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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

02/02/05

MEMORANDUM:

SUBJECT: **Propiconazole** (122101): Magnitude of Residues in/on wheat for The Registration of Stratego™ use on wheat. MRID 44757208.
DP Barcode: D271790
Reregistration Case: 3125

FROM: Yan Donovan, Chemist
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Syngenta (previously Novartis) previously submitted wheat field and processing studies (1999; MRID 44757208) among other submissions in support of registration of Stratego™ Twin-Pak™ and Stratego™ Fungicide uses on various crops. Stratego™ Twin-Pak™ and Stratego™ are end-use products containing a mixture of trifloxystrobin and propiconazole,. The proposed use patterns for Stratego™ Twin-Pak™ and Stratego™ Fungicide formulations are: maximum single application rate of 0.08 lb ai/A, maximum of two applications per growing season, PHI 35 days. 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.

Residue data for trifloxystrobin were reviewed in PP#9F5070 (DP Barcodes D254213, D254217, D254218, and D254221, 4/6/00, L. Cheng). The propiconazole data from the above submission have not been reviewed and are now the subject of this Agency memorandum. The review was originally drafted by Dynamac Corporation under contract to EPA in 2000, and has been updated to reflect current Agency policies. Based on these studies and previously reviewed studies, HED makes the following conclusions:

Wheat crop field trials.
The numbers and the geographic representation of residue data are adequate for Section 3 registration of propiconzole on wheat. Twenty one field trials were conducted during the 1996 and 1997 growing seasons to support the registration of propiconazole and trifloxystrobin for use as pre-pak formulations on wheat. Following the last of two foliar applications at 0.11 lb ai/A/application, the total residues of propiconazole and its metabolites (determined as the 2,4-DCBA methyl ester) ranged from <0.05 ppm (nondetectable) to 0.30 ppm in/on **wheat grain** (35 days PHI), and ranged from 1.4 ppm to 12.0 ppm in/on **wheat straw** (31-38 days PHI). **The new recommended tolerance for wheat grain is 0.3 ppm and for wheat straw is 15 ppm.**

Following one foliar application of the 3.6 lb/gal EC formulation to wheat plants (Feekes Growth Stage 5) at 0.11 lb ai/A/application, the total residues of propiconazole ranged from <0.05 ppm (nondetectable) to 2.0 ppm in/on wheat forage (30 days PHI) and ranged from 0.05 ppm to 1.5 ppm in/on wheat hay (45 days PHI). **Based on these data, HED recommends the establishment of higher tolerances for wheat forage and hay at 2.0 ppm.**

Processed commodities.
The submitted wheat processing studies are adequate. Total propiconazole residues did 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 of 0.3 ppm. **A tolerance for**

wheat bran at 1.0 ppm is needed.

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 submitted processing study. 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 01/19/05, 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 Section18 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.**

PROPICONAZOLE
Case 3125; PC Code 122101
(DP Barcode TBA)

Registrant's Response To Residue Chemistry Data Requirements

September 25, 2000

Contract No. 68-W-99-053

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

Submitted by:
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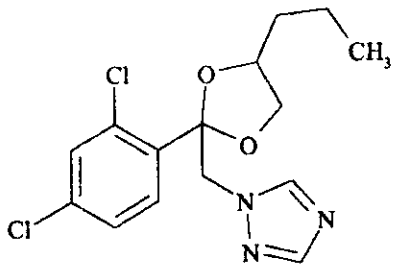
PROPICONAZOLE



PC Code 122101; Case No. 3125

(DP Barcode TBA)

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

BACKGROUND

Novartis Crop Protection, Inc. (now Syngenta) previously submitted wheat field and processing studies (1999; MRID 44757208) among other submissions in support of an application to register Stratego™ Twin-Pak™ and Stratego™ Fungicide which are end-use products containing a mixture of trifloxystrobin and propiconazole. Residue data for trifloxystrobin were reviewed in PP#9F5070 (DP Barcodes D254213, D254217, D254218, and D254221, 4/6/00, L. Cheng). The propiconazole data from the above submission have not been reviewed and are now the subject of this Agency memorandum.

The qualitative nature of propiconazole residues in plants and animals is adequately understood. HED MARC has recommended that **for risk assessment, the residues of concern in/on plant and animal commodities are the parent propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (2,4-DCBA). For tolerance expression, the residue of concern is parent only.**

Tolerances have been established for 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-DCBA and expressed as parent compound in/on raw agricultural commodities [40 CFR §180.434]. No tolerances have been established for residues in processed food/feed commodities. Codex MRLs have been established for residues of propiconazole in/on various plant and animal commodities, and are expressed in terms of propiconazole *per se*. **HED recommends to change the current tolerance expression for propiconazole to parent only.**

CONCLUSIONS AND RECOMMENDATIONS

OPPTS GLN 860.1200: Direction for Use

1. The directions on the Stratego™ Fungicide label state that the formulation can be applied to wheat up to 2 times per season at the rate of 10 oz product/A (0.08 lb ai/A) per application, with a minimum interval of 14 days between applications. No application should be made after Feekes growth stage 8 (the ligule of the flag leaf emerges). PHI is specified as 35 days for grains, 30 days for forage, and 45 days for hay. The proposed use pattern (maximum single application rate of 0.08 lb ai/A, maximum of two applications per growing season, PHI 35 days, imply a higher maximum seasonal rate when 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 assuming the petitioner will satisfactorily fulfill all residue chemistry data gaps identified in PP#9F5070 (DP Barcodes D254213, D254217, D254218, and D254221, 4/6/00, L. Cheng).

OPPTS GLN 860.1340: Residue Analytical Methods

2. A GC/ECD method (AG-454B) was the principal method used in the analysis of wheat commodity samples collected from the field and processing studies. This method uses 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 concurrent method recoveries indicate that this method is adequate for determining residues of propiconazole in/on wheat commodities. With a few exceptions, recoveries were within the range of 70-120%.

OPPTS GLN 860.1380: Storage Stability Data

3. The storage conditions and intervals of wheat commodity samples collected from the field and processing studies are supported by adequate storage stability data.

OPPTS GLN 860.1500: Crop Field Trials

4a. In the Agency review of wheat data for trifloxystrobin, residues were assessed at PHIs of 35 days for wheat grain and straw, 30 days for wheat forage, and 45 days for wheat hay. For the purpose of uniformity, the propiconazole residue data in the current submission were also evaluated at the same preharvest and pregrazing intervals since both active ingredients are to be applied simultaneously in the proposed Stratego™ formulations.

Propiconazole (Tilt® 3.6 lb/gal EC formulation; EPA Reg. No. 100-617) together with trifloxystrobin water dispersible granules (50% WG) was applied as a post foliar spray application to wheat plants. To generate residue data for forage and hay, a single application of the propiconozole test formulation was applied to established wheat plants that were at Feekes growth stage 5 at an application rate of 0.11 lb ai/A. To generate residue data for grain and straw, the test formulation was applied once or twice at this same rate, with the final application being administered 14 days after the first application and at Feekes growth stage 10.5. The total applied rate for wheat forage and wheat hay was 0.11 lb ai/A/season, and for wheat grain and wheat straw the maximum applied rate amounted to 0.22 lb ai/A/season.

4b. Wheat grain

Total residues of propiconazole and its metabolites (determined as the 2,4-DCBA methyl ester) ranged from <0.05 ppm (nondetectable) to 0.30 ppm in/on wheat grain harvested 34-38 days following the last of two foliar applications at 0.11 lb ai/A/application. **A tolerance for wheat grain at 0.3 ppm is needed.**

At registrant's discretion, the currently registered propiconazole labels may be revised to reflect a maximum of two foliar applications per growing season at a maximum single application rate of 0.11 lb ai/A.

4c. Wheat forage

Total residues of propiconazole ranged from <0.05 ppm (nondetectable) to 2.0 ppm in/on wheat forage harvested 30-32 days following one foliar application of the 3.6 lb/gal EC formulation to established wheat plants (Feekes Growth Stage 5) at 0.11 lb ai/A/application.

No tolerance is presently established for wheat forage. A tolerance for wheat forage at 2.0 ppm is needed based on data from the current submission.

4d. Wheat hay

Total residues of propiconazole ranged from 0.05 ppm to 1.5 ppm in/on wheat hay harvested 44-46 days following one foliar application of the 3.6 lb/gal EC formulation to established wheat plants (Feekes Growth Stage 5) at 0.11 lb ai/A/application.

No tolerance is presently established for wheat hay. A tolerance for wheat hay at 2.0 ppm is needed.

4e Wheat straw

Total residues of propiconazole ranged from 1.4 ppm to 12.0 ppm in/on wheat straw harvested 31-38 days following the last of two foliar applications of the 3.6 lb/gal EC formulation to established wheat plants (Feekes Growth Stage 10.5 and 14 days earlier) at

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0.11 lb ai/A/application.

A tolerance for wheat straw at 15.0 ppm is needed based on the submitted data. In addition, a revised Section F specifying a 35-day PHI for wheat straw is needed.

OPPTS GLN 860.1520: Processed Food/Feed

5a. Wheat flour, middlings, shorts, and germ

The submitted wheat processing studies are adequate. Total propiconazole residues did 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. Propiconazole residues concentrated slightly (1.4x) in shorts from one study but declined or did not concentrate from seven other studies. These data are consistent with previously evaluated wheat processing data submitted in support of reregistration. No tolerances are required for wheat flour, middlings, shorts, and germ.

5b Wheat bran

The processing studies showed that total propiconazole residues concentrated in wheat bran. For the purpose of determining concentration factors, RRB4 will only consider the results from studies where wheat grain samples bore measurable residues prior to processing. Using this criterion, the concentration factors in wheat bran from the current submission are: 3.0x (Caddo, OK; 1x rate), 4.1x (Caddo, OK; 3x rate), 4.5x (Caddo, OK; 5x rate), 1.7x (Finney, KS; 3x rate), and 3.0x (Finney, KS; 5x rate). 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. **Therefore, a tolerance on wheat bran at 1.0 ppm is needed.** The registrant must submit a revised Section F for this purpose.

5c Aspirated wheat grain fractions

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

All processing studies showed that total propiconazole residues concentrated in aspirated wheat grain fractions. For determination of concentration factors, RRB4 will only consider the results from studies where wheat grain samples bore measurable residues prior to processing. Using this criterion, the concentration factors in aspirated wheat grain fractions from the current submission are: 2x (Caddo, OK; 1x rate), 3.6x (Caddo, OK; 3x rate), 1.4x (Caddo, OK; 5x rate), 27.5x (Finney, KS; 3x rate), and 34x (Finney, KS; 5x rate). The average concentration factor of residues in aspirated wheat grain fraction is 13.7x. **Based on the field trials, the proposed tolerance on wheat grain is 0.3ppm, 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 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 (HED memo of 06/09/97, W. Cutchin, D235371). This Section18 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.**

OPPTS GLN 860.1850: Rotational Crops

6. Based on the label, treated areas may be replanted immediately following harvest or as soon as practical following the last application with any crop listed on the label. The following crops may be replanted 30 days after the last application: celery, cereals, sweet corn, pineapple, and sugarcane. For all other crops, a 105-day plantback interval must be observed. These restrictions are supported by adequate previously reviewed data.

DETAILED CONSIDERATIONS

OPPTS GLN 860.1200: Direction for Use

Currently registered use pattern: According to the draft Residue Chemistry Chapter for Propiconazole RED, the 3.6 lb/gal EC (EPA Reg. Nos. 100-617 and 100-737) and 45% WP (EPA Reg. No. 100-780) formulations are registered for use on wheat for foliar application at a maximum single and seasonal application rate of 0.1125 lb ai/A using ground or aerial equipment. There are also 21 SLN propiconazole registrations on wheat, and the application rates for these SLN registrations are consistent with those of Section 3 labels. No PHI has been established for Section 3 labels whereas the SLN labels specify a PHI of 40 days.

Proposed registered use pattern (SLN): According to PP#9F5070 (DP Barcodes D254213, D254217, D254218, and D254221, 4/6/00, L. Cheng), Stratego™ Twin-Pak™ and Stratego™ Fungicide are the end-use products proposed for use on wheat. The use directions described below were copied from the above trifloxystrobin petition review and were slightly modified to include parameters relevant to propiconazole.

"Stratego™ Twin-Pak™ (EPA Reg. No. 100-948) is a mixture of trifloxystrobin (50%) and propiconazole formulated as a water dispersible granule (WG). The directions on the label state that "use the entire contents [18 ounces] to treat 7 acres", which translates to a use rate of 0.08 lb ai /A/application. The formulation can be applied to wheat when conditions are favorable for disease development; a second application may be made after a minimum interval of 14 days. Furthermore, no application should be made after Feekes

growth stage 8 (the ligule of flag leaf emerges). Applications of product mixed with water can be made using ground application equipment, with a minimum of 10 GPA recommended, or aerially, with a minimum of 5 GPA recommended. The product must not be applied by chemigation. Treated areas may be replanted immediately following harvest or as soon as practical following the last application with any crop listed on the label. The following crops may be replanted 30 days after the last application: celery, cereals, corn, pineapple, and sugarcane. For all other crops, a 105-day plantback interval must be observed. No one is permitted entry into treated areas during the REI of 24 hours without wearing coveralls, chemical-resistant gloves, shoes plus socks, and protective eyewear.

Stratego™ Fungicide (EPA Reg. No. 264-779) is a liquid mixture of trifloxystrobin (11.4%) and propiconazole (11.4%) with a bulk density of 9.08 lbs per gallon (e-mail from registrant, 2/15/2000). The directions on the label state that the formulation can be applied to wheat up to 2 times per season at the rate of 10 oz product/A (0.08 lb ai/A) per application, with a minimum interval of 14 days between applications. No application should be made after Feekes growth stage 8 (the ligule of the flag leaf emerges). PHI is specified as 35 days for grains, 30 days for forage, and 45 days for hay. 30- day feeding and grazing restrictions are imposed post treatment. Applications of product mixed with water can be made using ground application equipment, with a minimum of 10 GPA recommended, or aerially, with a minimum of 5 GPA recommended. The product must not be applied by chemigation. Treated areas may be replanted immediately following harvest or as soon as practical following the last application with any crop listed on the label. The following crops may be replanted 30 days after the last application: celery, cereals, sweet corn, pineapple, and sugarcane. For all other crops, a 105-day plantback interval must be observed. No one is permitted entry into treated areas during the REI of 12 hours without wearing coveralls, chemical-resistant gloves, shoes plus socks, and protective eyewear.

The application rate used in the crop field trials was 2 applications of 0.11 lb ai/A for a total of 0.22 lb ai/A/season, with 14 days between treatments, with the last treatment made at Feekes growth stage 10.5, and with considerable variation in PHIs for all wheat RACs except for wheat forage."

OPPTS GLN 860.1340: Residue Analytical Methods

Samples of wheat RACs and processed commodities from the submitted field and processing studies were analyzed for residues of propiconazole by ABC Laboratories, Inc. (Columbia, MO). Residues of propiconazole and its metabolites containing the 2,4-dichlorophenyl moiety were determined using a GC/ECD method (AG-454B) with minor modifications. This method uses 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 has been previously reviewed and deemed adequate for collecting data on

propiconazole residues in/on several plant commodities. Additional samples were analyzed for residues of "parent" propiconazole using the FDA PAM Vol.1, Section 302, Methods E4 and DG5 with minor modifications. Brief discussions of the two methods follow.

AG-454B: Propiconazole residues are extracted with ammonium hydroxide:methanol (20:80, v:v) by refluxing (1 hour), and filtered. Residues are concentrated and propiconazole residues are oxidized to 2,4-DCBA by refluxing in potassium permanganate in 1 N sodium hydroxide for 75 minutes. After reflux, the potassium permanganate is deactivated, and the extract is acidified using water, sodium meta-bisulfite, and 6 N HCl. Residues are partitioned into diethyl ether:hexane (10:90, v:v), evaporated to dryness, and methylated using diazomethane. Residues are then cleaned-up on an acidic alumina Sep-Pak eluted with hexane prior to analysis by GC/ECD. The reported LOQ is 0.05 ppm. Raw data, sample calculations, and representative chromatograms were submitted. The results of concurrent method recoveries for wheat forage, grain, hay, and straw and wheat processed commodities are presented in Table 1. These data indicate that the GC/ECD method (AG-454B) is adequate for determining residues of propiconazole in/on wheat RACs and processed commodities. With a few exceptions, recoveries were within the range of 70-120%.

PAM "Parent" methods E4 and DG5: Propiconazole residues are extracted with water:acetone (35:65, v:v) and filtered. The filtrate is added to a separatory funnel containing dichloromethane (DCM), petroleum ether is added, and the separatory funnel is shaken to separate the aqueous and organic layers. The aqueous layer is drained and discarded. The organic layer is dried through anhydrous sulfate, evaporated, and reconstituted with acetone. The organic layer is re-evaporated, the volume is adjusted using either a gentle stream of nitrogen or the addition of acetone. Residues are analyzed using GC/NPD. The reported LOQ is 0.05 ppm. Raw data, sample calculations, and representative chromatograms were submitted. The results of concurrent method recoveries for wheat forage, grain, hay, and straw and wheat processed commodities is presented in Table 1. These data indicate that the GC/NPD method (PAM "Parent" methods E4 and DG5) is adequate for determining residues of propiconazole in/on wheat RACs and processed commodities. With a few exceptions, recoveries were within the range of 70-120%.

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Table 1. Recoveries of propiconazole from fortified samples of wheat commodities analyzed using either GC/ECD method AG-454B or PAM "parent" methods E4 + DG5.

Matrix	Fortification Level (ppm)	No. of Samples	Percent Recovery Range; **Mean** ± S.D.
GC/ECD Method AG-454B			
Wheat forage	0.05-10.0	29	69–116; **88** ± 12.1. One was below 70%.
Wheat hay	0.05-5.0	27	71-104; **85** ± 10.5
Wheat straw	0.05-20.0	45	62-108; **87** ± 11.6. Three were below 70%.
Wheat grain	0.05-0.50	48	65-124; **90** ± 15.6. Three were below 70% and two were above 120%.
Wheat aspirated grain fraction	0.05-0.10	11	69-113; **90** ± 13.4. One was below 70%.
Wheat germ			
Wheat bran			
Wheat middlings			
Wheat shorts			
Wheat low grade flour			
Wheat patent flour			
GC/NPD PAM "Parent" Methods E4 + DG5			
Wheat forage	0.05–10.0	29	87–117; **100** ± 6.2
Wheat hay	0.05–5.0	27	67–122; **94** ± 9.7. One was below 70%, and one was above 120%.
Wheat straw	0.05–5.0	44	51-130; **101** ± 14.0. One was below 70%, and three were above 120%.
Wheat grain	0.05–1.0	47	74-132; **99** ± 15.7. Five were above 120%.
Wheat aspirated grain fraction	0.05-0.10	15	66–122; **99** ± 15.5. One was below 70%, and one was above 120%.
Wheat germ			
Wheat bran			
Wheat middlings			
Wheat shorts			
Wheat low grade flour			
Wheat patent flour			

Data from pp. 63-67 and 124–128, MRID 44757208

OPPTS GLN 860.1380: Storage Stability Data

The wheat RAC samples from the field residue studies were frozen after harvest and shipped to Novartis Crop Protection (Greensboro, NC), where samples were prepared and stored frozen until shipment to ABC Laboratories (Columbia, MO) for residue analysis. Samples of wheat grain for processing from the OK and KS test sites were shipped to the Processing Facility of the GLP Program at Texas A & M University (Bryan, TX). Following processing, samples were frozen and sent to Novartis Crop Protection (Greensboro, NC) for sample preparation. After sample preparation, samples were stored in precisely labeled polyethylene bags and frozen. Samples were shipped frozen to the analytical laboratory, ABC Laboratories (Columbia, MO) for residue analysis. The total storage intervals between harvest and analysis for wheat RACs and processed fractions are presented below in Table 2.

Table 2. Frozen storage intervals of wheat commodities collected from field trial and processing studies.

Commodity	Analytical Method	Storage Interval	
		Days	Months
Wheat, forage	AG-454B	213-357	7.0-11.7
	PAM "parent" methods	352-501	11.6-16.4
Wheat, hay	AG-454B	198-324	6.5-10.6
	PAM "parent" methods	358-462	11.8-15.1
Wheat, straw	AG-454B	140-306	4.6-10.0
	PAM "parent" methods	148-350	4.9-11.5
Wheat, grain	AG-454B	133-329	4.4-10.8
	PAM "parent" methods	145-327	4.8-10.7
Wheat, aspirated grain fractions	AG-454B	221-284	7.2-9.3
	PAM "parent" methods	231-285	7.6-9.2
Processed fractions: germ, bran, middlings, shorts, low grade flour, patent flour	AG-454B	273-281	9.0-9.2
	PAM "parent" methods	264-268	8.7-8.8

Previously submitted storage stability data (HED memo of 02/23/05, T. Morton, D240856) indicate that residues of propiconazole are stable in/on various raw agricultural commodities, including wheat grain, as well as processed grain fractions (corn meal) stored frozen at -20 C for up to 36 months. In addition, storage stability data (DP Barcode D210742, M. Rodriguez, 3/15/95) for residues in grass forage, straw, and seed indicate that propiconazole is stable for up to 38 months at -20 C. These data support the sample storage intervals and conditions of samples collected from the current field and processing studies.

OPPTS GLN 860.1500: Crop Field Trials

Wheat

Established tolerances: Tolerances have been established for propiconazole residues in/on wheat grain and straw at 0.1 and 1.5 ppm, respectively [40 CFR §180.434]; no tolerances have been established for residues in/on wheat forage and hay and in wheat processed commodities.

Discussion of wheat field trial data (1999; MRID 44757208): Twenty one field trials were conducted during the 1996 and 1997 growing seasons to support the registration of propiconazole and trifloxystrobin for possible use as pre-pak formulations on wheat. Trials were conducted in EPA crop regions 2 (NC), 4 (AR), 5 (IL, KS, MN, MO, ND, and NE), 6 (OK), 7 (2 in MT, ND, SD), 8 (CO, 2 in KS, NM, OK, TX), 10 (CA), and 11 (WA). Included in the above tally of trials were residue decline studies performed at two sites (Fresno County, CA and Payne County, OK). Processing trials were also performed at two sites (Caddo County, OK and Finney County, KS). All 21 trials included one treated and one control plot except for the two sites that also had processing studies, which included additional treated plots.

Propiconazole (Tilt® 3.6 lb/gal EC formulation; EPA Reg. No. 100-617) together with trifloxystrobin water dispersible granules (50% WG) was applied as a post foliar spray application to wheat plants. To generate residue data for forage and hay, a single application of the propiconozole test formulation was applied to established wheat plants that were at Feekes growth stage 5 at an application rate of 0.11 lb ai/A. To generate residue data for grain and straw, the test formulation was applied once or twice at this same rate, with the final application being administered 14 days after the first application and at Feekes growth stage 10.5. The total applied rate for wheat forage and wheat hay was 0.11 lb ai/A/season, and for wheat grain and wheat straw the maximum applied rate amounted to 0.22 lb ai/A/season.

The two processing studies also included trials at 3x and 5x the maximum recommended application rate per season for the usage on wheat grain and wheat straw. Fifteen of the field trials were of winter wheat, mostly planted in 1996, with the rest being spring wheat. All crops were harvested in 1997. The first application was applied at Feekes growth stage 5. PHIs varied with the commodities and are discussed for them separately below. The material was applied to the wheat as a post foliar spray using various types of sprayers (often handheld or backpack CO_2 sprayers or tractor mounted sprayers) in a volume of 10.5–25 GPA. The fungicide trifloxystrobin was applied at the same times in corresponding multiples (i.e., 1x, 3x, or 5x) of the rate for that chemical. Two treated samples and one untreated control sample were collected for each commodity at each site. The method of sample collection was not described. There was a period of time for hay to dry before being frozen, ranging from 1 to 22 days. Except for samples to be used for the processing study, all samples were frozen and shipped frozen to Novartis Crop Protection (Greensboro, NC) where sample preparation was performed. After sample preparation, samples were stored in precisely labeled polyethylene bags and frozen. Samples were shipped frozen to the analytical laboratory, ABC Laboratories (Columbia, MO). Separate

samples of the different RACs related to wheat were homogenized and analyzed for propiconazole and metabolites containing the 2,4-dichlorophenyl moiety using GC/ECD method AG-454B (with minor modifications), which is described under "Residue Analytical Methods" section. Additional samples were analyzed for residues of "parent" propiconazole using the FDA PAM Vol.1, Section 302, Methods E4 and DG5. Sufficient sample chromatograms and calibration information were provided. Samples were stored frozen from the time of sample collection until analysis by GC/ECD for 4.4-11.7 months or by GC/NPD for 4.8-16.4 months. The results from the wheat field trials are summarized in Tables 3 and 4.

In wheat grain, wheat forage, and wheat hay, propiconazole was not detected at quantifiable levels in any control samples (i.e., they were below the LOQ of 0.05 ppm). Propiconazole was detected in 2 of the numerous control samples of wheat straw at 0.08 ppm. In all, propiconazole was detected in 2 (all in straw) of 144 control samples (of all wheat RACs).

Table 3: Residues of propiconazole in/on wheat grain, forage, hay, and straw following three different recommended treatment regimens for application of propiconozole (3.6 lb/gal EC), one regimen of which applies only to forage and hay and involves an application rate of 0.11 lb ai/A/season.

Test location: County, state (EPA crop region)	PHI[2]	Propiconazole residues (ppm)[1]					
		Treatment regimen 2: one application of 0.11 lb ai/A at Feekes Growth Stage 5		Treatment regimen 3: one application of 0.11 lb ai/A at Feekes Growth Stage 5		Treatment regimen 4: two applications of 0.11 lb ai/A at Feekes Growth Stage 10.5 and 14 days earlier	
		"parent"	"total"	"parent"	"total"	"parent"	"total"
Wheat Grain (pp 47-62 and 107–123, MRID 44757208)							
Fresno, CA (10) (decline study)	21	--	--	<0.05 (2)	0.07, 0.08	0.08 (2)	0.06, 0.12
	28	--	--	<0.05 (2)	0.06, 0.06	<0.05 (2)	0.07, 0.08
	63	--	--	< 0.05 (2)	<0.05 (2)	<0.05 (2)	0.06, 0.07
	70	--	--	< 0.05 (2)	0.05 (2)	<0.05 (2)	<0.05, 0.05
Champaign, IL (5)	40	--	--	< 0.05 (2)	<0.05, 0.07	<0.05 (2)	0.07, 0.08
Jackson, AR (4)	43	--	--	< 0.05 (2)	0.06, 0.07	<0.05 (2)	0.07, 0.07
Sampson, NC (2)	34	--	--	< 0.05 (2)	0.09, 0.10	<0.05 (2)	0.19, 0.23
Payne, OK (6) (decline study)	34	--	--	< 0.05 (2)	0.12, 0.14 [3]	<0.05 (2)	0.09, 0.10
	38	--	--	< 0.05 (2)	0.07, 0.10	<0.05 (2)	0.29, 0.30; HAFT=0.30
	44	--	--	< 0.05 (2)	<0.05 (2)	<0.05 (2)	0.10, 0.15
	51	--	--	< 0.05 (2)	<0.05, 0.05	<0.05 (2)	0.10, 0.11
Caddo, OK (8)	47	--	--	< 0.05 (2)	<0.05, 0.12	<0.05 (2)	0.07 (2)
Curry, NM (8)	27	--	--	< 0.05 (2)	<0.05 (2)	<0.05 (2)	0.13 (2)
Lubbock, TX (8)	32	--	--	< 0.05 (2)	<0.05 (2)	<0.05 (2)	<0.05 (2)
Fergus, MT (7)	36	--	--	< 0.05 (2)	<0.05 (2)	<0.05 (2)	0.08, 0.13
Judith Basin, MT (7)	43	--	--	< 0.05 (2)	0.06, 0.084	<0.05 (2)	0.16, 0.24
Grand Forks, ND (5)	57	--	--	< 0.05 (2)	<0.05 (2)	<0.05 (2)	<0.05 (2)
Polk, MN (5)	44	--	--	< 0.05 (2)	<0.05 (2)	<0.05 (2)	<0.05 (2)
McHenry, ND (7)	40	--	--	< 0.05 (2)	0.05, 0.17 [3]	<0.05 (2)	<0.05, 0.07
Charles Mix, SD (7)	31	--	--	< 0.05 (2)	0.05, 0.10	<0.05 (2)	0.06, 0.07
Grant, WA (11)	53	--	--	< 0.05 (2)	<0.05 (2)	<0.05 (2)	<0.05, 0.06
Lafayette, MO (5)	43	--	--	< 0.05 (2)	<0.05 (2)	<0.05 (2)	<0.05 (2)
Reno, KS (5)	49	--	--	< 0.05 (2)	<0.05 (2)	<0.05 (2)	0.05, 0.07
Finney, KS (8)	36	--	--	< 0.05 (2)	<0.05 (2)	<0.05 (2)	0.10, 0.15

(continued; footnotes follow)

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Table 3 (*continued*).

Test location: County, state (EPA crop region)	PHI[2]	Propiconazole residues (ppm)[1]					
		Treatment regimen 2: one application of 0.11 lb ai/A at Feekes Growth Stage 5		Treatment regimen 3: one application of 0.11 lb ai/A at Feekes Growth Stage 5		Treatment regimen 4: two applications of 0.11 lb ai/A at Feekes Growth Stage 10.5 and 14 days earlier	
		"parent"	"total"	"parent"	"total"	"parent"	"total"
Pawnee, KS (8)	35	–	--	< 0.05 (2)	<0.05, 0.07	<0.05 (2)	0.09, 0.14
Weld, CO (8)	38	–	--	< 0.05 (2)	<0.05 (2)	< 0.05 (2)	<0.05, 0.06
Hall, NE (5)	33	–	--	<0.05 (2)	<0.05 (2)	<0.05 (2)	<0.05 (2)
Wheat Forage (pp 47-62 and 107–123, MRID 44757208)							
Fresno, CA (decline study) (10)	0	3.9, 6.9	5.6, 7.3	–	–	–	–
	16	0.59, 0.81	1.1, 1.8	–	–	–	–
	23	0.12, 0.15	0.79, 0.91	–	–	–	–
	30	0.09, 0.14	0.62, 0.71	–	–	–	–
	37	0.07, 0.08	0.61, 0.78	–	–	–	–
Champaign, IL (5)	29	<0.05 (2)	0.19, 0.26	–	–	–	–
Jackson, AR (4)	30	<0.05 (2)	0.13, 0.17	–	–	–	–
Sampson, NC (2)	30	0.09, 0.12	0.48, 0.60	–	–	–	–
Payne, OK (decline study) (6)	0	11, 12	8.6, 9.8	–	–	–	–
	15	0.78, 0.79	1.7, 1.9	–	–	–	–
	22	0.16, 0.19	0.57, 0.75	–	–	–	–
	29	<0.05 (2)	0.21, 0.27	–	–	–	–
	35	<0.05 (2)	0.12, 0.13	–	–	–	–
Caddo, OK (8)	30	<0.05 (2)	0.16 (2)	–	–	–	–
Curry, NM (8)	32	<0.05 (2)	0.15, 0.20	–	–	–	–
Lubbock, TX (8)	30	<0.05 (2)	0.25, 0.29	–	–	–	–
Fergus, MT (7)	30	<0.05 (2)	0.07, 0.08	–	–	–	–
Judith Basin, MT (7)	30	<0.05 (2)	0.14, 0.17	–	–	–	–
Grand Forks, ND (5)	30	<0.05 (2)	0.19, 0.22	–	–	–	–
Polk, MN (5)	30	<0.05 (2)	0.92, 0.97	–	–	–	–
McHenry, ND (7)	30	<0.05 (2)	<0.05 (2)	–	–	–	–
Charles Mix, SD (7)	30	<0.05, 0.06	0.71, 0.78	–	–	–	–

(*continued; footnotes follow*).

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Table 3 (*continued*).

Test location: County, state (EPA crop region)	PHI[2]	Propiconazole residues (ppm)[1]					
		Treatment regimen 2: one application of 0.11 lb ai/A at Feekes Growth Stage 5		Treatment regimen 3: one application of 0.11 lb ai/A at Feekes Growth Stage 5		Treatment regimen 4: two applications of 0.11 lb ai/A at Feekes Growth Stage 10.5 and 14 days earlier	
		"parent"	"total"	"parent"	"total"	"parent"	"total"
Grant, WA (11)	30	<0.05 (2)	0.18, 0.24	--	--	--	--
Lafayette, MO (5)	31	<0.05 (2)	0.19, 0.29	--	--	--	--
Reno, KS (5)	32	0.23, 0.49	1.3, 2.0	--	--	--	--
Finney, KS (8)	30	<0.05 (2)	0.24, 0.27	--	--	--	--
Pawnee, KS (8)	30	0.10, 0.12	0.58, 0.65	--	--	--	--
Weld, CO (8)	30	<0.05 (2)	0.22, 0.28	--	--	--	--
Hall, NE (5)	31	<0.05 (2)	<0.05, 0.06	--	--	--	--
Wheat Hay (pp 107–123, MRID 44757208)							
Fresno, CA (decline study) (10)	31	0.16, 0.24	0.92, 1.3	--	--	--	--
	38	0.10, 0.11	1.3 (2)	--	--	--	--
	45	<0.05, 0.06	0.45, 0.60	--	--	--	--
	52	<0.05 (2)	0.24, 0.46	--	--	--	--
Champaign, IL (5)	44	<0.05 (2)	0.34, 0.36	--	--	--	--
Jackson, AR (4)	44	<0.05 (2)	0.13, 0.16	--	--	--	--
Sampson, NC (2)	45	0.05, 0.09	0.40, 0.58	--	--	--	--
Payne, OK (decline study) (6)	29	<0.05 (2)	0.20, 0.21	--	--	--	--
	35	<0.05 (2)	0.22, 0.26	--	--	--	--
	43	<0.05 (2)	0.22 (2)	--	--	--	--
	49	<0.05 (2)	0.19, 0.24	--	--	--	--
Caddo, OK (8)	48	<0.05 (2)	0.19 (2)	--	--	--	--
Curry, NM (8)	50	<0.05 (2)	0.14, 0.15	--	--	--	--
Lubbock, TX (8)	45	<0.05 (2)	0.50, 0.60	--	--	--	--
Fergus, MT (7)	45	<0.05 (2)	0.05, 0.05	--	--	--	--
Judith Basin, MT (7)	45	<0.05 (2)	0.31, 0.41	--	--	--	--
Grand Forks, ND (5)	45	<0.05 (2)	0.13, 0.15	--	--	--	--
Polk, MN (5)	45	0.06, 0.07	0.99, 1.0	--	--	--	--
McHenry, ND (7)	45	<0.05 (2)	0.06, 0.09	--	--	--	--

(*continued, footnotes follow*)

Table 3 (*continued*).

Test location: County, state (EPA crop region)	PHI[2]	Propiconazole residues (ppm)[1]					
		Treatment regimen 2: one application of 0.11 lb ai/A at Feekes Growth Stage 5		Treatment regimen 3: one application of 0.11 lb ai/A at Feekes Growth Stage 5		Treatment regimen 4: two applications of 0.11 lb ai/A at Feekes Growth Stage 10.5 and 14 days earlier	
		"parent"	"total"	"parent"	"total"	"parent"	"total"
Charles Mix, SD (7)	45	<0.05 (2)	0.16, 0.36	–	–		–
Grant, WA (11)	45	<0.05 (2)	0.19, 0.21	–	–		–
Lafayette, MO (5)	45	<0.05 (2)	0.37, 0.46	–	–		–
Reno, KS (5)	46	0.11, 0.20	1.3, 1.5	–	–		–
Finney, KS (8)	45	<0.05 (2)	0.10, 0.16	–	–		–
Pawnee, KS (8)	46	<0.05 (2)	0.48, 0.49	–	–		–
Weld, CO (8)	45	<0.05 (2)	0.34, 0.36	–	–		–
Hall, NE (5)	45	<0.05 (2)	0.06, 0.07	–	–		–
Wheat Straw (pp 107–123, MRID 44757208)							
Fresno, CA (decline study) (10)	21	–	--	0.68, 0.92	4.2, 6.0	0.96, 1.1	8.1, 8.5
	28	–	--	0.51, 0.72	3.5, 3.9	1.1 (2)	7.5 (2)
	63	–	--	0.40, 0.55	2.5, 3.2	0.35, 0.60	5.2, 6.3
	70	–	--	0.63, 0.87	3.8, 4.9	0.53, 0.63	7.3, 8.5
Champaign, IL (5)	40	–	--	<0.05 (2)	1.3, 1.6	0.06, 0.12	2.1, 3.8
Jackson, AR (4)	43	–	--	0.55, 0.56	1.9, 2.1	0.45, 0.68	3.1 (2)
Sampson, NC (2)	34	–	--	1.1, 1.3	2.1, 2.7	1.9, 2.2	11, 12[3]
Payne, OK (decline study) (6)	34	–	--	0.20, 0.25	0.99, 1.3	0.09, 0.13	1.4, 1.7
	38	–	--	0.19, 0.23	1.4, 1.5	0.16, 0.19	2.4, 2.5
	44	–	--	0.17, 0.19	0.83, 0.93	<0.05 (2)	0.88, 1.1
	51	–	--	0.16, 0.22	0.97, 1.1	<0.05 (2)	2.0, 2.2
Caddo, OK (8)	47	–	--	0.09, 0.12	0.89, 1.5	<0.05, 0.06	0.98, 1.2
Curry, NM (8)	27	–	--	0.20 (2)	1.4, 1.5	0.84, 1.1	5.5, 6.0
Lubbock, TX (8)	32	–	--	0.72, 0.78	2.1, 3.8	1.8, 2.6	7.1, 7.6
Fergus, MT (7)	36	–	--	1.2, 1.5	4.0, 4.0	1.6, 2.2	4.4, 5.7
Judith Basin, MT (7)	43	–	--	1.1, 1.6	3.7, 4.2	2.9, 3.5	7.6, 8.4
Grand Forks, ND (5)	57	–	--	0.09, 0.10	0.41, 0.43	<0.05 (2)	0.27, 0.31

(*continued; footnotes follow*).

Table 3 (*continued*).

Test location: County, state (EPA crop region)	PHI[2]	Propiconazole residues (ppm)[1]					
		Treatment regimen 2: one application of 0.11 lb ai/A at Feekes Growth Stage 5		Treatment regimen 3: one application of 0.11 lb ai/A at Feekes Growth Stage 5		Treatment regimen 4: two applications of 0.11 lb ai/A at Feekes Growth Stage 10.5 and 14 days earlier	
		"parent"	"total"	"parent"	"total"	"parent"	"total"
Polk, MN (5)	44	--	--	0.21, 0.29	2.4, 3.2	0.15, 0.27	3.2, 3.5
McHenry, ND (7)	40	--	--	0.15, 0.32	2.2, 3.7	0.06, 0.12	1.3, 2.5
Charles Mix, SD (7)	31	--	--	1.6 (2)	5.1, 7.1	1.0, 1.6	4.1, 6.5
Grant, WA (11)	53	--	--	0.06, 0.12	1.0, 1.6	0.05, 0.10	1.5, 2.0
Lafayette, MO (5)	43	--	--	<0.05 (2)	0.87, 1.3	<0.05 (2)	0.77, 1.6
Reno, KS (5)	49	--	--	0.18, 0.39	1.5, 2.5	0.46, 0.50	2.6, 3.3
Finney, KS (8)	36	--	--	0.06, 0.07	1.1, 2.9	<0.05, 0.12	2.3, 2.7
Pawnee, KS (8)	35	--	--	0.17, 0.18	1.3, 1.5	0.55, 0.60	3.0, 3.7
Weld, CO (8)	38	--	--	0.10, 0.15	1.6, 2.4	0.14, 0.26	1.6, 2.5
Hall, NE (5)	33	--	--	0.07, 0.20	1.5, 2.7	0.15, 0.17	2.4, 3.0

[1] Residue levels are not corrected for control values but are corrected for procedural recoveries < 100%.
[2] Preharvest interval (days).
[3] Samples were analyzed in duplicate; higher residue value was reported.

Table 4: Residues of propiconazole in/on wheat grain and straw following applications of propiconozole (3.6 lb/gal EC) at exaggerated application rates and with a re-treatment interval of 14 days.

Test location: County, state (EPA crop region)	PHI[2]	Propiconazole residues (ppm)[1]			
		Two applications of 0.33 lb ai/A (0.66 lb ai/A/season) at Feekes Growth Stage 10.5 and 14 days earlier (3x application rate of treatment regimen 4)		Two applications of 0.55 lb ai/A (1.10 lb ai/A/season) at Feekes Growth Stage 10.5 and 14 days earlier (5x application rate of treatment regimen 4)	
		"parent"	"total"	"parent"	"total"
Wheat Grain					
Caddo, OK (8)	47	<0.05	0.20	<0.05	0.31
Finney, KS (8)	36	<0.05	0.10	<0.05	0.15
Wheat Straw					
Caddo, OK (8)	47	0.38	3.5	0.68	5.4
Finney, KS (8)	36	0.31	6.0	1.7	17

Data from pp. 52-53, 59-60, 113, and 120, MRID 44757208

[1] Residue levels are not corrected for control values but are corrected for procedural recoveries <100%.

[2] Preharvest interval (days).

Overall, geographic representation of residue data is adequate. The recommended number of crop field trials for wheat is 20, and the recommended distribution in the different EPA crop regions is exactly as found in this study except that there is one trial too few in region 7, one trial too many in region 5, and one trial in region 10 where none is needed. If the one trial in NE had been shifted a few miles farther west in Hall County, the recommended distribution would have been in complete compliance with the OPPTS guidelines. The decline studies provided moderate to strong evidence of a decline in residues over time in/on wheat grain, wheat forage, and wheat hay. For wheat straw, there is evidence of an increase in residues over time.

Summary of wheat field trials:

The proposed use pattern for Stratego™ Twin-Pak™ and Stratego™ Fungicide formulations (maximum single application rate of 0.08 lb ai/A, maximum of two applications per growing season, PHI unspecified) imply a higher maximum seasonal rate when compared to currently registered propiconazole formulations (maximum single application of 0.11 lb ai/A, maximum of one application per growing season, PHI unspecified). Therefore, for the purpose of reregistration, the wheat RAC tolerances should be reassessed using data from the current submission assuming the petitioner will satisfactorily fulfill all residue chemistry data gaps identified in PP#9F5070 (DP Barcodes D254213, D254217, D254218, and D254221, 4/6/00, L. Cheng).

In the Agency review of wheat data for trifloxystrobin, residues were assessed at PHIs of 35 days for wheat grain and straw, 30 days for wheat forage, and 45 days for wheat hay. For the purpose of uniformity, the propiconozole residue data in the current submission were also evaluated at the same preharvest and pregrazing intervals since both active ingredients are to be applied simultaneously in the proposed Stratego™ formulations.

Wheat grain: Total residues of propiconazole and its metabolites (determined as the 2,4-DCBA methyl ester) ranged from <0.05 ppm (nondetectable) to 0.30 ppm in/on wheat grain harvested 34-38 days following the last of two foliar applications of the 3.6 lb/gal EC propiconazole formulation to established wheat plants (Feekes Growth Stage 10.5 and 14 days earlier) at 0.11 lb ai/A/application. The existing tolerance on wheat grain at 0.1 ppm is needed to be revised to 0.3 ppm. At registrant's discretion, the currently registered propiconazole labels may be revised to reflect a maximum of two foliar applications per growing season at a maximum single application rate of 0.11 lb ai/A.

Wheat forage: Total residues of propiconazole ranged from <0.05 ppm (nondetectable) to 2.0 ppm in/on wheat forage harvested 30-32 days following one foliar application of the 3.6 lb/gal EC formulation to established wheat plants (Feekes Growth Stage 5) at 0.11 lb ai/A/application.

No tolerance is presently established for wheat forage, HED recommends the establishment of a tolerance for wheat forage at 2.0 ppm based on data from the current submission.

Wheat hay: Total residues of propiconazole ranged from 0.05 ppm to 1.5 ppm in/on wheat hay harvested 44-46 days following one foliar application of the 3.6 lb/gal EC formulation to established wheat plants (Feekes Growth Stage 5) at 0.11 lb ai/A/application.

No tolerance is presently established for wheat hay, HED now recommends the establishment of a tolerance for wheat hay at 2.0 ppm.

Wheat straw: Total residues of propiconazole ranged from 1.4 ppm to 12.0 ppm in/on wheat straw harvested 31-38 days following the last of two foliar applications of the 3.6 lb/gal EC formulation to established wheat plants (Feekes Growth Stage 10.5 and 14 days earlier) at 0.11 lb ai/A/application. The wheat straw tolerance(currently 3.0 ppm) needs to be revised to15.0 ppm. Additionally, currently registered propiconazole label must be amended to reflect a 35-day PHI for wheat straw.

OPPTS GLN 860.1520: Processed Food/Feed

Wheat

Several processing studies were conducted on wheat grain. Details about the field tests that provided the samples used in the processing studies are described under wheat in "OPPTS GLN 860.1500: Crop Field Trials" section. The Processing Facility of the GLP Program at Texas

A&M University (Bryan, TX) processed the wheat to produce aspirated grain fractions. This processing simulates industrial practice used in terminal elevators to remove grain dust. After generation of aspirated grain fractions, the wheat samples were processed into germ, bran, middlings, shorts, low grade flour, and patent flour. An unprocessed sample (RAC seed) was taken prior to processing. The sample of 495 lb of wheat grain from the Oklahoma test site was received on 7/14/97, and the sample of 225.5 lb of wheat grain from the Kansas test site was received on 7/25/97. Processing of the Oklahoma sample occurred between 8/18/97 and 9/9/97, and on 9/10/97 the frozen sample was sent to Novartis Crop Protection (Greensboro, NC) for sample preparation. Processing of the Kansas sample occurred between 9/21/97 and 10/14/97, and on 10/15/97 the frozen sample was sent to Novartis Crop Protection (Greensboro, NC) for sample preparation. After sample preparation, samples were stored in precisely labeled polyethylene bags and frozen. Samples were shipped frozen to the analytical laboratory, ABC Laboratories (Columbia, MO). Samples were analyzed for regulable residues using the analytical methods described under "OPPTS GLN 860.1340: Residue Analytical Methods" section of this document. Information pertaining to sample storage conditions and intervals along with supporting storage stability data are presented under "OPPTS GLN 860.1380: Storage Stability Data" section. The results of the wheat processing studies are shown in Table 5.

Table 5: Residues of propiconazole in the processed commodities of wheat harvested 47 or 36 days following either 1 application or 2 applications, at 14 day intervals, of the propiconazole (3.6 lb/gal EC) formulation at either 0.11, 0.33, or 0.55 lb ai/A/application (0.11, 0.22, 0.66, or 1.10 lb ai/A/season; ca. 0.5x, 1x, 3x and 5x the maximum proposed seasonal rate).

Substrate	Propiconazole residues, ppm [1]		Concentration/Reduction Factor	
	"parent"	"total"	"parent"	"total"
Caddo, OK - 1 application, 0.11 lb ai/A/season (0.5x) with a 47 day PHI				
Grain before processing	<0.05	<0.05	--	--
-Aspirated Grain Fractions	<0.05	0.13	1x	>2.6x
-Germ	<0.05	<0.05	1x	1x
-Bran	<0.05	0.14	1x	>2.8x
-Middlings	<0.05	<0.05	1x	1x
-Shorts	<0.05	<0.05	1x	1x
-Low Grade Flour	<0.05	<0.05	1x	1x
-Patent Flour	<0.05	<0.05	1x	1x
Caddo, OK - 2 applications, 0.22 lb ai/A/season (1x) with a 47 day PHI				
Grain before processing	<0.05	0.07	--	--
-Aspirated Grain Fractions	<0.05	0.14	1x	2x
-Germ	<0.05	0.05	1x	0.7x
-Bran	<0.05	0.22	1x	3x
-Middlings	<0.05	<0.05	1x	<0.7x
-Shorts	<0.05	<0.05	1x	<0.7x
-Low Grade Flour	<0.05	<0.05	1x	<0.7x
-Patent Flour	<0.05	<0.05	1x	<0.7x
Caddo, OK - 2 applications, 0.66 lb ai/A/season (3x) with a 47 day PHI				
Grain before processing	<0.05	0.16	--	--
-Aspirated Grain Fractions	<0.05	0.58	1x	3.6x
-Germ	<0.05	0.13	1x	0.8x
-Bran	<0.05	0.66	1x	4.1x
-Middlings	<0.05	0.10	1x	0.6x
-Shorts	<0.05	0.15	1x	0.9x
-Low Grade Flour	<0.05	0.06	1x	0.4x
-Patent Flour	<0.05	<0.05	1x	<0.3x

(continued; footnotes follow)

Table 5 (*continued*).

Substrate	Propiconazole residues, ppm [1]		Concentration/Reduction Factor	
	"parent"	"total"	"parent"	"total"
Caddo, OK - 2 applications, 1.10 lb ai/A/season (5x) with a 47 day PHI				
Grain before processing	<0.05	0.22	–	--
-Aspirated Grain Fractions	0.15	0.30	>3x	1.4x
-Germ	<0.05	0.20	1x	0.9x
-Bran	<0.05	1.0	1x	4.5x
-Middlings	<0.05	0.17	1x	0.8x
-Shorts	<0.05	0.21	1x	1x
-Low Grade Flour	<0.05	0.10	1x	0.5x
-Patent Flour	<0.05	0.09	1x	0.4x
Finney, KS - 1 application, 0.11 lb ai/A/season (0.5x) with a 36 day PHI				
Grain before processing	<0.05	<0.05	–	--
-Aspirated Grain Fractions	<0.05	0.44	1x	>8.8x
-Germ	<0.05	<0.05	1x	1x
-Bran	<0.05	<0.05	1x	1x
-Middlings	<0.05	<0.05	1x	1x
-Shorts	<0.05	<0.05	1x	1x
-Low Grade Flour	<0.05	<0.05	1x	1x
-Patent Flour	<0.05	<0.05	1x	1x
Finney, KS - 2 applications, 0.22 lb ai/A/season (1x) with a 36 day PHI				
Grain before processing	<0.05	<0.05	–	--
-Aspirated Grain Fractions	0.11	0.71	>2.2x	>2.2
-Germ	<0.05	<0.05	1x	1x
-Bran	<0.05	0.06	1x	>1.2x
-Middlings	<0.05	<0.05	1x	1x
-Shorts	<0.05	<0.05	1x	1x
-Low Grade Flour	<0.05	<0.05	1x	1x
-Patent Flour	<0.05	<0.05	1x	1x

(*continued; footnotes follow*).

Table 5 (*continued*).

Substrate	Propiconazole residues, ppm [1]		Concentration/Reduction Factor	
	"parent"	"total"	"parent"	"total"
Finney, KS - 2 applications, 0.66 lb ai/A/season (3x) with a 36 day PHI				
Grain before processing	<0.05	0.12	-	-
-Aspirated Grain Fractions	0.40	3.3	>8x	27.5x
-Germ	<0.05	0.06	1x	0.5x
-Bran	<0.05	0.20	1x	1.7x
-Middlings	<0.05	0.12	1x	1x
-Shorts	<0.05	0.11	1x	0.9x
-Low Grade Flour	<0.05	<0.05	1x	<0.4
-Patent Flour	<0.05	<0.05	1x	<0.4
Finney, KS - 2 applications, 1.10 lb ai/A/season (5x) with a 36 day PHI				
Grain before processing	<0.05	0.13	-	-
-Aspirated Grain Fractions	1.9	4.4	>38x	34x
-Germ	<0.05	0.13	1x	1x
-Bran	<0.05	0.39	1x	3x
-Middlings	<0.05	0.07	1x	0.5x
-Shorts	<0.05	0.18	1x	1.4x
-Low Grade Flour	<0.05	<0.05	1x	<0.4x
-Patent Flour	<0.05	<0.05	1x	<0.4x

Data from pp. 53-54, 60-61, 113-114 and 120-121, MRID 44757208
[1]Residue levels are not corrected for control values but are corrected for procedural recoveries <100%

Conclusions

The submitted wheat processing studies are adequate. Total propiconazole residues did 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. Propiconazole residues concentrated slightly (1.4x) in shorts from one study but declined or did not concentrate from seven other studies. These data are consistent with previously evaluated wheat processing data submitted in support of reregistration. No tolerances are required for wheat flour, middlings, shorts, and germ.

The processing studies showed that total propiconazole residues concentrated in wheat bran. For the purpose of determining concentration factors, RRB4 will only consider the results from studies where wheat grain samples bore measurable residues prior to processing. Using this criterion, the concentration factors in wheat bran from the current submission are: 3.0x (Caddo, OK; 1x rate), 4.1x (Caddo, OK; 3x rate), 4.5x (Caddo, OK; 5x rate), 1.7x (Finney, KS; 3x rate), and 3.0x (Finney, KS; 5x rate). 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 (see Table 3). Therefore, HED recommends the establishment of a tolerance for wheat bran at 1.0 ppm. The registrant must submit a revised Section F for this purpose.

All processing studies showed that total propiconazole residues concentrated in aspirated wheat grain fractions. For determination of concentration factors, HED will only consider the results from studies where wheat grain samples bore measurable residues prior to processing. Using this criterion, the concentration factors in aspirated wheat grain fractions from the current submission are: 2x (Caddo, OK; 1x rate), 3.6x (Caddo, OK; 3x rate), 1.4x (Caddo, OK; 5x rate), 27.5x (Finney, KS; 3x rate), and 34x (Finney, KS; 5x rate). The average concentration factor of residues in aspirated wheat grain fraction is 13.7x.

The maximum expected propiconazole residues in soybean aspirated grain fractions would be 3.5 ppm (memo of 01/19/05, T. Morton, D246884). A 20 ppm AFG 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 Section18 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.**

OPPTS GLN 860.1850: Rotational crops

Treated areas may be replanted immediately following harvest or as soon as practical following the last application with any crop listed on the label. The following crops may be replanted 30 days after the last application: celery, cereals, sweet corn, pineapple, and sugarcane. For all other crops, a 105-day plantback interval must be observed.

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AGENCY MEMORANDA CITED IN THIS DOCUMENT

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 Barcodes:	D254213, D254217, D254218, and D254221
Subject:	PP#9F5070. Trifloxystrobin on Almond, Fruiting Vegetables, Hops, Sugar Beet, Potato, and Wheat. Review of Analytical Methods and Residue Data.
From:	L. Cheng
To:	C. Giles-Parker/J. Whitehurst
Date:	4/6/00
MRID(s):	44757207 through 44757219

DP Barcode:	D240856
Subject:	MRP rice, wheat and processed wheat, RAM, SSD, CRC
From:	Thurston G. Morton,
To:	Mark Hartman/Kathy Monk, PM #52
Date:	02/23/05
MRID:	44411201, 44411204-44411208

MASTER RECORD IDENTIFICATION NUMBERS

44757202 Vincent, T.P. and Ediger, K. (1999) Propiconazole and CGA-279202 - Magnitude of the Residues in or on Wheat. Laboratory Project Identification: 43-97. Unpublished study prepared by Novartis Crop Protection, Inc. 1304 p.

CC: Yan Donovan