12/31/00 pending review of a modified mid-dose

Table B (continued).

carcinogenicity study in mice (64 FR 13086, 13105, 3/17/99). HED believes that residues from corn AGF will not likely to be higher than that from wheat based on the fact that wheat grain has higher residues than corn grain, therefore, HED recommends a 5.0 ppm tolerance on aspirated grain fractions for propiconazole.

39. The available data pertaining to field corn commodities may be translated to popcorn commodities.

40. The product labels for the 41.8% ECs (EPA Reg. Nos. 100-617 and 100-737) must be modified to specify a 45-day PHI for rice.

41. DP Barcode D195566, 11/2/93, C. Swartz; preliminary 6 (a) (2) data on rice.

42. Section 18 Exemption with associated time-limited tolerance on cranberries. Use of propiconazole has been proposed by IR-4 under pending petition PP#7E4860.

43. Data supporting the currently registered maximum use pattern (MRID 44411207) are adequate. The product labels for the 41.8% ECs (EPA Reg. Nos. 100-617 and 100-737) and the 45% WP (EPA Reg. No. 100-780) must be amended to specify a PHI of no less than 45 days for wheat grain and straw. The registrant submitted data reflecting a new use pattern (2x the current use pattern) but did not state whether they wished to support this new use pattern. If the registrant desires to support this use pattern, then additional data would be required (see D240856)

44. PP#9F3758 on wild rice, apricots, nectarines, peaches, plums, prunes. DP Barcode D183633, 4/8/93, M. Rodriguez.

45. Adequate data supporting the currently registered maximum use pattern for wheat hay and forage have been received and reviewed (HED memo of 02/02/05, Y. Donovan, D271790). They can be translated to barley hay and rye forage. The product labels for the 41.8% EC (EPA Reg. Nos. 100-617 and 100-737) and the 45% WP (EPA Reg. No. 100-780) formulations must be modified to make the use patterns for barley and rye identical to wheat.

46. Outstanding deficiencies pertaining to use of propiconazole on oats (PP#2F04086) have been resolved by proposal of a tolerance for residues of propiconazole and its metabolites determined as 2,4-DCBA in/on oat hay (DP Barcode D218453, 8/24/95, M. Rodriguez). Because no data for oat hay were available, the appropriate level for this tolerance was calculated from data for oat forage using a 3x dry-down factor. Currently, data for wheat hay are available, and these data can be translated to oats to determine a more appropriate level for the oat hay tolerance.

47. Adequate data on wheat have been submitted and reviewed (HED memo of 02/02/05, Y. Donovan, D271790). No additional data are needed.

48. PP#1F3974, "Propiconazole (Tilt) in/on Grass Grown for seed Ciba-Geigy Amendment dated 7/2/93". M. Flood, 9/20/93, D192904

49. Banana field trial data were generated in Honduras, Republic of Ivory Coast, Martinique, and Belize. With one exception, residues did not exceed the tolerance following 1-13 aerial or ground applications of the 250EC formulation at 41 g ai/A/application (= 0.090lbs ai/A/application). The only

Table B (continued).

registered uses are in Hawaii and Puerto Rico, with the rate of 0.084 lbs ai/A/application and maximum 8 applications. HED concludes that the existing tolerance on banana is adequate.

50. Use of propiconazole on mint is currently supported by IR-4 and is registered under SLN OR960007. A tolerance was established in connection with PP#2E4037.

51. Use on mushrooms is being supported by IR-4. A tolerance was established in connection with PP#5E4437.

52. CBTS recommended for the establishment of time-limited tolerances for peanut commodities pending receipt of additional storage stability data (8F3654, DP Barcode D197841, 1/25/94, M. Flood). These data have since been received and reviewed (DP Barcode D240856).

53. The available data indicate that treatment of sugarcane pieces according to the currently registered use pattern can be considered a nonfood use.

54. The available data indicate that treatment of sunflower grown for seed can not be considered a nonfood use. Field trial data on sunflower are required to establish tolerance.

55. The available data for processed wheat commodities may be translated to barley and rye. (HED memo of 02/02/05, Y. Donovan, D271790).

56. Data must be submitted depicting the potential for concentration of propiconazole residues of concern in pineapple juice.

57. A new rice processing study has been submitted and reviewed by the Agency as acceptable (MRID450808) (LDER2).

58. The Agency has determined that adequate data pertaining to magnitude of the residue in the processed commodities of sorghum are available to support the Section 18 Exemption. A tolerance was proposed in connection with PP# 5F4498.

59. EFGWB concluded that this requirement has been fulfilled (DP Barcode D166460, 11/7/91, P. Mastrodone).

60. EFGWB No. 70298, 3/23/87, E. Regelman.

61. EFGWB No. 70297, 5/18/87, E. Regelman.

62. EFGWB No. 70102, 12/24/86, E. Regelman.

63. EFGWB No. 90613, 10/19/89, E. Regelman.

64. Additional data would be required to revise the plantback intervals currently specified on labels for products with uses on rotatable crops. Data are available depicting propiconazole residue in rotational lentils and peas to satisfy requirements for field rotational crop trial data for potential uses in the Pacific Northwest. Residues of propiconazole were <LOQ (0.05 ppm) in/on all matrices harvested from rotational legume crops planted 329-376 days posttreatment.

65. An analytical reference standard for propiconazole is available in the National Pesticide Standards Repository. Analytical reference standards of propiconazole must be supplied and supplies replenished as

Table B (continued).

requested by the Repository. The reference standards should be sent to the Analytical Chemistry Lab, which is located at Fort Meade, to the attention of either Theresa Cole or Frederic Siegelman at the following address: USEPA, National Pesticide Standards Repository/Analytical Chemistry Branch/OPP, 701 Mapes Road, Fort George G. Meade, MD 20755-5350 (Note that the mail will be returned if the extended zip code is not used.)

## TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues in/on *plant and animal commodities* are established under 40 CFR §180.434. They are currently expressed in terms of the combined residues of 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 and expressed as parent compound. HED has determined that **the current tolerance expressions for plant and animal commodities are not appropriate. The tolerance expressions should be revised to parent *per se***, that is, propiconazole (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole).

The Agency has recently updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS GLN 860.1000). As a result of changes to Table 1, tolerances are now required for RACs which have been added to Table 1. Also, some commodity definitions must be corrected. The reassessments of tolerances for some commodities are contingent upon the implementation of requested label revision(s). A summary of propiconazole tolerance reassessments is presented in Table C.

### Tolerances Established Under 40 CFR §180.434(a)

Sufficient field trial data reflecting the maximum label use pattern are available to reassess the established tolerances for the following RACs **as defined**: barley, grain; barley, straw; celery; corn, fodder; corn, forage; corn, grain; corn, sweet (kernels, plus cobs with husks removed); grass, forage; grass, hay (straw); mushrooms; oats, forage; oats, grain; oats, hay; oats, straw; peanuts; peanuts hay; pecans; pineapple; rice, grain; rice, straw; rye, grain; rye, straw; stonefruit group; wheat, grain; and wheat, straw. Likewise, acceptable feeding studies for ruminants and poultry are available to reassess the tolerances for the following animal commodities: milk, eggs, and the fat, kidney, liver, meat byproducts (except kidney and liver), and meat of cattle, goats, hogs, horses, poultry, and sheep.

The existing tolerance covers the registered uses of propiconazole on pecans. Syngenta is petitioning for a tree nut group tolerance (PP#9F3740, now incorporated into PP#2F6371), which will be handled by registration.

Field trial data for bananas were generated in Honduras, Republic of Ivory Coast, Martinique, and Belize. With one exception, residues did not exceed the tolerance following 1-13 aerial or ground applications of a 250EC formulation at 41 g ai/A/application (= 0.90 lbs ai/A/application). The only registered uses are in Hawaii and Puerto Rico(24C), with the rate of 0.084 lbs ai/A/application and maximum 8 applications. HED concludes that the existing tolerance on banana is adequate

The established tolerances for apricots, nectarines, peaches, plums, and prunes should be revoked because a stone fruit group tolerance has been established. The established tolerance for

pineapple fodder should be revoked because this commodity is no longer considered a significant livestock feed item.

The established tolerances for RACs listed under 40 CFR §180.434(a) are reassessed at the same levels except those listed for barley, rice, rye, and wheat; higher tolerances are required for these crops to reflect the results of recent field trials.

The established tolerances for cattle, goat, hog, horse, and sheep commodities listed under 40 CFR §180.434(a) are reassessed at the same levels as well, due to the fact that HED is unable to separate the parent residues from the metabolites, and the fact that there are several pending petitions for new uses which will likely to result in increasing of the dietary burden.

#### Tolerances To Be Proposed Under 40 CFR §180.434(a)

Because of changes to Table 1 (OPPTS 860.1000), tolerances for barley hay, rye forage, and wheat forage and hay must be proposed. The required data for wheat hay and forage will be translated to barley hay and rye forage. Because the tolerance level for oat hay was not determined from residue data but was calculated from the oat forage level using a 3x dry-down factor, the required data for wheat hay should be translated to oat hay to provide a more realistic level for this tolerance. Based on the cited field trials with Stratego™ Twin-Pak™ and Stratego™, **HED proposes new tolerances on wheat hay and forage at 2.0 ppm. The Agency now recommends that wheat hay data be translated to oats to establish a more appropriate level for the oat hay tolerance at 2.0 ppm.**

**HED is translating the wheat grain, wheat straw, wheat hay and forage data to barley and rye grain, straw, hay and forage.** Therefore, the reassessed tolerances for barley grain and rye grain should be 0.3 ppm, for barley and rye straw should be 15.0 ppm. New tolerances for barley hay and rye forage should be established at 2.0 ppm

The most recent wheat processing study (HED memo of 02/02/05, Y. Donovan, D271790) indicated that the maximum expected residues of total propiconazole in wheat bran is 0.99 ppm which is determined by multiplying the average concentration factor of 3.3x with the highest average field trial (HAFT) residue value of 0.3 ppm. **A tolerance for wheat bran at 1.0 ppm is needed.**

The average concentration factor of residues in aspirated wheat grain fraction is 13.7x from the new submitted processing study (HED memo of 02/02/05, Y. Donovan, D271790). Based on the field trials, the proposed tolerance on wheat grain is 0.3 ppm, and therefore, the maximum AGF residue would be 4.3 ppm. The maximum expected propiconazole residues in soybean aspirated grain fractions would be 3.5 ppm (memo of 03/10/05, T. Morton, D246884). A 20 ppm AFG tolerance was established on barley based on a Section 18 use on barley, which is based on the tolerance level for grain sorghum grain (0.2 ppm), and the maximum concentration factor of 100x. This Section 18 tolerance will expire on 06/30/05. No data are yet available on aspirated grain



fractions derived from corn (A 0.1 ppm tolerance on corn grain has been established). However, HED believes that residues from corn AGF will not likely to be higher than that from wheat based on the fact that wheat grain has higher residues than corn grain, therefore, **HED recommends a 5.0 ppm tolerance on aspirated grain fractions for propiconazole.**

The commodity definitions for corn RAC tolerances are currently expressed as corn *per se*. When the definition is revised to "corn, field", tolerances for popcorn grain and stover, expressed in terms of "corn, pop", will need to be established at levels of 0.1 ppm and 12 ppm, respectively. In addition, tolerances for "corn, sweet, forage" and "corn, sweet, stover" will need to be established at 12 ppm.

A new rice processing study has been submitted and reviewed as acceptable by the Agency (MRID 45080811.DER2), the review indicated that the concentration factor for rice bran is 2.9x, for rice hulls is 3.8x, and for polished rice is 0.12x. The registrant needs to propose new tolerances for rice bran at 1.0 ppm and for rice hulls at 1.2 ppm.

Additional data have also been required for pineapple juice.

**HED notice that due to the change of tolerance expression from parent plus all its metabolites containing the 2,4-dichlorophenyl moiety (2,4-DCBA) to parent only, in some cases the tolerance levels will be over estimated. Since all field data were reported as propiconazole and all its metabolites containing the 2,4-dichlorophenyl moiety (2,4-DCBA), due to the fact that the analytical/data collection method is a moiety method that detects all residues convertible to 2,4-dichlorobenzoic acid (DCBA), HED is unable to separate out the parent residue from the metabolites at this time. HED recommends that the registrant analyze parent and metabolites separately in all field trials so that more realistic tolerances can be set in the future.**

#### Time-Limited Tolerances Established Under 40 CFR §180.434(b)

Time-limited tolerances, due to expire 12/31/05, are established for cranberry, dry bean forage, dry bean hay, and dry beans. In addition, time-limited tolerances, due to expire 06/30/05, are established for aspirated grain fractions (20 ppm), sorghum grain, and stover [40 CFR §180.434(b)]. Time-limited tolerances are being recommended by RD to be established in/on soybeans at 0.5 ppm, in/on soybean forage at 8 ppm, and in soybean hay at 25 ppm, in/on blueberry at 1.0 ppm.

#### Tolerances with Regional Registrations Established Under 40 CFR §180.434(c)

Tolerances with regional registrations have been established for the following RACs **as defined**: mint, tops (leaves and stems) and wild rice. The tolerance for mint is restricted to use west of the Cascade Mountains only, and the tolerance for wild rice is restricted to MN. Sufficient field trial

data are available to assess the established tolerances with regional registrations for mint and wild rice at the same levels.

#### Pending Tolerance Petitions

PP# 4F3007: Syngenta has proposed the establishment of tolerances for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in/on **pecans**.

PP# 4G3075: Syngenta has proposed the establishment of tolerances for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in/on rice and wheat.

PP#9F3470: Syngenta has proposed the establishment of tolerances for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in/on tree nuts at 0.1 ppm and almond hulls at 0.1 ppm. The petitioner also proposes removal of the established tolerance for pecans on establishment of the proposed tree nut crop group tolerance. The petition is currently in reject status pending resolution of certain label deficiencies and revision of the proposed use pattern (DP Barcodes D229114 and D234297, 3/27/97, L. Kutney; DP Barcode D229723, 3/26/97, L. Kutney; DP Barcode D222232 and D216602, 3/28/96, W. Cutchin).

PP#2F6371: Syngenta has proposed the establishment of tolerances for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound equivalent in or on strawberries, sugar beets, wheat, corn, rice, sorghum, carrots, onions, berry group dry beans, soybeans, almonds, and tree nuts as follows. This petition supercedes PP# 4F3007, 4G3075, 5F4424, 5F4498, 5F4591, 9F3740 (DP Barcode D312277, 313278, 313693, not reviewed)

PP#5F4591: Syngenta has proposed the establishment of tolerances for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in/on the berry crop group at 1.0 ppm, green onions at 8.0 ppm, dry bulb onions at 0.3 ppm, and carrots at 0.2 ppm. Following data review, HED recommended against establishment of the proposed permanent tolerances because of deficiencies pertaining to plant metabolism, residue analytical methods, and storage stability. HED recommended for establishment of time limited tolerances for the above commodities at the proposed levels pending revisions to label and use patterns (DP Barcode D219664, 6/12/96, L. Kutney). This petition has been superseded by PP#2F6371.

PP#5F4424: Syngenta has proposed the establishment of tolerances for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in/on soybeans at 0.5 ppm, soybean forage at 8.0 ppm, soybean fodder/straw at 8.0 ppm, soybean hay at 25.0 ppm, dry beans at 0.5 ppm, dry bean vines/forage at 8.0 ppm, and dry bean hay at 8.0 ppm. The petition is currently in reject status pending revision of the proposed use pattern (DP Barcode D246884, and DP Barcodes D210266 and D210295, 3/5/97, M. Rodriguez), (D246884, 03/10/2005, T. Morton). This petition has been superseded by PP#2F6371.

PP#5F4498: Syngenta Crop Protection, Inc. has proposed the establishment of inadvertent/rotational crop tolerances for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound equivalent in or on grain sorghum, grain at 0.2 ppm; grain sorghum, forage at 0.3 ppm; grain sorghum, fodder (stover) at 0.3 ppm; alfalfa, forage at 0.1 ppm; and alfalfa, hay at 0.1 ppm. (DP Barcode D216415; not reviewed). This petition has been superseded by PP#2F6371.

PP#9F3740: Syngenta Crop Protection, Inc. has proposed the establishment of tolerances for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound equivalent in or on almonds and the tree nuts crop group. (DP Barcode D234716, not reviewed). This petition has been superseded by PP#2F6371.

PP#6E4788: Inter-regional Project No. 4 (IR-4) has proposed the establishment of tolerances for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound equivalent in or on celery. (DP Barcode D238458, not reviewed)

PP#7E4860: Inter-regional Project No. 4 (IR-4) has proposed the establishment of tolerances for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound equivalent in or on cranberry. (DP Barcode D238468, not reviewed)

PP#8E4931: Inter-regional Project No. 4 (IR-4) has proposed the establishment of tolerances for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound equivalent in or on mint. (DP Barcode D247313, D313963, not reviewed)

Table C. Tolerance Reassessment Summary for Propiconazole.

| Commodity  | Current Tolerance, ppm | Reassessed Tolerance, ppm | Comment<br>[Correct Commodity Definition]  |
|--|------------------------|---------------------------|--|
| <b>Tolerances Established Under 40 CFR §180.434(a)</b> |                        |                           |  |
| Bananas  | 0.2                    | 0.2                       | [Banana]   |
| Barley, grain  | 0.1                    | 0.3                       | Translated from wheat data. Memo of 02/02/05, Y. Donovan, D271790.   |
| Barley, straw  | 1.5                    | 15.0                      | Translated from wheat data. Memo of 02/02/05, Y. Donovan, D271790.   |
| Cattle, fat  | 0.1                    | 0.1                       | 0.08 ppm combined residues in fat were expected from MTDB.   |
| Cattle, kidney   | 2.0                    | 2.0                       | 1.01 ppm combined residues in kidney were expected from MTDB. However, several new uses are pending which may increase the MTDB. |
| Cattle, liver  | 2.0                    | 2.0                       | 1.33 ppm combined residues in liver were expected from MTDB. However, several new uses are pending which may increase the MTDB.  |
| Cattle, meat byproducts, except kidney and liver       | 0.1                    | 0.1                       | (see comments above in fat)  |
| Cattle, meat   | 0.1                    | 0.1                       | 0.04 ppm combined residues in meat were expected from MTDB. However, several new uses are pending which may increase the MTDB.   |
| Celery   | 5.0                    | 5.0                       |  |
| Corn, field, stover                                    | 12                     | 12                        | Expiration date 11/30/08<br>[Corn, field, stover]  |
| Corn, field, forage                                    | 12                     | 12                        | Expiration date 11/30/08<br>[Corn, field, forage]  |
| Corn, field, grain                                     | 0.1                    | 0.1                       | Expiration date 11/30/08<br>[Corn, field, grain]   |
| Corn, sweet, kernels plus cobs with husks removed      | 0.1                    | 0.1                       | Expiration date 11/30/08<br>[Corn, sweet, kernels plus cobs with husks removed]  |
| Eggs   | 0.1                    | Revoke                    | Feeding study data indicate that tolerances for poultry commodities are not necessary.   |
| Fruit, Stone, group 12                                 | 1.0                    | 1.0                       | [Fruit, stone, group 12]   |
| Goat, fat  | 0.1                    | 0.1                       | (see comments in cattle)   |
| Goat, kidney   | 2.0                    | 2.0                       | (see comments in cattle)   |
| Goat, liver  | 2.0                    | 2.0                       | (see comments in cattle)   |

| Commodity                                      | Current Tolerance, ppm | Reassessed Tolerance, ppm | Comment<br>[Correct Commodity Definition]   |
|--|------------------------|---------------------------|---|
| Goat, meat byproducts, except kidney and liver | 0.1                    | 0.1                       | (see comments in cattle)  |
| Goat, meat                                     | 0.1                    | 0.1                       | (see comments in cattle)  |
| Grass, forage                                  | 0.5                    | 0.5                       |   |
| Grass, hay (straw)                             | 40                     | 40                        | [Grass, hay]  |
| Grass, straw                                   | 40                     | 40                        | [Grass, straw]  |
| Hog, fat                                       | 0.1                    | 0.1                       | (see comments in cattle)  |
| Hog, kidney                                    | 2.0                    | 2.0                       | (see comments in cattle)  |
| Hog, liver                                     | 2.0                    | 2.0                       | (see comments in cattle)  |
| Hog, meat byproducts, except kidney and liver  | 0.1                    | 0.1                       | (see comments in cattle)  |
| Hog, meat                                      | 0.1                    | 0.1                       | (see comments in cattle)  |
| Horse, fat                                     | 0.1                    | 0.1                       | (see comments in cattle)  |
| Horse, kidney                                  | 2.0                    | 2.0                       | (see comments in cattle)  |
| Horse, liver                                   | 2.0                    | 2.0                       | (see comments in cattle)  |
| Horse, mbyprod (except kidney and liver)       | 0.1                    | 0.1                       | [Horse, meat byproducts, except kidney and liver](see comments in cattle)   |
| Horse, meat                                    | 0.1                    | 0.1                       | (see comments in cattle)  |
| Milk   | 0.05                   | 0.05                      | 0.03 ppm combined residues in milk were expected from 26.5ppm MTDB.   |
| Mushroom                                       | 0.1                    | 0.1                       | Use of propiconazole on mushrooms is being supported by IR-4. Currently there are no registered uses of propiconazole on mushrooms.<br>[Mushroom] |
| Oat, forage                                    | 10.0                   | 10.0                      | [Oat, forage]   |
| Oat, grain                                     | 0.1                    | 0.1                       | [Oat, grain]  |
| Oat, hay                                       | 30.0                   | 2.0                       | Translated from wheat hay.<br>[Oat, hay]  |
| Oat, straw                                     | 1.0                    | 1.0                       | [Oat, straw]  |
| Peanut   | 0.2                    | 0.2                       | Expiration date 11/30/08<br>[Peanut]. Parent accounted 30% of the TRR based on peanut metabolism (MARC memo of 4/4/02, D279299).                  |
| Peanut, hay                                    | 20.0                   | 20.0                      | Expiration date 11/30/08<br>[Peanut, hay]   |
| Pecans   | 0.1                    | 0.1                       | Syngenta has proposed removal of the  |

| Commodity   | Current Tolerance, ppm    | Reassessed Tolerance, ppm | Comment<br>[Correct Commodity Definition]  |
|---|---------------------------|---------------------------|--|
|   |                           |                           | established tolerance for pecans on establishment of the proposed tree nut crop group tolerance (pending tolerance petition PP#9F3470).  |
| Pineapple   | 0.1                       | 0.1                       | Expiration date 11/30/08   |
| Pineapple, fodder   | 0.1                       | Revoke                    | Expiration date 11/30/08; no longer considered a significant livestock feed item.  |
| Plum, prune, fresh  | 1.0                       | Revoke                    | This tolerance has been replaced by the stone fruits group tolerance.  |
| Rice, grain   | 0.1                       | 0.3                       | The available data, reflecting the maximum registered use pattern, indicate that the maximum combined residues of propiconazole and its metabolites determined as 2,4-DCBA were 0.28 ppm in/on rice grain. (HED memo of 02/23/05, T. Morton, D240856). |
| Rice, straw   | 3.0                       | 3.0                       | (HED memo of 02/23/05, T. Morton, D240856).  |
| Rye, grain  | 0.1                       | 0.3                       | Translated from wheat data. Memo of 02/02/05, Y. Donovan, D271790.   |
| Rye, straw  | 1.5                       | 15.0                      | Translated from data for wheat straw.  |
| Sheep, fat  | 0.1                       | 0.1                       | (see comments in cattle)   |
| Sheep, kidney   | 2.0                       | 2.0                       | (see comments in cattle)   |
| Sheep, liver  | 2.0                       | 2.0                       | (see comments in cattle)   |
| Sheep, meat byproducts, except kidney and liver           | 0.1                       | 0.1                       | (see comments in cattle)   |
| Sheep, meat   | 0.1                       | 0.1                       | (see comments in cattle)   |
| Wheat, grain  | 0.1                       | 0.30                      | Memo of 02/02/05, Y. Donovan, D271790.   |
| Wheat, straw  | 1.5                       | 15.0                      | Memo of 02/02/05, Y. Donovan, D271790.   |
| <b>Tolerances To Be Proposed Under 40 CFR §180.434(a)</b> |                           |                           |  |
| Grain, aspirated fractions                                | 20 (sorghum) <sup>1</sup> | 5.0                       | Memo of 02/02/05, Y. Donovan, D271790. [Grain, aspirated fraction]   |
| Barley, hay   | None established          | 2.0                       | Translate from wheat hay   |
| Corn, pop. grain  | None established          | 0.1                       | Translate from field corn  |
| Corn, pop. stover   | None established          | 12                        | Translate from field corn  |

| Commodity  | Current Tolerance, ppm | Reassessed Tolerance, ppm | Comment<br>[Correct Commodity Definition]   |
|--|------------------------|---------------------------|---|
| Corn, sweet, forage                                    | None established       | 12                        | Translate from field corn   |
| Corn, sweet, stover                                    | None established       | 12                        | Translate from field corn   |
| Rice, bran   | None established       | 1.0                       | Concentration factor for rice bran is 2.9x. (MRID45080811DER2)                                  |
| Rice, hulls  | None established       | 1.2                       | Concentration factor for rice hulls is 3.8x. (MRID45080811DER2)                                 |
| Rye, forage  | None established       | 2.0                       | Memo of 02/02/05, Y. Donovan, D271790.  |
| Wheat forage   | None established       | 2.0                       | Memo of 02/02/05, Y. Donovan, D271790. [wheat, forage]  |
| Wheat hay  | None established       | 2.0                       | Memo of 02/02/05, Y. Donovan, D271790. [Wheat, hay]   |
| Wheat Bran   | None established       | 1.0                       | Memo of 02/02/05, Y. Donovan, D271790. [Wheat, bran]  |
| <b>Tolerances Established Under 40 CFR §180.434(b)</b> |                        |                           |   |
| Blueberry  | 1.0                    | N/A                       | Expiration date 11/31/07. Recommended in Agency memo of 02/22/05, D. Rate, D313289. [Blueberry] |
| Cranberry  | 1.0                    | N/A                       | Expiration date 12/31/05 [Cranberry]  |
| Dry bean forage  | 8.0                    | N/A                       | Expiration date 12/31/05 [Bean, dry, forage]  |
| Dry bean hay   | 8.0                    | N/A                       | Expiration date 12/31/05 [Bean, dry, hay]   |
| Dry bean   | 0.5                    | N/A                       | Expiration date 12/31/05 [Bean, dry]  |
| Sorghum, aspirated grain fractions                     | 20                     | N/A                       | Expiration date 06/30/05  |
| Sorghum, grain, grain                                  | 0.2                    | N/A                       | Expiration date 06/30/05 [Sorghum, , grain, grain]  |
| Sorghum, grain, stover                                 | 1.5                    | N/A                       | Expiration date 06/30/05  |
| Soy bean, bean   | 0.5 (pending)          | N/A                       | Agency memo of 04/14/04, J. R. Tomerlin, D262299.   |
| Soybean, forage  | 8.0 (pending)          | N/A                       | Agency memo of 04/14/04, J. R. Tomerlin, D262299.   |
| Soybean, hay   | 25.0 (pending)         | N/A                       | Agency memo of 04/14/04, J. R. Tomerlin, D262299.   |
| <b>Tolerances Established Under 40 CFR §180.434(c)</b> |                        |                           |   |

| Commodity                              | Current Tolerance, ppm | Reassessed Tolerance, ppm | Comment<br><i>[Correct Commodity Definition]</i>   |
|--|------------------------|---------------------------|--|
| Sunflower                              | None established       | TBD <sup>2</sup>          |  |
| Peppermint, tops;<br>[Spearmint, tops] | 0.3                    | 0.3                       | Regional registration for use west of the Cascade Mountains only. <i>[Peppermint, tops]</i> <i>[Spearmint, tops]</i> |
| Rice, wild                             | 0.5                    | 0.5                       | MN<br><i>[Rice, wild]</i>  |

<sup>1</sup> The 20-ppm tolerance for sorghum aspirated grain fractions is a time-limited tolerance to support a Section 18 Exemption.

<sup>2</sup> Tolerance can not be established until field data are submitted.



## CODEX HARMONIZATION

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for propiconazole in/on various raw agricultural commodities. The Codex MRLs are expressed in terms of propiconazole *per se*, which is in harmonized with the US tolerance expression. HED has harmonized tolerance levels on most commodities that have Codex MRLs to the extent possible. A numerical comparison of the Codex MRLs and the corresponding **reassessed** U.S. tolerances is presented in Table D.

Table D. Codex MRLs for Propiconazole and applicable U.S. tolerances.

| Codex                                 |                          |      | Reassessed U.S. Tolerance (ppm) | Recommendation and Comments          |
|---------------------------------------|--------------------------|------|---------------------------------|--------------------------------------|
| Commodity (As Defined)                | MRL <sup>1</sup> (mg/kg) | Step |                                 |                                      |
| Almonds                               | 0.05                     | CXL  | --                              | No U.S. registration.                |
| Banana                                | 0.1                      | CXL  | TBD                             |                                      |
| Barley                                | 0.05                     | CXL  | 0.3                             |                                      |
| Coffee beans                          | 0.1                      | CXL  | --                              | No U.S. registration.                |
| Edible offal (mammalian)              | 0.05                     | CXL  | --                              | No U.S. registration.                |
| Eggs                                  | 0.05 (*)                 | CXL  | --                              | No U.S. registration.                |
| Grapes                                | 0.5                      | CXL  | --                              | No U.S. registration                 |
| Mango                                 | 0.05                     | CXL  | --                              | No U.S. registration.                |
| Meat (from mammals other than marine) | 0.05 (*)                 | CXL  | 0.1                             |                                      |
| Milks                                 | 0.01 (*)                 | CXL  | 0.05                            | Unable to harmonize <sup>2</sup>     |
| Oats                                  | 0.05 (*)                 | CXL  | 0.1                             |                                      |
| Peanut                                | 0.05                     | CXL  | 0.1                             | Unable to harmonize <sup>2</sup>     |
| Peanut, whole                         | 0.1                      | CXL  | -                               | Not currently regulated by U.S. EPA. |
| Pecan                                 | 0.05                     | CXL  | 0.1                             | Unable to harmonize <sup>2</sup>     |
| Poultry meat                          | 0.05 (*)                 | CXL  | --                              | No U.S. registration.                |
| Rape seed                             | 0.05                     | CXL  | --                              | No U.S. registration.                |
| Rye                                   | 0.05 (*)                 | CXL  | 0.3                             | Unable to harmonize <sup>2</sup>     |
| Stone fruits                          | 1                        | CXL  | 1.0                             |                                      |
| Sugar beet                            | 0.05                     | CXL  | --                              | No U.S. registration.                |
| Sugar beet leaves or tops             | 0.5                      | CXL  | --                              | No U.S. registration.                |

| Codex                  |                          |      | Reassessed U.S. Tolerance (ppm) | Recommendation and Comments                   |
|------------------------|--------------------------|------|---------------------------------|---|
| Commodity (As Defined) | MRL <sup>1</sup> (mg/kg) | Step |                                 |   |
| Sugar cane             | 0.05                     | CXL  | --                              | Use in the U.S. is considered a non food use. |
| Wheat                  | 0.05 (*)                 | CXL  | 0.30                            | Unable to harmonize due to higher use rate    |

<sup>1</sup> Asterisk designates MRL set at the limit of quantitation.

<sup>2</sup> Can not harmonize because current use patterns in the U.S. supports the higher value.

AGENCY MEMORANDA RELEVANT TO REREGISTRATION

CB No.: None  
Subject: PP#4F3007 (Acc. Nos. 072212-072217 and 072219): CGA-64250 (Tilt) in Pecans. Evaluation of Residue Data and Analytical Method  
From: A. Smith  
To: H. Jacoby and Toxicology Branch  
Dated: 5/15/84  
MRID: 00067905, 00074495-99, 00074500-04, 00074508, 00074509, 00129915, and 00155645

CB No.: None  
Subject: PP#4F0326: Tilt on Bananas. Evaluation of Analytical Methods and Residue Data. Accession Nos. 072283, 072284, 072285.  
From: K. Arne  
To: H. Jacoby and Toxicology Branch  
Dated: 6/20/84  
MRID: 00137150

CB No.: None  
Subject: PP#4F3074 (Accession Nos. 072490, 072556, 072557): Tilt® on Small Grains. Evaluation of Residue Data and Analytical Method.  
From: A. Smith  
To: H. Jacoby and Toxicology Branch  
Dated: 7/12/84  
MRID: 00137861

EFGWB No.: 70289  
Subject: EFGWB Review of Additional Environmental Data for Propiconazole  
From: E. Regelman  
To: L. Rossi  
Dated: 3/23/87  
MRID: 00129915, 00155645, and 00164802

CB No.: 2108  
Subject: PP#4F3074, 4F3007, and 4E3026. Propiconazole (Tilt® or CGA-64250) on Crops and Livestock Commodities. Results of the Multiresidue Method Testing.  
From: S. Malak  
To: L. Rossi  
Dated: 4/28/87  
MRID: 40100101

CB No.: 2174  
Subject: PP#'s 4F3074, 4F3007, and 4E3026. Propiconazole (Tilt® or CGA-64250) on Crops and Livestock Commodities. Additional Recovery Data, Sample Chromatograms, and Sample Calculation on Analytical Methods AG-454A and AG-517. Letter of April 6, 1987.  
From: S. Malak  
To: L. Rossi  
Dated: 5/7/87  
MRID: 40154501

CB No.: 2172  
Subject: PP#'s 4F3074, 4F3007, and 4E3026. Propiconazole (Tilt® or CGA-64250) on Crops and Livestock Commodities. Residue Data in or on Livestock Commodities Using Ciba-Geigy's Method AG-359. Amendment of April 2, 1987.  
From: S. Malak  
To: L. Rossi and Toxicology Branch  
Dated: 5/14/87  
MRID: 40150701

CB No.: 2262  
Subject: PP#'s 4F3074, 4F3007, and 4E3026. Propiconazole (Tilt® or CGA 64250) on Crops and Livestock Commodities. Revisions to Analytical Methods AG-454A and AG-517. Amendment of May 2, 1987.  
From: S. Malak  
To: L. Rossi and Toxicology Branch  
Dated: 5/15/87  
MRID: 40180700-40180702

EFGWB No.: 70297  
Subject: EFGWB Review of Submission of Metabolism Data for Propiconazole  
From: E. Regelman  
To: L. Rossi  
Dated: 5/18/87  
MRID: 00155644

CB No.: 2303  
Subject: PP#'s 4F3074. Propiconazole (Tilt®, Banner, or CGA-64250®) on Crops and Livestock Commodities. Revised Sections F and B. Amendment of May 12, 1987.  
From: S. Malak  
To: L. Rossi and Toxicology Branch  
Dated: 5/28/87  
MRID: None

CB No.: None  
Subject: PP#4F3074, 4F3007, and 4E3026. Propiconazole (Tilt® or CGA-64250) on Crops and Livestock Commodities. Evaluation of Method Trial Report for Ciba-Geigy's Method AG454A and AG-517.  
From: S. Malak  
To: L. Rossi and Toxicology Branch  
Dated: 5/28/87  
MRID: None

CB No.: 4108  
Subject: PP# 8F3654, Tilt® (Propiconazole) In or On Peanuts and Peanut Hulls/Hay. Evaluation of Analytical Methodology and Residue Data.  
From: H. Fonouni  
To: L. Rossi and Toxicology Branch  
Dated: 11/22/88  
MRID: 40692201-40692206

CB No.: 4279  
Subject: PP# 8F3674. Propiconazole in/on Celery, Corn, Pineapples, and Legume Vegetables. Evaluation of the Analytical Methodology and Residue Data.  
From: C. Deyrup  
To: L. Rossi and Toxicology Branch  
Dated: 12/14/88  
MRID: 40783301, 40783303, 40783305, 40783306

CBRS No. 4687  
Subject: EPA Reg. No. 100-617. Tilt® (propiconazole) residues on grass seed screenings incorporated into animal feed.  
From: L. Propst  
To: L. Rossi  
Dated: 12/15/88  
MRID: None

EFGWB No.: 90613  
Subject: EFGWB Review of Request to Amend Federal Label to Permit Double-Cropping of Treated Winter Wheat with Soybeans for Propiconazole.  
From: E. Regelman  
To: S. Lewis/Stone  
Dated: 10/19/89  
MRID: 41102001

CBTS No.: 5226 - 5228  
Subject: PP#9F3758 & Reg. Nos. 100-617 & 100-702. Propiconazole (Tilt) in or on Wild Rice and Stone Fruit. Evaluation of Residue Data and Analytical Methods.  
From: S. Malak  
To: S. Lewis and Toxicology Branch  
Dated: 11/28/89  
MRID: 41063800-41063803

CB No.: 6724  
Subject: PP#0F3869: Propiconazole (Tilt®) in or on Celery. Amendment of 3/1/90.  
From: W. Chin  
To: S. Lewis and Toxicology Branch  
Dated: 8/15/90  
MRID: 41486801 and 41486802

CB No.: 7822  
Subject: PP No. 1F3974. Propiconazole on Grass Seed Screenings, Straw, and Forage. Evaluation of Residue Data and Analytical Methodology. HED Project No. 1-0964.  
From: S. Willett  
To: S. Lewis/J. Stone and Toxicology Branch  
Dated: 6/11/91  
MRID: 41823300-41823305

DP Barcode: D164460  
Subject: EFGWB Review of Request to Remove Double Cropping Restriction from Label for Propiconazole (EPA Reg. No. 100-617).  
From: P. Mastradone  
To: S. Lewis/S. Jackson  
Dated: 11/7/91  
MRID: None

DP Barcode: D171368  
Subject: PP No. 9F3706. Propiconazole on Grass Seed Screenings, Straw, and Forage. Ciba-Geigy Request for a Waiver for Aerial Field Trial Data Requirements.  
From: S. Willett  
To: S. Lewis/J. Stone and Toxicology Branch  
Dated: 12/18/91  
MRID: None

DP Barcode: D170759  
Subject: PP#2E04037. Propiconazole (Tilt® Fungicide, EPA Reg. No. 100-617) in or on mint. Evaluation of analytical method and magnitude of residue data.  
From: W. Wassell  
To: H. Jamerson and Toxicology Branch  
Dated: 2/14/92  
MRID: 42061301

DP Barcode: D183633  
Subject: PP#9F3758: Propiconazole (Tilt, Orbit) in Wild Rice, Apricots, Nectarines, Peaches, Plums, and Prunes. Amendment of October 8, 1992. EPA Reg. Nos. 100-618, 100-617, 100-702.  
From: M. Rodriguez  
To: S. Lewis/S. Jackson  
Dated: 4/8/93  
MRID: 42511401

DP Barcode: D189618  
Subject: PP#2E04037. Propiconazole (Tilt® Fungicide, EPA Reg. No. 100-617) in or on mint. Questions concerning outstanding data requirements (letter dated 3/22/93).  
From: W. Wassell  
To: H. Jamerson  
Dated: 4/12/93  
MRID: None

DP Barcode: D185251  
Subject: PP#8F3674 – Propiconazole (Tilt®) in/on Corn and Pineapple. Ciba-Geigy Amendment Dated 11/20/92.  
From: M. Flood  
To: S. Lewis/S. Jackson  
Dated: 5/6/93  
MRID: 42564004-42564006

DP Barcode: D187417, D190147, and D190263  
Subject: PP#1F3974. Propiconazole (Tilt®) in/on Grasses Grown for Seed. Ciba-Geigy Amendment Dated 1/14/93.  
From: M. Flood  
To: S. Lewis/S. Jackson and A. Kocialski  
Dated: 5/12/93  
MRID: 42449501, 42634101, and 42634102



DP Barcode: D190499  
Subject: PP#9F3758: Propiconazole (Tilt®, Orbit®) in Wild Rice, Apricots, Nectarines, Peaches, Plums, and Prunes. Amendment of April 20, 1993. EPA Reg. Nos. 100-618, 100-617, 100-702.  
From: M. Rodriguez  
To: S. Lewis/S. Jackson and A. Kocialski  
Dated: 6/2/93  
MRID: None

DP Barcode: None  
Subject: PP#8F3674 – Propiconazole in/on Corn and Pineapple. Need for DRES Analysis.  
From: M. Flood  
To: S. Lewis/S. Jackson and A. Kocialski/S. Willett  
Dated: 6/15/93  
MRID: None

DP Barcode: D174248 and D175989  
Subject: PP#2F4086. Propiconazole (Tilt) in/on Oat Grain and Straw. Evaluation of Analytical Method and Residue Data.  
From: R. Lascola  
To: S. Jackson/S. Lewis  
Date: 7/20/93  
MRID(S): 42182901

DP Barcode: D191918  
Subject: PP#8F3674. Propiconazole (Tilt®) in/on Corn and Pineapple. Ciba-Geigy Amendment Dated 5/28/93.  
From: M. Flood  
To: S. Jackson  
Date: 9/20/93  
MRID(S): None

DP Barcode: D192904  
Subject: PP#1F3974. Propiconazole (Tilt) in/on Grasses Grown for Seed. Ciba-Geigy Amendment Dated 7/2/93.  
From: M. Flood  
To: S. Jackson and A. Kocialski  
Date: 9/20/93  
MRID(S): None

DP Barcode: D195566  
Subject: Propiconazole. List C Reregistration Case No. 3125/Chemical ID No. 112101. 6(a)(2) Data: Over-tolerance Residues in Rice Grain and Processed Fractions.  
From: C. Swartz  
To: B. Sidwell  
Dated: 11/2/93  
MRID: 42915600 and 42915601

DP Barcodes: D186202, D186203, D186205, D186206, and D195499  
Subject: PP#8F3654. Propiconazole (Tilt®) in/on Peanuts. Amendment Dated 12/23/92. (Received CBTS 10/1/93).  
From: M. Flood  
To: C. Lewis  
Dated: 11/8/93  
MRID: 42605801

DP Barcode: D197841  
Subject: PP#8F3654. Propiconazole (Tilt®) in/on Peanuts. Amendment Dated 12/6/93. Request for Time-Limited Tolerances.  
From: M. Flood  
To: S. Jackson/D. Greenway and A. Kocialski  
Dated: 1/25/94  
MRID: None

DP Barcode: D196789  
Subject: PP#8F3674. Propiconazole (Tilt®) in/on Corn and Pineapple. Submission Dated 10/25/93.  
From: M. Flood  
To: S. Jackson/D. Greenway  
Date: 3/24/94  
MRID: 42983001

DP Barcode: D198815  
Subject: Propiconazole. 90 Day Response. Chemical I.D. No. 122101. List C Case No. 3125.  
From: F. Fort  
To: R. Gebken/B. Sidwell  
Dated: 4/26/94  
MRID: None

DP Barcode: D210742  
Subject: PP2F04086: Propiconazole in/on Oats. Amendment Dated July 15, 1994; Response to CBTS #s 9325/9603.  
From: M. Rodriguez  
To: S. Lewis/D. Greenway and J. Smith  
Dated: 3/15/95  
MRID: 43314201 and 43314202

DP Barcode: D209195  
Subject: PP#5E04437, Evaluation of Analytical Method and Residue Data. Propiconazole on Mushrooms. Chemical # 122101.  
From: W. Cutchin  
To: H. Jamerson  
Dated: 3/29/95  
MRID: 43434201

DP Barcode: D209468  
Subject: PP#2E04037. Propiconazole (Tilt® Fungicide, EPA Reg. No. 100-617) in or on mint. Amendment submitted on 10/24/94.  
From: W. Wassell  
To: H. Jamerson and J. Smith  
Dated: 4/25/95  
MRID: 43424601

DP Barcode: D210252  
Subject: PP#4F04321, Propiconazole in/on Stone Fruit. Request for Group Tolerance. Chemical # 122101.  
From: W. Cutchin  
To: C. Welch and J. Smith  
Dated: 4/25/95  
MRID: None

DP Barcode: D217199  
Subject: PP#4F04321 Amended Petition: Request for Group Tolerance. Propiconazole in/on Stone Fruit. Crossover Studies for New Formulation. Chemical # 122101. CBTS #: 15866.  
From: W. Cutchin  
To: C. Welch  
Dated: 8/14/95  
MRID: 43655609

DP Barcode: D218453  
Subject: PP#2F04086: Propiconazole in/on oats. Amendment Dated April 7, 1995; Response to CBTS Review #14941.  
From: M. Rodriguez  
To: C. Welch/K. Scanlon  
Dated: 8/24/95  
MRID: None

DP Barcode: D209612  
Subject: Propiconazole. Registrant Response. Chemical ID No. 122101. List C Case No. 3125.  
From: F. Fort  
To: R. Gebken/B. Sidwell  
Dated: 12/19/95  
MRID: None

DP Barcodes: D216602 and D222232  
Subject: PP#9F3740 Propiconazole in/on Almonds, Almond Hulls, and Tree Nut Crop Group. Request for Group Tolerance. Revised Section Bs and New Section F. Chemical #122101.  
From: W. Cutchin  
To: C. Welch and D. McCall  
Dated: 3/28/96  
MRID(s): None

DP Barcode: D219664  
Subject: PP No. 5F04591, Propiconazole on the berry crop grouping, carrots, and onions (green and dry bulb). Chemical No. 122101.  
From: L. Kutney  
To: D. McCall  
Dated: 6/12/96  
MRID(s): 43786401-43786404

DP Barcode: D210266 and D210295  
Subject: PP#5F04424 and ID#000100-00618 CGA-64250 Technical: Propiconazole in/on Dry Beans and Soybeans. Evaluation of Residue Data and Analytical Methodology.  
From: M. Rodriguez  
To: D. McCall/S. Robbins  
Dated: 3/5/97  
MRID(s): 43386501 and 43386502

DP Barcode: D229723  
Subject: PP#9F3740 Propiconazole in/on Almonds, Almond Hulls, and Tree Nut Crop Group. Revised Section B for the ORBIT 45W Formulation. Chemical # 122101.  
From: L. Kutney  
To: C. Welch and K. Scanlon and D. McCall  
Dated: 3/26/97  
MRID: None

DP Barcodes: D229114 and D234297  
Subject: PP#9F3740 Propiconazole in/on Almonds, Almond Hulls, and Tree Nut Crop Group. Revised Section B and Section F for ORBIT and ORBIT GEL. Chemical # 122101.  
From: L. Kutney  
To: C. Welch and K. Scanlon and D. McCall  
Dated: 3/27/97  
MRID: None

DP Barcode: D250861  
Subject: EXTENSION OF TIME LIMITED TOLERANCES OF **PROPICONAZOLE ON CORN, PINEAPPLES (PP#8F3674) AND PEANUTS (PP#8F3654)**  
From: Margarita Collantes,  
To: Mary Waller, PM Team 21  
Dated: 11/19/98  
MRID: None

DP Barcode: D220935  
Subject: Propiconazole (122101): Residue Analytical Method (GLN 860.1340) and Storage Stability Data (GLN 860.1380). Case 3125.  
From: T. Morton  
To: M. Hartman/K. Monk  
Date: 3/25/99  
MRID: 43825401 and 43825402

DP Barcode: D233755  
Subject: Propiconazole (122101): Nature of the Residue Celery (GLN 860.1300) and Magnitude of the Residue in Sugar Cane (GLN 860.1500). Case 3125.  
From: T. Morton  
To: M. Hartman/K. Monk  
Dated: 9/14/99  
MRID: 44049601 and 44142401

DP Barcode: D245249  
Subject: Propiconazole (122101): Nature of the Residue in Spring Wheat (GLN 860.1300).  
From: T. Morton  
To: M. Hartman/K. Monk  
Dated: 12/14/99  
MRID: 44381402

DP Barcode: D284131  
from: Clark Swentzel  
TO: **Richard Keigwin**  
Dated : 07/08/02  
Subject : Review of "Profile of the Triazole-derivative Fungicide Compounds and their Common Metabolites". Ingredient(s) :004401 Amitrole, 120503 Bromuconazole, 128993 Cyproconazole, 128847 Difenconazole, 123909 Epoxiconazole, 129011 Fenbuconazole, 128835 Flusilazole, 128925 Hexaconazole, 128851 Prochloraz, 125601 Paclobutrazol, 122101 Propiconazole.  
MRID#: 45575501

DP Barcode: D267787, D272054.  
Subject: PP#0F06121. PC Code 129112. CAS # 141517-21-7. Trifloxystrobin on Barley, Citrus, Corn (Field and Pop), Pecan, Pistachio, Rice, and Stone Fruit. Review of Analytical Methods and Residue Data. EPA Reg #s: 3125-559, 3125-562.  
From: Leung Cheng, Chemist  
To: Cynthia Giles-Parker, Team 22  
Dated: 01/17/02  
MRID: 45080800, 45080806, 45080808, 45080809, 45080810, 45080811, 45126200, 45269400, 45269401, 45269402, 45276400, 45276401.

DP Barcode: D281520  
Subject: **Propiconazole** (122101): Reassessment of poultry and egg tolerances.  
From: Bonnie Cropp-Kohlligian  
To: Eric Olson, CRM  
Dated: 03/06/02  
MRID: **None**

DP Barcode: D279299  
Subject: **Propiconazole** (122101): Results of the HED Metabolism Assessment Review Committee (MARC) Meetings Held on 18-December-2001 and 08-January-2002. TXR# 0050349  
From: Bonnie Cropp-Kohlligian  
To: Yan Donovan  
Dated: 04/04/02  
MRID: **None**

DP Barcode: D 262299  
Subject: **Propiconazole** (122101): Risk Assessments for the Section 18 Request for Control of Soybean Rust

From: J. R. Tomerlin  
To: Andrew Ertman/Section 18 Team  
Dated: 04/14/04  
MRID: **None**

DP Barcode: D271790  
Subject: **Propiconazole** (122101): Magnitude of Residues in/on wheat for The Registration of **Stratego**<sup>™</sup> use on wheat. MRID 44757208.

From: Yan Donovan  
To: Susan Lewis/Patrick Dobak  
Dated: 02/02/05  
MRID: **MRID 44757208**

DP Barcode: D313289  
Subject: **Propiconazole** (122101): Human Health Risk Assessment for the Section 18 Request for Blueberry in Maine.

From: Debra Rate  
To: Dan Rossenblatt/Andrea Conrath  
Dated: 02/22/05  
MRID: **None**

DP Barcode: D240856  
Subject: Residue Analytical Method(GLN 860.1340), Storage Stability Data(GLN 860.1380), Magnitude of the Residue in Rice and Wheat (GLN 860.1500), and Magnitude of the Residue in Processed Food/Feed Commodities of Wheat (GLN 860.1520)

From: Thurston G. Morton, Chemist  
To: Mark Hartman/Kathy Monk  
Date: 02/23/05  
MRID: **MRID # 44411201, 44411202, 44411203, 44411204, 44411205, 44411206, 44411207, 44411208.**

DP Barcode: D246884  
Subject: PP#5F04424: MRP Soybean Aspirated Grain Fractions  
From: Thurston G. Morton, Chemist  
To: Mark Hartman/Kathy Monk  
Dated: 03/10/05  
MRID: 44549101



## MASTER RECORD IDENTIFICATION NUMBERS

### References Used To Support Reregistration

00067905 Fischer, W.C.; Cassidy, J.E. (1980) Balance and Metabolism of Triazole-<sup>14</sup>C-CGA-64250 in a Lactating Goat: Report No. ABR-80036. (Unpublished study received Jan 28, 1981 under 100-618; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:244269-G)

00074495 Marco, G.J.; Kahrs, R.A. (1981) CGA-64250--Rice and Pecans: Residues Observed and Metabolism Data Including the Analytical Methods Used: Report No. ABR-81020. (Unpublished study received Jun 8, 1981 under 100-EX-69; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:070163-A)

00074496 Madrid, S.; Cassidy, J.E. (1980) The Uptake, Distribution and Characterization of Triazole- and Phenyl-<sup>14</sup>C-CGA-64250 and Their Metabolites in Greenhouse-grown Peanuts: Report No. ABR-80006. (Unpublished study received Jun 8, 1981 under 100-EX-69; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:070164-A)

00074497 Madrid, S.O.; Cassidy, J.E. (1980) Structure Elucidation of Phase I Metabolites of CGA-64250 in Greenhouse-grown Peanut Stalks: Report No. ABR-80037. (Unpublished study received Jun 8, 1981 under 100-EX-69; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:070164-B)

00074498 Madrid, S.O.; Cassidy, J.E. (1981) The Uptake, Distribution and Characterization of Triazole-<sup>14</sup>C-CGA-64250 and Their Metabolites in Field-grown Peanuts: Report No. ABR-81013. (Unpublished study received Jun 8, 1981 under 100-EX-69; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:070164-C)

00074499 Seim, V.; Brown, G. (1979) Biological Report for the Metabolism of Triazole-<sup>14</sup>C-CGA-64250 and [Phenyl]-<sup>14</sup>C-CGA-64250 When Applied as a Foliar Spray to Greenhouse Grown Peanuts: Report No. BIOL-79007. (Unpublished study received Jun 8, 1981 under 100-EX-69; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:070164-D)

00074500 Blattmann, P. (1979) Metabolism of CGA 64 250 in Field Grown Wheat: Project Report 36/79. (Unpublished study received Jun 8, 1981 under 100-EX-69; prepared by Ciba-Geigy, Ltd., Switzerland, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:070164-E)

00074501 Blattmann, P. (1980) Proposed Pathways for the Degradation of CGA 64 250 in Field Grown Wheat: Project Report 17/80. (Unpublished study received Jun 8, 1981 under 100-EX-69; prepared by Ciba-Geigy Ltd., Switzerland, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:070164-F)

- 00074502 Blattmann, P. (1980) Metabolism of CGA 64 250 in Grapevine: Project Report 42/80. (Unpublished study received Jun 8, 1981 under 100-EX-69; prepared by Ciba-Geigy Ltd., Switzerland, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:070164-G)
- 00074503 Madrid, V.; Cassidy, J.E. (1981) Characterization of Metabolites in Urine, Milk and Liver of a Goat Treated with Triazole-<sup>14</sup>C-CGA-64250: Report No. ABR-81007. (Unpublished study received Jun 8, 1981 under 100-EX-69; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:070164-I)
- 00074504 Seim, V.W.; Thomas, W.A. (1980) Biological Report for the Metabolism of Triazole-<sup>14</sup>C-CGA-64250 in a Lactating Goat: Report No. BIOL-80004. (Unpublished study received Jun 8, 1981 under 100-EX-69; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:070164-J)
- 00074508 Ciba-Geigy Corporation (1981) [Residues of CGA-64250 in Rice Field Studies]: AG-A 6144. (Compilation; unpublished study, including AG-A 6195, AG-A 6196, AG-A 6212..., received Jun 8, 1981 under 100-EX-69; CDL:070165-A)
- 00074509 Ciba-Geigy Corporation (1981) [Residues of CGA-64250 in Pecans in Field Studies]: AG-A 6203. (Compilation; unpublished study, including AG-A 6291, received Jun 8, 1981 under 100-EX-69; CDL:070165-B)
- 00074510 Ciba-Geigy Corporation (1981) [Residues of CGA-64250 in Soybeans in Field Studies]: AG-A 6101. (Unpublished study received Jun 8, 1981 under 100-EX-69; CDL:070165-C)
- 00074511 Ross, J.A. (1981) Stability of Residues of CGA-64250 under Freezer Storage Conditions: Report No. ABR-81018. (Unpublished study received Jun 8, 1981 under 100-EX-69; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:070165-D)
- 00129915 Staley, J.; Madrid, S.; Cassidy, J. (1982) The Uptake of Triazole - <sup>14</sup>C-CGA-64250 and Its Soil Degradation Products in Field Rotational Winter Wheat, Lettuce, Corn and Carrots: Report No.: ABR-82007. (Unpublished study received Jul 21, 1983 under 100-641; submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:250783-G)
- 00133385 Ciba-Geigy Corp. (1983) CGA-64250: Pecans. (Compilation; unpublished study received Dec 12, 1983 under 100-617; CDL:072212-A; 072213; 072214; 072215; 072216; 072217)
- 00137150 Ciba-Geigy Corp. (1984) CGA-64250--Bananas. (Compilation; unpublished study received Jan 17, 1984 under 4E3026; CDL:072285-A)
- 00137861 Ciba-Geigy Corp. (1984) [Residue: CGA-64250--Rice]. (Compilation; unpublished study received Apr 6, 1984 under 4F3074; CDL: 072556-A; 072557)
- 00138266 Honeycutt, R. (1983) Rotational Crop Studies with CGA-64250: Report No. EIR-83014. (Unpublished study received Apr 4, 1984 under 100-617; submitted by Ciba-Geigy Corp., Greensboro,

NC; CDL: 253013-A)

00153327 Cheung, M. (1985) CGA-64250-Pecans: Response to EPA's Questions Regarding Section D: Residue Chemistry : Report No. ABR-85050. Unpublished study prepared by Ciba-Geigy Corp. 9 p.

00155644 Szolics, I.; Simoneaux, B. (1985) Metabolism Data and Correlation of Metabolites in Target and Rotation Crops of Propiconazole: Report No. ABR-85056. Unpublished study prepared by Ciba-Geigy. 45 p.

00155645 Madrid, S.; Cassidy, J. (1983) Soil Uptake of Phenyl Carbon-14 vs. Triazole Carbon-14 -CGA-64250 in Target Peanuts Followed by Rotational Winter Wheat and Corn -- A Side by Side Comparison Study in the Greenhouse: Report No. 83030. Unpublished study prepared by Ciba-Geigy. 38 p.

00164802 Honeycutt, R. (1986) Additional Residue Information on Terrestrial Rotation Crops Grown after Use of Propiconazole on Wheat, Barley or Rye: Report No. EIR-86016. Unpublished compilation prepared by Ciba-Geigy Corporation. 378 p.

40100101 Rhoads, W. (1987) Determination of the Characteristics of Tilt and Its Metabolites, Including 1,2,4-Triazole, When Subjected to Analysis by the United States Food and Drug Administration (FDA) Multiresidue Protocols I, II, III and IV: (Residue Analytical Method): Final Report : Laboratory/Study No. Ciba-Geigy 1055. Unpublished study prepared by Ciba-Geigy Corp. 194 p.

40150701 Cheung, M. (1987) Response to EPA's Concern Regarding the Validity of Analytical Method AG-359 to Determine Propiconazole Residues in Animal Commodities: 2,4-Dichlorobenzoic Acid by Capillary Gas in Animal Commodities: (Magnitude of Residues): Lab Study No.: ABR-87039. Unpublished study prepared by Ciba-Geigy Corp. 624 p.

40154501 Cheung, M. (1987) Response to EPA's Request for Additional Recovery Information on Analytical Methods AG-454A and AG-517: Lab Study No.: ABR-87040. Unpublished study prepared by Ciba-Geigy Corp. 68 p.

40180701 Toth, J.; Manuli, P. (1986) Determination of Total Residues of Propiconazole in Crops as 2,4-Dichlorobenzoic Acid by Capillary Gas Chromatography: Method No. AG-454A. Unpublished study prepared by Ciba-Geigy Corp. 5 p.

40180702 Manuli, P. (1987) Determination of Total Residues of Propiconazole in Meat, Milk and Eggs as 2,4-Dichlorobenzoic Acid by Capillary Gas Chromatography: Laboratory/Study No. AG-517. Unpublished study prepared by Ciba-Geigy Corp. 4 p.

40692201 Cheung, M. (1988) Propiconazole--Peanuts: Magnitude of Residue: Laboratory Project ID: ABR-88068. Unpublished study prepared by Ciba-Geigy Corp. 128 p.

40692203 Perez, R.; Toth, J. (1985) Determination of Total Residues of Propiconazole in Crops as 2,4-dichlorobenzoic acid by Capillary Gas Chromatography: Laboratory Project ID: AG-454. Unpublished study prepared by Ciba-Geigy Corp. 31 p.

40692204 Perez, R. (1985) Validation of Analytical Methods AG-448 and AG-454 for the Determination of Residues of Propiconazole in Crops by Conversion to 2,4-dichlorobenzoic acid: Laboratory Project ID: ABR-85055. Unpublished study prepared by Ciba-Geigy Corp. 11p.

40692206 Nixon, W.; Rhoads, W. (1983) Validation of Analytical Methods AG-448 and AG-454 for the Determination of Residues of CGA-64250 in Crops by Conversion to 2,4-dichlorobenzoic acid: Laboratory Project ID: ABR-83078. Unpublished study prepared by Ciba-Geigy Corp. 14 p.

40783301 Cheung, M. (1988) Propiconazole-Celery: Magnitude of Residue: Project ID: ABR-88057. Unpublished study prepared by Ciba-Geigy Corp. 77 p.

40783303 Cheung, M. (1988) Propiconazole--Corn: Magnitude of Residues: Project ID: ABR-88054. Unpublished study prepared by Ciba-Geigy Corp. 208 p.

40783305 Cheung, M. (1988) Propiconazole-Pineapple: Magnitude of Residue: Project ID: ABR-88014. Unpublished study prepared by Ciba-Geigy Corp. 70 p.

40783306 Perez, R.; Toth, J. (1985) Determination of Total Residues of CGA-64250 in Pineapples as 2,4-Dichlorobenzoic Acid by Capillary Gas Chromatography: Project ID: AG-448. Unpublished study prepared by Ciba-Geigy Corp. 30 p.

40890701 Cheung, M. (1988) Propiconazole--Grasses Grown for Seed Magnitude of Residue: Laboratory Project ID ABR-88134. Unpublished study prepared by Ciba-Geigy Corp. 83 p.

41063801 Cheung, M. (1989) Propiconazole--Wild Rice Residue Summary: Project ID: ABR-89004. Unpublished study prepared by Ciba-Geigy Corp. 99 p.

41063802 Cheung, M. (1989) Propiconazole-Stoned Fruit Residue Summary: Project ID: ABR-89007. Unpublished study prepared by Ciba-Geigy Corp. 152 p.

41102001 Cheung, M. (1989) Propiconazole in Soybean Beans, Forage, Hay, and Fodder Double-Cropped behind Winter Wheat: Project No. ABR-89030. Unpublished study prepared by Ciba-Geigy Corp. 127 p.

41486801 Cheung, M. (1990) Propiconazole: Response to EPA Conclusions: Propiconazole-celery Magnitude of Residue (Addendum to ABR-88057, MRID No. 4078330, MRID No. 40783301): Lab

Project I.D.: ABR-90026. Unpublished study prepared by Ciba-Geigy Corp., Agricultural Div. 49 p.

41486802 Darnow, J. (1990) Propiconazole: Determination of Extract Storage Stability for Total Propiconazole Residues in Weathered Crops: Lab Project I.D.: ABR-90017. Unpublished study prepared by Ciba-Geigy Corp., Agricultural Div. 56 p.

41823301 Doweyko, A. (1990) Metabolism of [Phenyl {carbon 14}] Propiconazole in Goats: Lab Project Number: F-00052. Unpublished study prepared by Ciba-Geigy Corp. 66 p.

41823302 Doweyko, A. (1990) Metabolism of Phenyl [carbon 14]Propiconazole in Chickens: Lab Project Number: F-00051. Unpublished study prepared by Ciba-Geigy Corp. 71 p.

41823304 Yokley, R. (1990) Validation of Analytical Method AG-517 for the Determination of Total Residues of Propiconazole in Goat Tissues, Milk, and Blood and Poultry Tissues: Lab Project Number: ABR-90067. Unpublished study prepared by Ciba-Geigy Corp. 54 p.

41823305 Beidler, W. . (1991) Propiconazole: Magnitude of Residues of Propiconazole in Grasses Grown for Seed Following Application of Tilt 3.6E: Lab Project Number: ANR-90101. Unpublished study prepared by Ciba-Geigy Corp. 155 p.

42061301 Biehn, W. (1991) Propiconazole--Magnitude of Residue on Mint: Lab Project Number: IR-4 PR 4127. Unpublished study prepared by Ciba-Geigy Corp. 101 p.

42182901 Cheung, M. (1991) Propiconazole Residues in Oat Forage, Straw, Grain and Oat Grain Processed Fractions Resulting from Application of Tilt: Residue Summary with Amendment 1: Lab Project Number: ABR-89102. Unpublished study prepared by Ciba-Geigy Corp. 214 p.

42511401 Smith, J. (1991) Propiconazole: Response to EPA Review of Propiconazole (TILT 3.6E) on Wild Rice Including Results of Additional Field Trials: Lab Project Number: ABR-90091. Unpublished study prepared by Ciba-Geigy Corp. 74 p.

42564004 Cheung, M. (1992) Responses to EPA Review of Residue Data for Propiconazole on Corn: Lab Project Number: ABR-92064. Unpublished study prepared by Ciba-Geigy Corp. 91 p.

42564005 Manuli, P. (1992) Magnitude of Residues of Propiconazole in Field Corn Forage and Grain and Processed Fractions following Application of Tilt 3.6E Formulation to Field Corn: Lab Project Number: ABR-92047. Unpublished study prepared by Ciba-Geigy Corp. 161 p.

42564006 Doweyko, A. (1992) F-00052: Metabolism of [Phenyl-carbon 14] Propiconazole in Goats: Addendum 1 to Final Report. Unpublished study prepared by Ciba-Geigy Corp. 9 p.

42605801 Cheung, M. (1992) Propiconazole: Responses to EPA Review of Residue Data for Propiconazole on Peanuts Reported in ABR-88068 MRID Number 40692201: Lab Project Number:

ABR-92066. Unpublished study prepared by Ciba-Geigy Corp. 26 p.

42634101 Smith, J. (1992) Magnitude of Residues of Propiconazole in or on Grasses Grown for Seed following Application of Tilt 3.6E: Lab Project Number: ABR-92070. Unpublished study prepared by Ciba-Geigy Corp. 165 p.

42634102 Wurz, R. (1993) Propiconazole: Magnitude of the Residue in or on Grass Seed Screening Pellets Obtained from Market Basket Samplings: Lab Project Number: ABR-92071. Unpublished study prepared by Ciba-Geigy Corp. 83 p.

42915601 Watson, G. (1993) Letter sent to C. Lewis dated September 3, 1993 concerning a report of Propiconazole residues above current tolerance in rice commodities. Prepared by Ciba-Geigy Corp. 10 p.

42983001 Doweyko, A. (1990) Metabolism of (Phenyl-(carbon 14)) -Propiconazole in Chickens: Addendum I: Lab Project Number: F-00051. Unpublished study prepared-84022 and 83091; and F-00051. Unpublished study prepared by Ciba-Geigy Corp. 11 p.

43314201 Wurz, R. (1994) Stability of Total Residues of Propiconazole in Weathered Grass Straw, Forage and Seed Samples under Freezer Storage Conditions: Lab Project Number: ABR/94008. Unpublished study prepared by Ciba-Geigy Corp., Biochemistry Dept. 62 p.

43314202 Beidler, W. (1994) Response to EPA Review of Petition for Tolerances of Propiconazole in Oat Grain and Straw: Lab Project Number: ABR/93068. Unpublished study prepared by Ciba-Geigy Corp. Biochemistry Dept. 11 p.

43424601 Thompson, D. (1994) Propiconazole: Magnitude of Residue on Mint--Amendment: Lab Project Numbers: A4127: 4127: A4127.93-CIR01. Unpublished study prepared by EPL Bioanalytical Services, Inc.; and Ciba Plant Protection. 402 p.

43434201 Biehn, W. (1994) Propiconazole: Magnitude of Residue on Mushroom: Lab Project Number: 5056: 207S01: 5056.92-PA05. Unpublished study prepared by EPL Bio-Analytical Services, Inc.; and Lehigh Agricultural & Biological Services, Inc. 291 p.

43655609 Selman, F. (1995) Propiconazole--Magnitude of the Residues in or on Cherries Following Post Foliar Applications of Orbit: Lab Project Number: ABR/95004. Unpublished study prepared by Ciba Plant Protection. 225 p.

43825401 Lin, K. (1995) Propiconazole: Investigations into the Methylation of 2,4-Dichlorobenzoic Acid as a Part of Analytical Methods AG-517 and AG-454B: Lab Project Number: ABR-94065: 411925: 280-94. Unpublished study prepared by Ciba-Geigy Corp. 141 p.

43825402 Eudy, L. (1995) Propiconazole: Stability of Propiconazole Fortified into Crops and Processed Fractions Under Freezer Storage Conditions: Interim Report 61-94. Lab Project Number:

ABR-95092: 411925: 207-94. Unpublished study prepared by Ciba-Geigy Corp. 113 p.

44049601 Simoneaux, B. (1996) Uptake and Metabolism of CGA-64250 in Greenhouse Grown Celery after Spray Treatment with Phenyl-(carbon 14)-CGA-64250: Lab Project Number: ABR-95100: 271-94: BIOL-94015. Unpublished study prepared by Ciba Crop Protection. 144 p.

44142401 Close, C. (1996) (Carbon 14)-Propiconazole: Uptake and Metabolism in Seed Piece Dipped Sugarcane: (Final Report): Lab Project Number: ABR-96097: 73-95: ANPHI-96005. Unpublished study prepared by Ciba-Geigy Corp. 56 p.

44381402 Swain, W. (1997) Uptake and Metabolism of CGA-64250 in Greenhouse Grown Spring Wheat after Spray Treatment with Phenyl--(carbon 14)-CGA--64250: Lab Project Number: ABR-97039: 502-95: BIOL-95018. Unpublished study prepared by Syngenta Crop Protection, Inc. 170 p.

44411201 Lin, K. (1997) Determination of Total Residues of Propiconazole in Crops as 2,4-Dichlorobenzoic Acid Methyl Ester by Capillary Gas Chromatography: Lab Project Number: AG-626: 571-97: 411925. Unpublished study prepared by Syngenta Crop Protection, Inc. 45 p. {OPPTS 860.1340}

44411204 Lin, K. (1997) Determination of Total Residues of Propiconazole in Meat, Milk and Eggs as 2,4-Dichlorobenzoic Acid Methyl Ester by Capillary Gas Chromatography: Lab Project Number: AG-629: 572-97: 411925. Unpublished study prepared by Syngenta Crop Protection, Inc. 44 p. {OPPTS 860.1340}

44411205 Eudy, L. (1997) Stability of Propiconazole Fortified into Crops and processed Fractions Under Freezer Storage Conditions: Lab Project Number: ABR-97085: 207-94: 477925. Unpublished study prepared by Syngenta Crop Protection, Inc. 84 p. {OPPTS 860.1380}

44411206 Vincent, T. (1997) Propiconazole--Magnitude of the Residues in or on Wheat, Including Processed Fractions and Rotational Lentils and Peas, Following Post Foliar Applications of Tilt: Lab Project Number: ABR-95062: 29-92: 411124. Unpublished study prepared by Syngenta Crop Protection, Inc. 506 p.

44411207 Vincent, T. (1997) Propiconazole--Magnitude of the Residues in or on Wheat, Including Processed Fractions, Following an Application of Tilt: Lab Project Number: ABR-97101: 94-95: 411926. Unpublished study prepared by Syngenta Crop Protection, Inc. 314 p. Relates to L0000296.

44411208 Vincent, T. (1997) Propiconazole--Magnitude of the Residues in or on Rice Following Application of Tilt: Lab Project Number: ABR-97110: 49-96: 411927. Unpublished study prepared by Syngenta Crop Protection, Inc. 120 p.

93194060 Senzel, A.; Ross, J.; Clear, C. (1990) Ciba-Geigy Corp. Phase 3 Summary of MRID 00155643 and Related MRIDs 00164802-00164823. Field Rotational Crop Studies of Propiconazole:

Project EIR-84002. Prepared by CIBA-GEIGY CORP. 67 p.

93194062 Swidersky, P. (1990) Ciba-Geigy Corp. Phase 3 Summary of MRID 00155644 and Related MRIDs 00074496, 00074499, 00074497, 00155646. Metabolism Data and Correlation of Metabolites in Target and Rotation Crop of Propiconazole: Report No. ABR-85056. Prepared by CIBA-GEIGY CORP. 17 p.

93194064 Wurz, R. (1990) Ciba-Geigy Corp. Phase 3 Summary of MRID 40180701 and Related MRIDs 40022401, 40154501, 40692204. Analytical Method for the Determination of Total Residues of Propiconazole in Crops as 2,4-Dichlorobenzoic Acid: AG-454A. Prepared by CIBA-GEIGY CORP. 14 p.

93194066 Wurz, R. (1990) Ciba-Geigy Corp. Phase 3 Summary of MRID 40100101. Determination of the Characteristics of Tilt and its Metabolites When Subjected to Analysis by the FDA Multiresidues Method Protocols I, II, III, and IV. Prepared by Colorado Analytical Research & Dev. Corp. 25 p.

93194067 Wurz, R. (1990) Ciba-Geigy Corp. Phase 3 Summary of MRID 40180702 and Related MRIDs 40145401. Analytical Method for the Determination of Total Residues of Propiconazole in Meat, Milk, and Eggs as 2,4-Dichlorobenzoic Acid: AG-517. Prepared by CIBA-GEIGY CORP. 13 p.

93194068 Beidler, W.; Senzel, A. (1990) Ciba-Geigy Corp. Phase 3 Summary of MRID 00133385 and Related MRIDs 00074510, 00074511. Stability of Propiconazole Residues on of Total Residues of Propiconazole of Propiconazole Residues in Crops Under Freezer Storage Conditions: Projects ABR-83086 and ABR-81018. Prepared by CIBA-GEIGY CORP. 11 p.

93194070 Senzel, A.; Ross, J.; Clear, C. (1990) Ciba-Geigy Corp. Phase 3 Summary of MRID 00137861. Cow Meat and Milk--Feeding: Propiconazole Residues: Projects ABR-84022 and 83091; and Poultry Meat and Eggs: Feeding: Propiconazole Residues: Projects ABR-84022 and 83092. Prepared by Ciba-Geigy Corporation. 36 p.

93194071 Senzel, A.; Ross, J.; Clear, C. (1990) Ciba-Geigy Corp. Phase 3 Summary of MRID 00137150. Magnitude of the Residues of Propiconazole in Bananas: ABR-83100. Prepared by CIBA-GEIGY CORP. 19 p.

93194072 Senzel, A.; Ross, J. (1990) Ciba-Geigy Corp. Phase 3 Summary of MRID 00163643. Magnitude of the Residues of Propiconazole in Wheat, Barley, and Rye: Project ABR-84018. Prepared by CIBA-GEIGY CORP. 16 p.

93194073 Senzel, A.; Ross, J.; Clear, C. (1990) Ciba-Geigy Corp. Phase 3 Summary of MRID 40890701. Magnitude of the Residues of Propiconazole in Grasses for Seed: Project ABR-83100. Prepared by CIBA-GEIGY CORP. 17 p.

93194074 Senzel, A.; Ross, J. (1990) Ciba-Geigy Corp. Phase 3 Summary of MRID 00133385 and



Related MRIDs 00074508, 00074509, 00074495, 00153327. Magnitude of the Residues of Propiconazole in Pecans: Project ABR-83069. Prepared by CIBA-GEIGY CORP. 17 p.

93194075 Senzel, A.; Ross, J. (1990) Ciba-Geigy Corp. Phase 3 Summary of MRID 00163687 and Related MRIDs 00074508, 00074509, 00074495, 00137861, 00163643, 41063801. Magnitude of the Residues of Propiconazole in Rice: Project ABR-84022. Prepared by CIBA-GEIGY CORP. 15 p.

93194077 Senzel, A.; Ross, J.; Clear, C. (1990) Ciba-Geigy Corp. Phase 3 Summary of MRID 00131090. Magnitude of the Residues of Propiconazole in Sugarcane: Project ABR-83065. Prepared by CIBA-GEIGY CORP. 28 p.

93194079 Senzel, A.; Ross, J. (1990) Ciba-Geigy Corp. Phase 3 Summary of MRID 00163687 and Related MRIDs 00074495, 00074508. Magnitude of the Residues of Propiconazole in Processed Food/Feed from Rice: Project ABR-84022. Prepared by CIBA-GEIGY CORP. 20 p.

93194080 Senzel, A.; Ross, J.; Clear, C. (1990) Ciba-Geigy Corp. Phase 3 Summary of MRID 00163643. Magnitude of the Residues of Propiconazole in Processed Food/Feed from Wheat: Project ABR-84018. Prepared by CIBA-GEIGY CORP. 18 p.

93194085 Madrid, V.; Cassidy, J. (1990) Ciba-Geigy Corp. Phase 3 Reformat of MRID 00074503 and Related MRIDs 00067905, 00074504. Characterization of Metabolites in Urine, Milk and Liver of a Goat Treated with Triazole-(Carbon 14)-CGA-64250: Propiconazole. Prepared by CIBA-GEIGY CORP. 54 p.

45080807 Eudy, L. (2000) Propiconazole and CGA-279202-Magnitude of the Residues in or on Sugar Beet: Final Report: Lab Project Number: 152-98: 0W-FR-216-98: 0W-FR-312-98. Unpublished study prepared by Novartis Crop Protection, Inc. 141 p. {OPPTS 860.1500}

45080809 Vincent, T. (2000) Propiconazole and CGA-279202-Magnitude of the Residues in or on Field Corn and Pop Corn: Final Report: Lab Project Number: 751-99: MW-FR-317-99: MW-FR-318-99. Unpublished study prepared by Novartis Crop Protection, Inc. 84 p. {OPPTS 860.1500, 860.1520}

45080810 Vincent, T. (2000) Propiconazole and CGA-279202-Magnitude of the Residues in or on Field Corn and Pop Corn: Final Report: Lab Project Number: 144-98: 04-FR-004-98: 0S-FR-201-98. Unpublished study prepared by Novartis Crop Protection, Inc. 922 p. {OPPTS 860.1500, 860.1520}

45080811 Vincent, T. (2000) Propiconazole and CGA-279202-Magnitude of the Residues in or on Rice: Final Report: Lab Project Number: 150-98: 03-FR-001-98: 03-FR-104-98. Unpublished study prepared by Novartis Crop Protection, Inc. 475 p. {OPPTS 860.1500, 860.1520}

44757208 Citation: Vincent, T.; Ediger, K. (1999) Propiconazole and CGA-279202--Magnitude of the Residues in or on Wheat: Final Report: Lab Project Number: 43-97: 0S-FR-103-97: 02-FR-002-97. Unpublished study prepared by Novartis Crop Protection, Inc. 1304 p. {OPPTS 860.1000, 860.1500,

860.1520}

45080800 Citation: Novartis Crop Protection, Inc. (2000) Submission of Residue Chemistry and Environmental Fate Data in Support of the Application for Registration of Flint and Trifloxystrobin Technical, and the Petition for Tolerance of Trifloxystrobin in/on Barley, Citrus Fruit Crop Group, Corn, Popcorn, Rice, Pecans, and Stone Fruit Crop Group. Transmittal of 12 Studies.

---

1. **Bolded** references were evaluated in the Propiconazole Phase 4 Review dated 6/25/92, by B. Cropp-Kohlligian, F. Fort, and F. Toghrol; because a number of the references cited in the Phase 4 Review were reviewed in connection with petitions for uses which have since been registered, in some cases the original review documents are noted as well. All other references were reviewed as noted.
2. Syngenta is required to amend the product labels for the 41.8% EC formulations (100-617 and 100-737) to indicate the propiconazole concentration in terms of lb ai/gal. In addition, label restrictions which prohibit the feeding of treated forage and/or hay of cereals and corn to livestock must be removed from the 41.8% EC (100-617 and 100-737) and the 45% WP (100-780) formulations. The use directions for rice on all labels should be amended to specify a 45-day PHI. HED notice that the maximum number of applications for peanuts on Stratego™ label is not very clear. After discussing with RD and the registrant, it is understood that the maximum number of six applications is intended only for the 7.0 oz ai/A rate, where the restricted number of application at 14 oz ai/A is only two. HED recommends that the petitioner to amend the Stratego™ label to specify these instructions. Since there are adequate field trial data to support Section 3 registration of propiconazole uses on wheat at the rate of 0.08 - 0.11 lbs ai/A/application, maximum 2 applications, and 35 day PHI (HED memo of 02/02/05, Y.Donovan, D271790), HED recommends increasing the existing tolerances on wheat RAC to cover Stratego Fungicide (EPA Reg. No. 264-779) uses on wheat. These new reassessed tolerances will cover all 24C uses on wheat as well. HED recommends to cancel all 24C uses while revising the Section 3 label to include these 24C uses.
3. PP#4F3007 on pecans, RCB#711, 5/15/84, A. Smith.
4. DP Barcode D233755, 9/14/99, T. Morton.
5. DP Barcode D245249, 12/14/99, T. Morton.
6. Although the Phase 4 Review concluded that additional animal metabolism data were required, the Agency concluded, based on the registrant's 90-day response to the DCI, that the available data were adequate to satisfy data requirements (CB#13166, DP Barcode D198815, 4/26/94, F. Fort).
7. PP#8F3674, CB#11976, DP Barcode D191918, 9/20/93, M. Flood.
8. PP#1F3974 on grass seed screenings, CB No. 7822, 6/11/91, S. Willett.

- 
9. PP#8F3674 on corn and pineapple, CB#10974, D185251, 5/6/93, M. Flood.
  10. PP#8F3674 on corn and pineapple, CB#12839, DP Barcode D196789, 3/28/94, M. Flood.
  11. In the Phase 4 Review, the registrant was required to conduct enforcement method validation for Method AG-454A using bananas. This requirement is no longer needed.
  12. PP#4F3026, RCB#826, 6/20/84, K. Arne.
  13. PP#4F3074 on small grains, CB No. 2174, 5/7/87, S. Malak.
  14. PP#4F3074 on small grains, CB No. 2262, 5/15/87, S. Malak.
  15. PP#8F3654 on peanuts, CB No. 4108, 11/22/88, H. Fonouni.
  16. PP#8F3674 on legumes, CB No. 4279, 12/14/88, C. Deyrup.
  17. PP#9F3758 on rice, wild rice, stone fruits, CB Nos. 5226-5228, 11/28/89, S. Malak.
  18. PP#0F3869 on cherry, CB No. 6724, 8/15/90, W. Chin.
  19. PP#2E4027 on mint, DP Barcode D170759, 2/14/92, W. Wassell.
  20. PP#2F4086 on oats, CB#9325, DP Barcodes D174248 and D175989, 7/20/93, R. Lascola.
  21. PP#8F3674 on peanuts, CB#12638, DP Barcodes D186202, D186203, D186205, D186206, and D195499, 11/8/93, M. Flood.
  22. PP#1F3979 on grass grown for seed, CB# 11304, DP Barcodes D187417, D190147, and D190263, 5-12/93, M. Flood.
  23. PP#2E4037 on mint hay, CB#14711, DP Barcode D209458, 4/25/95, W. Wassell.
  24. PP#5E4437 on mushroom, CB#14693, DP Barcode D209195, 3/29/95, W. Cutchin
  25. DP Barcode D220935, 3/25/99, T. Morton.
  26. DP Barcode D240856, 02/23/05, T. Morton.
  27. PP#4F3074 on small grain/pecans, CB No. 2172, 5/14/87, S. Malak.
  28. PP#4F3074 on small grain/pecans CB No. 2108, 4/28/87, S. Malak.
  29. PP#2F4086 on rice, CB# 14941, DP Barcode D210742, 3/15/95, M. Rodriguez.

- 
30. The Phase 4 Review concluded that additional storage stability data were required to support the livestock feeding studies. In their 90-day response to the DCI, the registrant presented data to satisfy this data requirement (DP Barcode D198815, 4/26/94, F. Fort).
  31. Section 18 Exemption with associated time-limited tolerance on dry beans. Use of propiconazole on dry beans has been proposed under pending petition PP#5F4424 (now incorporated into PP#2F6371).
  32. Establishment of a stone fruit group tolerance was approved on further consideration of new and available data for cherries (PP# 4F4321, DP Barcode D217199, 8/14/95, W. Cutchin and DP Barcode D210252, 4/25/95, W. Cutchin).
  33. Section 18 Exemption with associated time-limited tolerance on blueberry in Maine (Agency memo of 02/22/05, D. Rate, D313289). Use of propiconazole on the berries group has been proposed under pending petition PP#5F4591, now incorporated into PP#2F6371.
  34. Section 18 Exemption with associated time-limited tolerance on tree nuts. Use of propiconazole on tree nuts has been proposed under pending petition PP#9F3470, now incorporated into PP#2F6371.
  35. The existing tolerance covers the registered uses of propiconazole on pecans. Syngenta is petitioning for a tree nut group tolerance (PP#9F3740, now incorporated into PP#2F6371), which will be handled by registration.
  36. The available data pertaining to propiconazole residues of concern in/on wheat grain and straw supporting the currently registered maximum use pattern (D271790) can be translated to barley grain and straw and rye grain and straw.
  37. PP#4F3074, RCB#898, 7/12/84, A. Smith.
  38. PP#8F3674 on corn and pineapple, 03/28/94, D196789, M. Flord. The new submitted storage stability data are adequate and indicate that propiconazole is stable at  $-20^{\text{B}}$  C for up to 36 months in the following commodities: peaches, bananas, corn meal, wheat grain, celery, corn oil, and peanut nutmeat, hay, and hulls. Propiconazole is also stable in carrots for up to 10 months at  $-20^{\text{B}}$  C (Barcode D240856). Time-limited tolerances have been extended to 12/31/00 pending review of a modified mid-dose carcinogenicity study in mice (64 FR 13086, 13105, 3/17/99). HED believes that residues from corn AGF will not likely to be higher than that from wheat based on the fact that wheat grain has higher residues than corn grain, therefore, HED recommends a 5.0 ppm tolerance on aspirated grain fractions for propiconazole.
  39. The available data pertaining to field corn commodities may be translated to popcorn commodities.

- 
40. The product labels for the 41.8% ECs (EPA Reg. Nos. 100-617 and 100-737) must be modified to specify a 45-day PHI for rice.
41. DP Barcode D195566, 11/2/93, C. Swartz; preliminary 6 (a) (2) data on rice.
42. Section 18 Exemption with associated time-limited tolerance on cranberries. Use of propiconazole has been proposed by IR-4 under pending petition PP#7E4860.
- The registrant submitted data reflecting a new use pattern (2x the current use pattern) but did not state whether they wished to support this new use pattern. If the registrant desires to support this use pattern, then additional data would be required (see D240856).
44. PP#9F3758 on wild rice, apricots, nectarines, peaches, plums, prunes. DP Barcode D183633, 4/8/93, M. Rodriguez.
45. Adequate data supporting the currently registered maximum use pattern for wheat hay and forage have been received and reviewed (HED memo of 02/02/05, Y. Donovan, D271790). They can be translated to barley hay and rye forage. The product labels for the 41.8% EC (EPA Reg. Nos. 100-617 and 100-737) and the 45% WP (EPA Reg. No. 100-780) formulations must be modified to make the use patterns for barley and rye identical to wheat.
46. Outstanding deficiencies pertaining to use of propiconazole on oats (PP#2F04086) have been resolved by proposal of a tolerance for residues of propiconazole and its metabolites determined as 2,4-DCBA in/on oat hay (DP Barcode D218453, 8/24/95, M. Rodriguez). Because no data for oat hay were available, the appropriate level for this tolerance was calculated from data for oat forage using a 3x dry-down factor. Currently, data for wheat hay are available, and these data can be translated to oats to determine a more appropriate level for the oat hay tolerance.
47. Adequate data on wheat have been submitted and reviewed (HED memo of 02/02/05, Y. Donovan, D271790). No additional data are needed.
48. Additional data are required reflecting residues of propiconazole in/on grass hay. The Agency is in the process of revising its policy with respect to residue data requirements for grass grown for seed. According to the revised policy, residue data for hay may be based on regrowth after the seed has been harvested.
49. Banana field trial data were generated in Honduras, Republic of Ivory Coast, Martinique, and Belize. With one exception, residues did not exceed the tolerance following 1-13 aerial or ground applications of the 250EC formulation at 41 g ai/A/application (= 0.090lbs ai/A/application). The only registered uses are in Hawaii and Puerto Rico, with the rate of 0.084 lbs ai/A/application and maximum 8 applications. HED concludes that the existing tolerance on banana is adequate.
50. Use of propiconazole on mint is currently supported by IR-4 and is registered under SLN

---

OR960007. A tolerance was established in connection with PP#2E4037.

51. Use on mushrooms is being supported by IR-4. A tolerance was established in connection with PP#5E4437.
52. CBTS recommended for the establishment of time-limited tolerances for peanut commodities pending receipt of additional storage stability data (8F3654, DP Barcode D197841, 1/25/94, M. Flood). These data have since been received and reviewed (DP Barcode D240856).
53. The available data indicate that treatment of sugarcane pieces according to the currently registered use pattern can be considered a nonfood use.
54. The available data indicate that treatment of sunflower grown for seed can not be considered a nonfood use. Field trial data on sunflower are required to establish tolerance.
55. The available data for processed wheat commodities may be translated to barley and rye. (HED memo of 02/02/05, Y. Donovan, D271790).
56. Data must be submitted depicting the potential for concentration of propiconazole residues of concern in pineapple juice.
57. Preliminary rice processing data have been submitted, indicating the potential for concentration of propiconazole residues of concern in rice bran and hulls. The results of the full study have not been submitted and remain outstanding.
58. The Agency has determined that adequate data pertaining to magnitude of the residue in the processed commodities of sorghum are available to support the Section 18 Exemption. A tolerance was proposed in connection with PP# 5F4498.
59. EFGWB concluded that this requirement has been fulfilled (DP Barcode D166460, 11/7/91, P. Mastrodone).
60. EFGWB No. 70298, 3/23/87, E. Regelman.
61. EFGWB No. 70297, 5/18/87, E. Regelman.
62. EFGWB No. 70102, 12/24/86, E. Regelman.
63. EFGWB No. 90613, 10/19/89, E. Regelman.
64. Additional data would be required to revise the plantback intervals currently specified on labels for products with uses on rotatable crops. Data are available depicting propiconazole residue in rotational lentils and peas to satisfy requirements for field rotational crop trial data for potential uses in the Pacific Northwest. Residues of propiconazole were <LOQ (0.05 ppm) in/on all

---

matrices harvested from rotational legume crops planted 329-376 days posttreatment.



13544

**R129264**

**Chemical: Propiconazole**

**PC Code:  
122101**

**HED File Code: 11000 Chemistry Reviews**

**Memo Date: 6/15/2006**

**File ID: DPD329394**

**Accession #: 412-06-0192**

**HED Records Reference Center  
7/13/2006**