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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

February 23, 2005

MEMORANDUM:

SUBJECT: **Propiconazole** (122101): 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). **DP Barcode #** D240856. **Case 3125. MRID #** 44411201, 44411202, 44411203, 44411204, 44411205, 44411206, 44411207, 44411208.

FROM: Thurston G. Morton, Chemist
Reregistration Branch 4
Health Effects Division (7509C)

2/23/05

THROUGH: Susan V. Hummel, Branch Senior Scientist
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Susan V. Hummel

TO: Patrick Dobak/Susan Lewis
Reregistration Branch I
Special Review & Reregistration Division (7508C)

EXECUTIVE SUMMARY:

All submitted studies (cited above) were reviewed by Dynamac Corporation under contract to EPA. The attached Dynamac review was modified to reflect current Agency policies. Based on these studies and previously reviewed studies, HED's conclusions are listed below.

- 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. In addition, use directions for rice on all labels should be amended to specify a 45-day PHI.

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- The 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.

- The submitted wheat study (MRID 44411207), reflecting the currently registered use pattern (one application at 0.11 lb ai/A), is not adequate. As the Agency no longer considers feeding prohibitions practical for wheat forage or hay, residue data for wheat forage and hay are required for uses on wheat. Label use directions for wheat must be amended by removing the feeding/grazing prohibitions for forage and hay and specifying appropriate PHIs for forage and hay which are supported by residue data. In addition, labels must be amended to specify a PHI of no less than 45 days for wheat grain and straw.

- Residues of propiconazole were <0.05 ppm in/on wheat grain and 0.11-0.98 ppm in/on straw harvested 45-48 days following a single foliar application of propiconazole at 0.11 lb ai/A (the maximum registered use rate). For samples harvested at 64-87 days posttreatment, residues were <0.05 ppm in/on grain and 0.08-2.9 ppm in/on straw.

- Sufficient wheat residue data reflecting the currently registered use pattern are available to support the established 0.1 ppm tolerance for propiconazole residues in/on wheat grain. However, new formulations which contain both propiconazole and trifloxystrobin for use on wheat have been requested. Refer to the memorandum Y. Donovan, D271790, 2/2/5) for recommended reassessed tolerances on wheat raw agricultural commodities (RACs).

- As the tolerance expression as been revised to contain propiconizole *per se* only, the submitted residue analytical methods are inadequate for tolerance enforcement purposes. **For enforcement purpose, residue method AG-354 is available for the determination of propiconazole *per se* in/on plant commodities using gas chromatography and flame ionization detection. The reported LOQ is 0.05 ppm. The petitioner may submit an independent laboratory validations of this method if this is what the registrant wish to use as an enforcment method, but it is not a requirement since Multiresidue Methods Section 302 (Luke Method; Protocol D) picks up parent propiconazole.**

- In addition, proposing an increase of the application rate on wheat is not a reregistration action. In future submissions of wheat residue data, the registrant should clearly identify which use pattern on wheat they intend to support. The amended use application with supporting data should be submitted to the Registration Division (RD).

- The submitted wheat processing studies are adequate and indicate that propiconazole residues concentrate in wheat bran (2x) and aspirated grain fractions (8.3x), but do not concentrate significantly in shorts, germ, middlings or flour. Based upon highest average field trial (HAFT) residues of 0.08 ppm in/on wheat grain resulting from the proposed use pattern and the average concentration factors, the maximum anticipated propiconazole residues would be 0.16 ppm in bran and 0.66 ppm in/on aspirated grain fractions.

- For reassessed tolerances on wheat processed commodities refer to the memorandum (Y. Donovan, D271790, 2/2/05).

- The current propiconazole labels specify an unrestricted plant-back interval of 105 days for all rotational crops, but the plant-back interval in the submitted study was approximately 1 year.

cc : Chem F, Chron F. Morton

RDI:Team: 1/14/05; SVH:2/23/05

TM, Thurston Morton, Rm. 816D CM2, 305-6691, mail code 7509C

PROPICONAZOLE
Shaughnessy No. 122101; Case 3125
(DP Barcode D240856)

Registrant's Response to Residue Chemistry Data Requirements

February 23, 2005

Contract No. 68-D4-0010

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

Submitted by:
Dynamac Corporation
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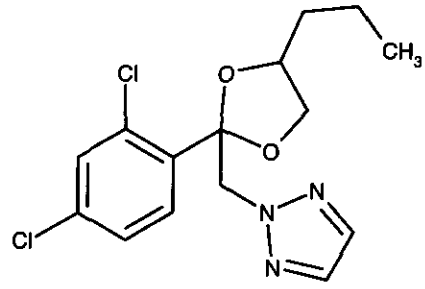
PROPICONAZOLE



Shaughnessy No. 122101; Case 3125

(DP Barcode D240856)

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

BACKGROUND

The Propiconazole Phase 4 Review, dated 6/25/92, required the registrant to amend labels to include a PHI for rice supported by the available field trial data, or provide additional rice field trials. Additional wheat field trials were also required along with a wheat processing study and label amendments specifying a PHI for wheat supported by the available residue data. In addition, storage stability data were required for residues in several commodities, and a subsequent petition review (PP#5F04591, DP Barcode D219664, L. Kutney, 6/14/96) also required storage stability data for residues in carrots.

In response to these requirements, Syngenta submitted residue data from rice field trials (1997, MRID 44411208), wheat field trails and processing studies (1997, MRIDs 44411206 and 44411207), and a storage stability study (1997, MRID 44411205) depicting the stability of propiconazole in crops and processed commodities stored at -20 C for up to 36 months. In conjunction with the wheat magnitude of the residue study (1997, MRID 44411206), the registrant also submitted data depicting propiconazole residues in rotational lentils and peas to support the use of propiconazole on wheat in the Pacific Northwest.

The registrant has also responded to an Agency request modify the proposed enforcement method to provide an alternative to diazomethane for derivatizing 2,4-dichlorobenzoic acid (2,4-DCBA). Syngenta has submitted (1997, MRIDs 44411201 and 44411204) method descriptions and validation data revising Methods AG-454B and AG-517 to include methyl iodide as the methylating agent.

These data are reviewed here for their adequacy in fulfilling residue chemistry data requirements.

The qualitative nature of propiconazole residues in plants is adequately understood. The residues of concern in/on plant commodities is propiconazole *per se*.

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 various plant and animal commodities; issues of compatibility between Codex MRLs and U.S. tolerances will be addressed when the reregistration eligibility decision for propiconazole is made. A Codex MRL has not been established for propiconazole in rice.

DETAILED CONSIDERATIONS

Residue Analytical Methods

Two GC/ECD analytical methods, AG-454 and AG-517, were approved for enforcing tolerances for residues of propiconazole and its metabolites in/on plant and animal commodities, respectively. These methods use a single moiety detection method in which residues are converted to 2,4-DCBA, determined as the 2,4-DCBA methyl ester, and reported as propiconazole equivalents using a 1.79 conversion factor. Both methods were successfully validated by the Agency and forwarded to FDA for publication in PAM, Vol. II for enforcement purposes. However, the Agency requested that the registrant find a safer and commercially available replacement for diazomethane, the derivatizing agent used in these methods.

As the tolerance expression as been revised to contain propiconizole *per se* only, the submitted residue analytical methods are inadequate for tolerance enforcement purposes. **For enforcement purpose, residue method AG-354 is available for the determination of propiconazole *per se* in/on plant commodities using gas chromatography and flame ionization detection. The reported LOQ is 0.05 ppm. The petitioner may submit an independent laboratory validations of this method if this is what the registrant wish to use as an enforcment method, but it is not a requirement since Multiresidue Methods Section 302 (Luke Method; Protocol D) picks up parent propiconazole.**

Method AG-454B

In conjunction with magnitude of the residue studies for rice, Syngenta (1997, MRID 44411208) submitted a description of a GC/ECD method (Ciba-Geigy method AG-454B) for determining propiconazole residues in/on rice grain and straw. The method has been previously reviewed and deemed adequate for collecting data on propiconazole residues in/on plant commodities. Sample analyses were performed by ABC Laboratories - California, Madera, CA using method AG-454B with minor modifications.

Briefly, propiconazole residues are extracted with NH_4OH/MeOH (20:80, v/v) (reflux, 1 hour), and filtered. Residues are concentrated and propiconazole residues are oxidized to 2,4-DCBA by refluxing in $KMnO_4$ and a 1N NaOH for 75 minutes. After reflux, the $KMnO_4$ is deactivated and the extract is acidified using water, sodium meta-bisulfite, and 6N 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 method LOD was not reported, but the validated LOQ is 0.05 ppm.

For method validation, control samples of rice grain and straw were fortified with propiconazole at 0.05-5.02 ppm and analyzed concurrently with treated and control samples from the field trials. Overall method recoveries of propiconazole from fortified control samples were 78-117% (Table 1). Apparent residues of propiconazole were <0.05 ppm in/on 16 control samples. Adequate sample calculations, raw data, and representative chromatograms were provided.
In conjunction with the wheat magnitude of the residue trials, processing studies, and study of propiconazole accumulation in rotational lentils and peas, Syngenta (1997, MRID 44411206) submitted a description for a GC/ECD method for determining propiconazole residues in/on wheat RACs and processed commodities and in/on rotational lentils and peas. The method, AG-454B, is identical to the one described above for rice. Sample analyses were performed by EPL Bio-Analytical Services, Harristown, IL. Chromatograms and sample calculations were provided. The results of concurrent method recoveries for wheat forage, grain, and straw, wheat processed commodities, and the rotational crops are depicted in Table 1.

For the wheat magnitude of the residue study conducted in 1992-3, control samples of wheat forage, grain and straw were fortified with propiconazole at 1.0-10.0, 0.05, and 0.1 ppm, respectively. Concurrent recoveries from 12 wheat forage control samples fortified at 1.0 ppm were 55-102% with two values, 55% and 66%, outside the acceptable range (70-120%); recoveries were all acceptable at the 5.0-10.0 ppm fortification level (79-110%). Concurrent recoveries for wheat grain and straw fortified at with propiconazole at 0.05 and 0.10 ppm, respectively, were 70-120%. Apparent residues of propiconazole were <LOQ (<0.05 ppm) in/on control samples of wheat forage (n=25), grain (n=12) and straw (n=11). Three forage and one straw control sample bore apparent propiconazole residues of 0.06-0.08 ppm.

For concurrent recoveries in processed wheat commodities, four or five control samples of wheat grain and each wheat processed commodity were fortified with propiconazole at 0.05 ppm. Concurrent recoveries were 66-120%; one recovery value, for bran, was outside the acceptable range at 66%. Apparent residues of propiconazole on four or five wheat grain and processed commodity control samples were all <LOQ (<0.05 ppm). The analytical laboratory reported one control sample of patent flour with apparent residues of 0.05 ppm. However, the uncorrected value for this sample (0.04 ppm) is <LOQ (<0.05 ppm)

In the field accumulation in rotational crops study, three control samples of each RAC from lentils and peas (both succulent and dried) were fortified with propiconazole at 0.05-0.50 ppm. Concurrent method recoveries were 72-110%. Apparent residues of propiconazole were <LOQ (<0.05 ppm) in/on 24 control samples from rotational crop matrices.

In conjunction with the 1996 wheat magnitude of the residue trial and processing study, Syngenta (1997, MRID 44411207) submitted a description of a GC/ECD method for determining propiconazole residues in/on wheat grain and straw and processed commodities. The method, AG-454B, is identical to the one described above for rice. Sample analyses were performed by ABC Laboratories, Inc., Columbia, MO. Chromatograms and sample calculations were provided. The registrant provided concurrent method recovery data for all matrices which are presented in Table 1.

For the wheat magnitude of the residue study conducted in 1996, control samples of wheat grain and straw were fortified with propiconazole at 0.05-0.01 ppm and 0.05-20.0 ppm, respectively. Concurrent recoveries from 12 wheat grain control samples fortified at 0.05 ppm (10 samples) and 1.0 ppm (2 samples) were 69-114% with one value outside the acceptable range at the 0.05 ppm fortification level at 69%. Concurrent recoveries from wheat straw were unacceptable at the 0.10 ppm fortification level (60%, 64% and 82%); however, recovery values were acceptable from all five control samples fortified with propiconazole at the 0.05, 0.50 and 20.0 ppm (72-85%). Apparent residues of propiconazole in/on 15 control samples of wheat grain and straw were <LOQ (<0.05 ppm). One straw control sample bore propiconazole residues at 0.06 ppm. In this case, an uncorrected value of 0.04 ppm was corrected by the registrant to >LOQ due to a poor recovery (64%).

For concurrent recoveries in wheat processed commodities, four control samples of wheat grain and each processed fraction were fortified with propiconazole at 0.05 and 0.01 ppm. Aspirated grain fractions were also fortified at the 0.05 ppm level. Concurrent recoveries for 32 control samples of wheat grain and processed commodities were 62-114% with five samples outside the acceptable range with recoveries of 62-69%. Apparent residues of propiconazole in/on all wheat grain and processed commodity control samples were all <LOQ (<0.05 ppm).

Table 1. Concurrent recoveries of propiconazole from fortified control samples.

MRID	Crop	Commodity	Fortification level	Number of samples	% Recovery [a]
44411208	Rice	grain	0.05-0.10	9	78-93
		straw	0.05-5.0	9	78-117
44411206	Wheat	forage	1.0-10.0	28	55-110 (2)
		grain	0.05	19 [b]	70-120
		straw	0.10	12	71-120
		aspirated grain fractions	0.05	4	82-103
		bran	0.05	5	66-102 (1)
		middlings, shorts, low grade flour, patent flour	0.05	20 [c]	71-104
	Lentils	forage	0.50	3	82-98
		hay	0.10	3	80-109
		lentils	0.05	3	80-102
	Peas, green	peas	0.05	3	84-110
		vines	0.10	3	72-86
	Peas, dried	peas	0.05	3	87-103
		straw	0.10	3	97-106
		vines	0.50	3	84-94
44411207	Wheat	grain	0.05-0.10	12	69-114 (1)
		straw	0.05-20.0	8	60-85 (2)
		aspirated grain fractions	0.05-0.50	4	64-82 (1)
		germ	0.05-0.10	4	62-99 (1)
		bran	0.05-0.10	4	63-97 (1)
		middlings, shorts, low grade flour, patent flour	0.05-0.10	16 [c]	64-104 (1)

[a] The number of samples with recoveries outside the acceptable 70-120% range is listed parenthetically.

[b] Number of samples includes 4 recoveries made using bulk grain samples prior to processing, and 3 made to wheat grain subsamples selected for reanalysis.

[c] Four or five fortified control samples of each processed commodity were analyzed.

In response to an Agency request to provide a safer alternative for derivatizing 2,4-DCBA than diazomethane, the registrant revised methods AG-454B and AG-517 to include the use of methyl iodide as the methylating agent.

Method AG-626

Syngenta (1997, MRID 44411201) submitted a description of a GC/ECD method, AG-626, for determining propiconazole residues in/on plant commodities along with method validation data using various plant commodities. Method AG-626 is essentially the same as Method AG-454B with the exception that 2,4-DCBA is methylated using methyl iodide in the presence of tetrabutyl ammonium hydroxide (TBAH). Methylated 2,4-DCBA is then partitioned into hexane and cleaned-up on an acidic alumina Sep-Pak eluted with hexane prior to analysis by GC/ECD. The method LOQ is 0.05 ppm. For confirmation, procedures for analysis by GC/MSD are included in the method. The time required for the analysis of 5-6 samples was reported to be 16 work hours.

For method validation, control samples were fortified with propiconazole at 0.05-1.0 ppm (citrus fruit, lentils, and onions), 0.05-3.0 ppm (celery and wheat forage), and 0.05-0.5 ppm (wheat chaff and grain). Method recoveries were 72-122% from all commodities (Table 2); one sample each of celery and wheat forage had recoveries outside the acceptable range at 122% and 121%, respectively. Apparent residues of propiconazole were <0.05 ppm in/on all control samples of citrus fruit (n=3), lentils (n=2), immature wheat plants (n=2), and wheat grain (n=2). Apparent propiconazole residues were also <0.05 ppm in/on one control sample each of onion and wheat chaff. However, apparent residues of propiconazole were detected at 0.074 and 0.16 ppm in/on two onion controls, 0.054 and 0.06 ppm in/on two celery controls, 0.11 and 0.15 ppm in/on two wheat forage controls, and 0.12 ppm in/on one wheat chaff control. The registrant indicated that similar levels of interference were noted when Method AG-454B was originally validated. Adequate sample calculations, raw data, and representative chromatograms were provided.

Method AG-626 was also radiovalidated using samples of celery and wheat forage and chaff from metabolism studies. Results for these analyses are presented in Table 3. Extractability of ^{14}C-residues was 82-121% of the TRR, and 68-87% of the TRR was determined by GC/ECD to consist of ^{14}C-residues convertible to 2,4-DCBA.

As the tolerance expression as been revised to contain propiconizole *per se* only, the submitted residue analytical methods are inadequate for tolerance enforcement purposes. Therefore, new residue analytical methods must be submitted which analyzes for propiconizole *per se* only, if such a method is not already available.

Table 2. Method recoveries of propiconazole, determined as 2,4-DCBA-Me, from control samples of various plant commodities using the GC/ECD Method AG-626.

Crop	Commodity	Fortification level	Number of samples	% Recovery	
				Range [a]	Average (CV) [b]
Citrus	whole fruit	0.05-1.0	8	80-98	83 (6.7)
Lentil	seed	0.05-1.0	8	86-112	99 (8.4)
Onion	dry bulb	0.05-1.0	8	72-98	84 (12)
Celery	petiole	0.05-3.0	4	81-122 (1)	92 (22)
Wheat	immature whole plant	0.05-3.0	6	73-121 (1)	94 (20)
	forage	0.05-3.0	7	74-111	88 (15)
	chaff	0.05-0.40	9	79-119	96 (14)
	grain	0.05-0.50	7	72-99	84 (11)

[a] The number of samples with recoveries outside the acceptable 70-120% range is listed parenthetically.
[b] The coeffiecent of variation (CV) is listed parenthetically.

Table 3. Radiolabeled method validation of GC/ECD method AG-626 using samples from the wheat and celery metabolism studies.

Crop/commodity	Treatment rate (lb ai/A)	TRR (ppm)	Solvent extractable ^{14}C-residues		Total propiconazole residues determined by GC/ECD analysis [a]	
			ppm [b]	% TRR	ppm [b]	%TRR
Immature whole wheat plants	0.5	3.78	3.36	89	3.27	87
Wheat forage	0.1	3.45	2.84	82	2.4	70
Wheat chaff	0.5	0.28	0.23	82	0.19	68
Celery	0.5	0.85	1.03	121	0.72	84
	2.5	3.1	2.9	95	2.3	73

[a] Total propiconazole residues determined as 2,4-DCBA methyl ester by GC/ECD and expressed as propiconazole.
[b] Data are expressed in propiconazole equivalents and are the average from the analysis of three samples.

Method AG-629

Syngenta (1997, MRID 44411204) submitted a description of a GC/ECD method, AG-629, for determining propiconazole residues in/on meat, milk, poultry, and eggs along with method validation data using various animal commodities. Method AG-629 is essentially the same as Method AG-517, which has been previously described (Phase 4 Review), except that residues of 2,4-DCBA are methylated using methyl iodide in the presence of TBAH instead of diazomethane and there is an optional clean-up step following methylation. Methylated residues can be partitioned into hexane and cleaned-up on an acidic alumina Sep-Pak eluted with hexane:ethyl ether (90:10, v:v) prior to analysis by GC/ECD. The method LOQ is 0.05 ppm for residues in meat, poultry and eggs and 0.02 ppm for residues in milk. For confirmation, procedures for analysis by GC/MSD are included in the method. The time required for the analysis of 5-6 samples was reported to be 16 work hours.

For method validation, control samples of meat, liver, kidney, fat and eggs were fortified with propiconazole at 0.05-1.0 ppm and control samples of milk were fortified at 0.02-0.5 ppm. Method recoveries of propiconazole were 71-117% from beef meat, fat, kidney and liver and poultry meat and liver (Table 4). Method recoveries from milk were 68-97%, with one sample outside the acceptable range; method recoveries from eggs were 67-88%, with three recovery values at 67-69%. Apparent residues of propiconazole were <LOQ (<0.05 ppm) in/on three control samples each of beef fat, kidney, meat, milk, and eggs and in/on two control samples of beef liver. One control sample each of poultry meat and liver had apparent residues of <0.05 ppm, and the other control sample from each of these matrices had apparent propiconazole residues of 0.05 and 0.053 ppm, respectively. Adequate sample calculations, raw data, and representative chromatograms were provided.

As the tolerance expression as been revised to contain propiconizole *per se* only, the submitted residue analytical methods are inadequate for tolerance enforcement purposes. **For enforcement purpose, the petitioner may submit new method and an independent laboratory validations of this method which detects only the parent, but it is not a requirement since Multiresidue Methods Section 302 (Luke Method; Protocol D) picks up parent propiconazole.**

Table 4. Method recoveries of propiconazole, determined as 2,4-DCBA-Me, from control samples of animal commodities using the GC/ECD Method AG-629.

Animal	Commodity	Fortification level	Number of samples	% Recovery [a]	
				Range	Average (CV) [b]
Beef/Dairy cattle	meat (muscle)	0.05-1.0	9	74-90	80 (7.8)
	fat	0.05-1.0	8	74-102	83 (13)
	liver	0.05-1.0	9	72-117	89 (18)
	kidney	0.05-1.0	8	75-106	85 (15)
	milk	0.02-0.50	8	68-97 (1)	79 (13)
Poultry	meat (muscle)	0.05-1.0	8	71-117	86 (20)
	liver	0.05-1.0	8	81-115	92 (13)
	eggs	0.05-1.0	8	67-88 (3)	74 (9.6)

[a] The number of samples with recoveries outside the acceptable 70-120% range is listed parenthetically.
[b] The average recovery and coefficient of variation (CV) were determined using all recovery values.

Storage Stability Data

In response to the Phase 4 Review, the registrant has submitted a storage stability study (1997, MRID 44411205) depicting the stability of propiconazole in a variety of plant matrices stored at -20° C for up to 36 months. Storage stability data on carrots which was requested by the Agency after a petition review (L. Kutney, 6/14/96) has also been provided.

Control samples of peach, banana, corn meal, wheat grain, celery, corn oil, carrot and peanut nutmeat were fortified with propiconazole at 1.0 ppm; peanut hay and hulls were fortified at 5.0 ppm. Sampling intervals were 0, 4-5, 12-13, 25-27 and 36 months for all crops except carrots. The sampling interval for carrots was 0, 4 and 10 months. At each sampling interval a control sample, two freshly fortified samples, and two stored fortified samples were analyzed for each matrix. Residues of propiconazole in/on each crop matrix were determined using GC/ECD Method, AG-454B described above. In the current study, the validated LOQ for propiconazole in/on all matrices was 0.05 ppm.

Recoveries from freshly fortified and frozen stored samples were corrected for apparent propiconazole residues detected in control samples. The recovery of propiconazole from frozen stored samples was corrected using the average of two concurrent method recovery samples. The results are presented in Table 5. The submitted 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 stable in carrots at least 10 months at -20° C.

Table 5. Stability of propiconazole in crop matrices fortified with propiconazole at 1.0 ppm (peanut hay and hulls, 5.0 ppm) and stored at -20° C for up to 36 months.

Matrix	Storage Interval (months)	Percent Recovery		
		Freshly fortified [a]	Stored Fortified [b]	Stored Average
Peaches	0	61, 66	100, 120	110
	4	65, 63	130, 120	125
	13	73, 77	81, 93	87
	27	87, 94	95, 93	94
	36	72, NA	110, 89	100
Bananas	0	65, 66	93, 88	91
	4	98, 84	97, 110	104
	13	72, 77	97, 88	93
	27	97, 92	110, 100	105
	36	72, 74	110, 99	105
Corn meal	0	68, 72, 82, 74 [c]	120, 110, 110, NA [c]	113
	4	76, 84	120, 110	115
	12	65, 79	100, 110	105
	27	98, 107	110, 100	105
	36	64, 85	110, 130	120
Wheat grain	0	85, 89	87, 96	92
	4	89, 82	110, 100	105
	13	66, 69	100, 100	100
	27	93, 96	99, 96	98
	36	68, 78	120, 120	120
Peanut hay	0	69, 85	104, 74	89
	4	79, 89	106, 92	99
	12	64, 71	106, 102	104
	26	90, 90	100, 94	97
	36	92, 82	98, 92	95
Peanut hulls	0	78, 72	120, 100	110
	4	62, 79	110, 108	109
	12	76, 71	96, 100	98
	26	88, 92	94, 100	97
	36	77, 72	102, 100	101
Peanut nutmeat	0	77, 76	87, 95	91
	4	82, 85	88, 100	94
	12	58, 63	100, 110	105
	25	86, 82	100, 96	98
	36	70, 76	100, 100	100
Celery	0	NA, 79	100, 110	105
	4	62, 72	100, 100	100
	12	61, 66	110, 100	105
	26	74, 81	100, 100	100
	37	61, 63	110, 120	115

(*Continued*)

Table 5. Continued.

Matrix	Storage Interval (months)	Percent Recovery		
		Freshly fortified [a]	Stored Fortified [b]	Stored Average
Corn oil	0	66, 69	93, 92	93
	5	53, 61	88, 100	94
	12	63, 76	110, 100	105
	26	69, 73	100, 100	100
	37	34, 36, 55, 31 [c]	120, 110, 88, 110	107
Carrots	0	79, 83	95, 99	97
	4	107, 112	110, 110	110
	10	76, 80	100, 100	100

[a] Method recoveries are corrected for apparent residues of propiconazole found in control samples.

[b] Recoveries from frozen fortified samples are corrected for the average of method recovery, and for apparent residues of propiconazole found in control samples.

[c] Samples were reanalyzed. NA indicates that values were not available because sample was lost.

In the current crop field trial submissions, samples of rice and wheat RACs were stored frozen following harvest for up to 6 months and 3-19 months, respectively. Wheat processed fractions were stored frozen 1-14 months. In the rotational crop study, RACs from lentil and pea were stored frozen for up to 5 months prior to analysis.

The available storage stability data support the current field trial and processing studies conducted on rice and wheat. The data show that residues of propiconazole are stable in various raw agricultural commodities, including wheat grain, as well as processed grain fractions (cornmeal) stored frozen at -20° C for up to 36 months. Residues of propiconazole have also been shown to be stable in frozen soybean fodder and grain for up to 6 months (PP#8F3654, M. Flood, 11/8/93). These data can be translated to support the storage intervals for samples from the crop rotation study on lentils and peas. In addition, storage stability data (DP Barcode D210742, M. Rodríguez, 3/15/95) for residues in grass forage, straw and seed indicated that propiconazole is stable for up to 38 months at -20° C. These data support the sample storage intervals for rice straw and wheat forage and straw in the current studies.

Magnitude of the Residues in Plants

Rice

Tolerances have been established for propiconazole residues in/on rice grain and straw at 0.1 and 3.0 ppm, respectively [40 CFR §180.434]; no tolerance has been established for residues in rice processed food/feed commodities.

A REFS search dated 2/18/98 listed three propiconazole end-use products, a WP and two 3.6 lb/gal ECs registered to Syngenta for use on rice; however, the label for the WP (EPA Reg. No. 100-780) does not include use directions for rice. The 3.6 lb/gal ECs (EPA Reg. Nos. 100-617 and 100-737) permit two foliar applications to rice first at internode elongation (up to 2-inch panicle) and a second 10-14 days later but before boot split and head emergence at 0.17 lb ai/A/application, with a maximum seasonal rate of 0.34 lb ai/A. The label also allows a single application at first at internode elongation (up to 2-inch panicle) at 0.28 lb ai/A. The labels prohibit (I) use on rice in CA, (ii) use on stubble or ratoon rice crops, (iii) use on rice fields where commercial crayfish farming is practiced, (iv) draining of water from treated fields into ponds used for commercial catfish farming, or (v) using water from treated field for the irrigation of other crops. The label also specifies minimum application volume of 5 and 15 gal /A for aerial and ground applications, respectively. A PHI is not specified.

Syngenta submitted data (1997, MRID 44411208) from eight tests conducted during 1996 in AR (2), LA(2), MO(2) , and TX(2) depicting residues of propiconazole in/on rice grain and straw. In four of the tests, propiconazole (3.6 lb/gal EC) was applied twice foliarly to rice at 0.17 lb ai/A/application (0.34 lb ai/A/season; 1x the maximum seasonal application rate) first at internode elongation and again 6-21 days later at swollen boot. In the other four tests, propiconazole was applied once to rice at 0.28 lb ai/A (1x the maximum single application rate) at internode elongation in three tests and at swollen boot in one test. Applications were made using ground equipment in 15-32 gal of water per acre.

A single control and two treated samples of rice grain and straw were harvested from each test site 45 days following the last application, and again at full crop maturity, if necessary. After harvest, samples were stored frozen at the field site for 1-15 days until shipment to Syngenta, Greensboro, NC by freezer truck. Upon receipt by Syngenta, the samples were placed in frozen storage at -20° C and prepared for analysis by homogenization with dry ice within 33-78 days. The prepared samples were shipped packed in dry ice to ABC Laboratories, Inc, Madera, CA, and were placed in frozen storage prior to analysis. The total time the samples remained frozen from harvest to analysis was 100-175 days. The available storage stability data indicate that propiconazole is stable in wheat grain and grass straw stored at -20° C for up to 36 months; no additional storage stability data are required to support the current rice study.

Residues of propiconazole were determined using the adequate GC/ECD Method AG-454B described above. The validated LOQ is 0.05 ppm for propiconazole in/on rice grain and straw; a LOD was not reported. Residues of propiconazole were <0.05-0.28 ppm in/on rice grain and 0.50-1.75 ppm in/on straw harvested 45 days following the last of two foliar applications at 0.17 lb ai/A/application (Table 6). Two grain samples bearing propiconazole residues of 0.23 and 0.28 ppm exceeded the 0.1 ppm tolerance, and residues were at the tolerance in/on one sample. Propiconazole residues were <0.05-0.07 ppm in/on rice grain and 0.33-1.62 ppm in/on straw harvested 45-66 days following a single foliar application at 0.28 lb ai/A (Table 7). Apparent residues of propiconazole were <0.05 ppm in/on all 16 control samples of rice grain and straw. Adequate sample calculations, raw data, and representative chromatograms were provided.

Geographic representation of the residue data is adequate and a sufficient number of tests were conducted. Following Phase 4 Review recommendations regarding the location of field trials in for rice, the registrant conducted tests in Region 4 (4 tests), Region 5 (2 tests), and Region 6 (2 tests) for a total of 8 tests.

The submitted residue data are adequate and indicate that the established tolerance of 0.1 ppm for propiconazole residues in/on rice grain is too low. Residues of propiconazole in/on 2 of 8 rice grain samples were over-tolerance at 0.23 and 0.28 ppm following the last of two applications each at 0.17 lb ai/A (1x the maximum season rate). Similar results were obtained in preliminary residue rice trials (DP Barcode D185566, C. Swartz, 11/2/93) conducted by the registrant in AR and LA where residues were 0.11-0.19 ppm in/on 5 of 12 rice grain samples harvested ~54 days following treatment reflecting the registered use patterns. Regarding the current study, the registrant concluded that over-tolerance residues were due to treatment of the rice before or after the label recommended 10-14 day retreatment interval (RTI); however, the field trial reports indicate that the second application was made at swollen boot prior to boot split in accordance with label directions. Of the four tests having using two applications, only one test was applied according to the minimum specified RTI of 10-14 days.

The available residue data on rice 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. In addition, use directions for rice on all labels should be amended to specify a 45-day PHI.

Table 6. Residues of propiconazole in/on rice grain and straw harvested following the last of two foliar applications of propiconazole (3.6 lb/gal EC) at 0.17 lb ai/A/application (1x maximum seasonal rate).

Location	RTI (days)	PHI (days)	Propiconazole residues (ppm) [a]	
			grain	straw
Jackson, AR	15	45	<0.05, <0.05	0.83, 0.87
St. Landry, LA	21	45	0.23, 0.28	1.04, 1.43
Penniscot, MO	16	45	<0.05, <0.05	0.50, 0.67
Wharton, TX	6	45	0.10, 0.09	1.21, 1.75

[a] Residues are expressed in propiconazole equivalents and are not corrected for concurrent recoveries.

Table 7. Residues of propiconazole in/on rice grain and straw harvested following a single foliar application of propiconazole (3.6 lb/gal EC) at 0.28 lb ai/A (1x maximum single application).

Location by county/state	PHI (days)	Propiconazole residues (ppm) [a]	
		grain	straw
Jackson, AR	45	<0.05, <0.05	0.73, 0.42
	60	<0.05, <0.05	0.51, 0.32
St. Landry, LA	45	<0.05, 0.07	0.83, 1.00
	66	0.06, 0.05	0.68, 1.56
Penniscot, MO [b]	45	<0.05, <0.05	0.41, 0.33
Wharton, TX	45	<0.05, <0.05	1.24, 1.62
	51	<0.05, <0.05	1.13, 1.25

[a] Residues are expressed in propiconazole equivalents and are not corrected for concurrent recoveries.

[b] Propiconazole was applied at the swollen boot stage instead of at the label recommended internode elongation stage.

Wheat

The Propiconazole Phase 4 Review required the registrant to (I) amend all wheat labels to include a minimum PHI (ii) provide data depicting residues of propiconazole in/on wheat in 2 trials each located in separate parts of ND, WA, and OK, (iii) propose tolerances for processed wheat commodities or conduct new processing studies at the theoretical concentration factor (8x), and (iv) provide residue data on aspirated grain fractions. In response, the registrant has submitted two studies, one completed in 1996 supporting the registered maximum label rate of 0.11 lb ai/A/season, and another set of field trials conducted in 1992-93 supporting a new use of

two applications each at 0.11 lb ai/A. For the purposes of this review, the proposed 0.22 lb ai/A/season use rate will be considered the maximum use rate (1x); however the registrant needs to clarify exactly what use pattern they intend to support on wheat.

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.

A REFS search dated 2/18/98 listed three propiconazole end-use products, a WP and two 3.6 lb/gal ECs registered to Syngenta for use on wheat; however, the label for the WP (EPA Reg. No. 100-780) does not include use directions for wheat. The labels for the 3.6 lb/gal ECs (EPA Reg. Nos. 100-617 and 100-737) permit a single application at up to 0.11 lb ai/A to wheat and barley no later than the emergence of the ligule of the flag leaf (Feekes Growth Stage 8). A pre-harvest interval is not specified. The labels prohibit feeding or grazing of treated wheat by livestock or the cutting of the green crop for hay or silage. *(HED notes that label restrictions prohibiting the feeding of treated wheat forage and hay to livestock are no longer allowed.)* The label specifies a maximum seasonal application rate of 0.11 lb ai/A. Labeled rotational crop restrictions prohibit the planting of any other crop intended for food, grazing or animal feed or bedding for 105 days following application unless propiconazole is labeled for use on the crop. However, double cropping of cereal grains with soybeans is allowed provided the hay, forage or fodder of are not used for animal feed or bedding.

Syngenta submitted data (1997, MRID 44411207) from six tests conducted during 1996 in ND(2), OK(2), and WA(2) depicting residues of propiconazole in/on wheat grain and straw. Propiconazole (3.6 lb/gal EC) was applied foliarly to wheat at Feekes Growth Stage (FGS) 8 at 0.11 lb ai/A (0.5x the maximum proposed rate). Applications were made using ground equipment in 15.5-20.0 gal of water per acre.

A single control and two treated samples of wheat grain and straw were harvested from each test site 45-87 days following application. Residues in forage and hay were not examined in this residue study. After harvest, samples were stored frozen at the field site for 1-21 days until shipment to Syngenta, Greensboro, NC by freezer truck. Upon receipt by Syngenta, the samples were placed in frozen storage at -20° C and homogenized with dry ice within 29-71 days. The prepared samples were shipped packed in dry ice to ABC Laboratories, Inc, Madera, CA, and were placed in frozen storage at -20° C prior to analysis. Samples were analyzed within 5 days of extraction. The total time the samples remained frozen from harvest to analysis was ~3-6 months. The available storage stability data indicate that propiconazole is stable in wheat grain and grass straw stored at -20° C for up to 36 months; no additional storage stability data are required to support this wheat study.

Residues of propiconazole were determined using the adequate GC/ECD method AG-454B described above. The validated LOQ is 0.05 ppm for propiconazole in/on wheat grain and straw. Residues of propiconazole were <0.05 ppm in/on wheat grain and 0.11-0.98 ppm in/on straw

harvested 45-48 days following a single foliar application of propiconazole at 0.11 lb ai/A (0.5x rate); for samples harvested at 64-87 days posttreatment, residues were <0.05 ppm in/on grain and 0.08-2.9 ppm in/on straw (Table 8). Apparent residues of propiconazole were <0.05 ppm in/on eight control samples of grain and seven control samples of straw; one control sample of straw had apparent residues of 0.056 ppm. Adequate sample calculations, raw data, and representative chromatograms were provided.

Geographic representation of the residue data is adequate and a sufficient number of tests were conducted as stipulated in the Phase 4 Review. The registrant conducted tests in Region 11 (2 tests), Region 5 (2 tests), and Region 6 (2 tests) for a total of 6 tests.

The submitted wheat study (MRID 44411207), reflecting the currently registered use pattern (one application at 0.11 lb ai/A), is not adequate. As the Agency no longer considers feeding prohibitions practical for wheat forage or hay, residue data for wheat forage and hay are required for uses on wheat. Label use directions for wheat must be amended to remove the feeding/grazing prohibitions for forage and hay and to specify appropriate PHIs for forage and hay which are supported by residue data. In addition, labels must be amended to specify a PHI of no less than 45 days for wheat grain and straw.

Sufficient wheat data reflecting the registered use pattern are available to support the established 0.1 ppm tolerance for propiconazole residues in/on wheat grain. However, the available data indicate that the current 1.5 ppm tolerance for residues in/on wheat straw is too low. Propiconazole residues in/on two wheat straw samples harvested at 86 days following a single application at 0.11 lb ai/A from one WA test were over-tolerance at 1.9 and 2.9 ppm. Based on the available data, 5.0 ppm would be an appropriate tolerance for residues of propiconazole in/on wheat straw.

Table 8. Residues of propiconazole in/on wheat grain and straw following a single foliar application of propiconazole (3.6 lb/gal EC) at 0.11 lb ai/A (0.5x proposed maximum rate) at Feekes Growth Stage 8.

Location	PHI (days)	Propiconazole residues (ppm) [a]	
		Grain	Straw
Foster, ND	47-48 [b]	<0.05, <0.05	0.09, 0.08
	64	<0.05, <0.05	0.09, 0.11
Statsman, ND	45 [b]	<0.05, <0.05	0.59, 0.49
	69	<0.05, <0.05	0.23, 0.20
Caddo, OK	48	<0.05, <0.05	0.71, 0.71
Washita, OK	47	<0.05, <0.05	0.81, 0.83
Walla Walla, WA	86	<0.05, <0.05	1.9, 2.9
Walla Walla, WA	87	<0.05, <0.05	0.92, 1.1

[a] Residues expressed as propiconazole; values represent uncorrected data as determined by the analytical laboratory.

[b] Harvested prior to maturity, approximately milk to hard dough stage.

In addition to the residue trials required by the Agency for reregistration of propiconazole use on wheat, Syngenta has submitted residue data (1997, MRID 44411206) from 12 tests conducted during 1992-93 in CA(1), CO(1), ID(1), KS(1), MN(1), MO(1), ND(1), NY(1), OK(1), TX(1) and WA(1) depicting residues of propiconazole in/on wheat grain and straw after treatment at a proposed new rate. Propiconazole (3.6 lb/gal EC) was applied twice as a foliar spray to wheat at Feekes Growth Stages 5 and 8 at 0.11 lb ai/A/application (1x the proposed label rate) at retreatment intervals of 6-31 days. Applications were made using ground equipment in 15-41 gal of water per acre.

A single control and two treated samples of wheat forage were harvested from each test site 0 and 30-32 days following the last application; wheat grain and straw samples were harvested from each test site at maturity, 54-91 days following application. Wheat hay was not sampled. Samples frozen after harvest, shipped to Syngenta by freezer truck, and placed in frozen storage at -20° C. Prior to shipment to the analytical laboratory, samples were homogenized with dry ice. The prepared samples were shipped on dry ice to ABC Laboratories, Inc, Columbia, MO and were placed in frozen storage at -20° C prior to analysis. The entire sample storage intervals from harvest to analysis were ~3-19 months. The available storage stability data indicate that propiconazole is stable in wheat grain and grass straw stored at -20° C for up to 36 months; no additional storage stability data are required to support this wheat study.

Residues of propiconazole were determined using adequate GC/ECD method AG-454B described above. The validated LOQ is 0.05 ppm for propiconazole in/on wheat forage, grain and straw; a limit of detection was not reported. Residues in/on wheat forage harvested 0 and 30-32 days following the last of two foliar treatments of propiconazole each at 0.11 lb ai/A (1x proposed rate) were <1.2-10.7 ppm and 0.09-1.7 ppm, respectively. Residues in/on wheat grain and straw harvested 54-91 days following the 1x treatment were <0.05-0.08 ppm and <0.05-4.2 ppm, respectively. Apparent residues of propiconazole were <0.05 ppm in/on 21 control samples of wheat forage with three control samples bearing apparent residues of 0.06-0.08 ppm. Apparent residues of propiconazole in/on 12 grain controls and 11 straw controls were <0.05 ppm; one straw control sample bore apparent residues at 0.06 ppm. Adequate sample calculations, raw data, and representative chromatograms were provided.

Propiconazole residues in/on wheat forage, grain and straw harvested following two applications at 1x are presented in Table 9 together with supplemental data on wheat forage, grain and straw from tests conducted at 2x-5x the proposed maximum rate.

Geographic representation of the residue data is inadequate and an insufficient number of tests were conducted. The registrant conducted tests in Region 1 (1 test), Region 5 (3 tests), Region 6 (2 tests), Region 8 (2 tests), Region 10 (1 test) and Region 11 (3 tests) for a total of 12 tests representing 66% of the US crop production acreage. To provide adequate geographic representation as specified in the crop trial guidelines (OPPTS 860.1500), an additional 13 tests are required in Region 2 (1 test), Region 4 (1 test), Region 5 (2 tests), Region 7 (5 tests) and Region 8 (4 tests).

The submitted wheat study (MRID 44411206), reflecting a proposed use rate of two applications to wheat at 0.11 lb ai/A/application, is not adequate. An insufficient number of tests were conducted reflecting all wheat growing regions. In addition, no residue data were provided for wheat hay. As the Agency no longer considers a feeding prohibition practical for wheat hay; therefore, residue data for wheat hay are required to support this proposed use.

To support the above proposed use on wheat, 13 additional field trials are required depicting propiconazole residues in/on wheat forage, grain and straw in the following regions: Region 2 (1 test), Region 4 (1 test), Region 5 (2 tests), Region 7 (5 tests) and Region 8 (4 tests). A full set of 20 field trials as specified in OPPTS Guideline 860.1500 are also required depicting propiconazole residues in/on wheat hay. In addition, once all field trials are complete, PHIs and tolerances for forage and hay based on field trial data should also be proposed by the registrant, and labels must be amended to specify a 45-day PHI for wheat grain and straw.

Although incomplete, the available residue data for the proposed use support the established 0.1 ppm tolerance for propiconazole residues in/on wheat grain. However, these data also indicate that the current 1.5 ppm tolerance on wheat straw is too low and that a tolerance of 5 ppm would be more appropriate. The available forage data indicate that a tolerance of 2 ppm may be appropriate for propiconazole residues in/on wheat forage provided a 30-day PHI/PGI is

specified for forage on the label. Once acceptable residue data are available on wheat grain, straw, forage and hay, the registrant should propose the appropriate tolerances.

Table 9. Residues of propiconazole in/on wheat forage, grain and straw following the last of two foliar applications of propiconazole (3.6 lb/gal EC) at 0.11 lb ai/A/application (1x proposed maximum rate) [a].

Location	Application data			Propiconazole residues (ppm) [b]				
	FG Stage	RTI (days)	Rate (lb ai/A)	PHI (days)	Forage	PHI (days)	Grain	Straw
Fresno, CA	5 + 8	31	0.11+0.11	0	3.2, 4.2	91	0.06, 0.06	0.91, 0.94
				30	0.42, 0.52			
Weld, CO	5 + 8	14	0.11+0.11	0	6.7, 10.7	78	<0.05, <0.05	0.49, 0.39
				30	0.30, 0.35			
Kootenai, ID	5 +8	13	0.11+0.11	0	4.0, 3.5	75	<0.05, <0.05	1.8, 0.97
				30	1.1, 0.96			
			0.22+0.22	0	3.7	75	<0.05	4.6
				30	1.4			
Pawnee, KS	5 + 8	25	0.11+0.11	0	3.0, 3.4	54	<0.05, <0.05	1.0, 1.0
				31	0.35, 0.43			
			0.22+0.22	0	8.6, 7.9	54	<0.05, <0.05	3.2, 3.2
				31	1.1, 0.91			
			0.33+0.33	0	14.3, 13.4	54	0.05, 0.11 <0.05, <0.05	3.9, 3.3
				31	1.8, 2.2			
			0.56+0.56	0	18.3, 18.8	54	0.08,<0.05 [b]	4.0, 4.9
				31	3.1, 2.6			
Clay, MN	5 + 8	16	0.11+0.11	0	6.3, 4.3	86	<0.05, <0.05	0.12, 0.12
				32	0.37, 0.43			
Jackson, MO	5 + 8	30	0.11+0.11	0	1.2, 1.7	64	<0.05, <0.05	1.1, 0.90
				30	0.74, 0.67			
			0.22+0.22	0	4.1	64	<0.05	3.3
				30	1.3			
Cass, ND	5 + 8	16	0.11+0.11	0	7.5, 6.7	78	<0.05, <0.05	0.05, 0.06
				32	0.11, 0.12			

(*continued*)

Table 9. Continued.

Location	Application data			Propiconazole residues (ppm) [b]				
	FG Stage	RTI (days)	Rate (lb ai/A)	PHI (days)	Forage	PHI (days)	Grain	Straw
Columbia, NY	5 + 8	12	0.11+0.11	0	3.5, 1.6	69	<0.05, <0.05	0.60, 0.50
				30	0.77, 0.78			
Carter, OK	5 + 8	6	0.11+0.11	0	7.0, 6.8	82	<0.05, <0.05	0.43, 0.77
				30	1.7, 1.3			
	9	NA	0.56	0	17.6, 25.6	74	<0.05, <0.05 [b]	5.5, 5.5
				30	5.1, 2.5			
Umatilla, OR	5 + 8	37	0.11+0.11	0	2.6, 2.6	81	0.08, <0.05 <0.05, <0.05	2.0, 1.5
				30	1.4, 1.1			
	9	NA	0.56	0	9.8, 6.8	70	0.11, 0.11 0.10, 0.13	19.0, 15.0
				30	7.0, 7.5			
Burleson, TX	5 + 8	27	0.11+0.11	0	5.1, 4.0	74	<0.05, <0.05	<0.05, <0.05
				31	0.12, 0.09			
Walla Walla, WA	5 + 8	28	0.11+0.11	0	2.6, 2.7	85	<0.05 [c], 0.06	4.2, 3.5
				30	1.2, 1.5			
			0.22+0.22	0	5.4, 4.8	85	0.13, 0.06	6.8, 9.2
				30	2.1, 2.1			
			0.33+0.33	0	12.6, 7.2	85	0.14, 0.19	19.0, 12.0
				30	4.1, 2.8			
			0.56+0.56	0	12.2, 12.6	85	0.41, 0.24	56.0, 29.0
				30	6.2, 6.7			

[a] Data presented in the shaded regions reflects applications at the 1x the maximum proposed use rate of two applications at 0.11 lb ai/A/application.

[b] Residues expressed as propiconazole; values represent uncorrected data as determined by the analytical laboratory.

[c] Value was >LOQ when corrected, but under LOQ when uncorrected.

Magnitude of the Residues in Processed Food/Feed

Wheat

No tolerances have been established for residues of propiconazole in processed wheat commodities.

In conjunction with a magnitude of the residue study on wheat (1997, MRID 44411207) Syngenta submitted data from four tests conducted in 1996 in ND (2) and OK (2) depicting residues of propiconazole in wheat processed fractions. The 3.6 lb/gal EC was applied once at 0.55 lb ai/A (5x the current labeled rate) at Feekes growth stage 8.

Also, in conjunction with a magnitude of the residue study on wheat (1997, MRID 44411206) the registrant submitted data from four field trials conducted in 1992-93 in OK (1), OR (1), KS (1) and WA(1) depicting residues of propiconazole in wheat processed commodities. The 3.6 lb/gal EC was applied twice at 0.55 lb ai/A (5x the proposed maximum rate) at Feekes Growth Stages 5 and 8.

For the trials conducted in 1996, four treated and one control grain sample were harvested 47-68 days following application of propiconazole. Composite grain samples were shipped directly to the processing lab, Engineering Biosciences Research Center, Bryan, TX where they were placed in frozen storage at ~-12° C. Samples were processed according to simulated commercial procedures into aspirated grain fractions, germ, bran, middlings, shorts, low grade flour and patent flour. When processing was completed, frozen processed samples were shipped on dry ice overnight to Novartis Crop Protection, Inc., Greensboro, NC where they were stored at -20° C. Following homogenization with dry ice, the samples were shipped on dry ice to ABC Laboratories, Columbia, MO, for extraction and analysis. The grain and processed fractions were stored frozen for a total interval of ~ 2-5 months prior to analysis. The available storage stability data indicate that propiconazole is stable in wheat grain and corn meal stored at -20° C for up to 36 months; no additional storage stability data are required to support this processing study.

Wheat grain and processed commodities were analyzed using an adequate GC/ECD method, AG-454B, described above in the Analytical Methods section. The limit of quantitation was <0.05 ppm, and although not specifically stated, the data indicate that the limit of detection was <0.02 ppm. Apparent residues in/on 32 control samples of wheat grain and processed commodities were <LOQ. Sample calculations and chromatograms were submitted. Propiconazole residues in wheat grain, bran, and aspirated grain fractions are presented in Table 10; residue data for wheat germ, middlings, shorts, and flour are not presented as no concentration of residues was observed in these commodities.

For the trials conducted in 1992-93, treated and control grain samples were harvested 54-85 days following the last application of propiconazole. Samples were initially stored frozen at the field sites. Composite grain samples from one site were shipped by ACDS freezer truck directly to the

processing lab, Engineering Biosciences Research Center, Bryan, TX where they were stored at ≤3° C; the remaining sites shipped the samples overnight on dry ice to Novartis Crop Protection, Inc., Greensboro, NC where they were stored at - 20° C. The bulk grain samples designated for processing were shipped overnight on dry ice to the processing laboratory.

Samples were processed according to simulated commercial procedures into aspirated grain fractions, germ, bran, middlings, shorts, low grade flour and patent flour. Frozen processed samples were shipped packed on dry ice overnight to Novartis Inc., where they were stored at -20° C. Following homogenization with dry ice, the samples were shipped on dry ice to EPL Bio-Analytical Services, Inc., Harristown, IL, for extraction and analysis. The grain and processed fractions were stored frozen for a total interval of ~ 1-14 months prior to analysis. The available storage stability data indicate that propiconazole is stable in wheat grain and corn meal stored at -20° C for up to 36 months; no additional storage stability data are required to support this processing study.

Wheat grain and wheat processed commodities were analyzed using an adequate GC/ECD method, AG-454B, described above in the Analytical Methods section. The limit of quantitation was <0.05 ppm; The limit of detection was not reported. Apparent residues in/on 28 control samples of wheat grain and processed commodities were <LOQ. Sample calculations and chromatograms were submitted. Propiconazole residues in wheat grain, bran, shorts, and aspirated grain fractions are presented in Table 10; residue data for wheat germ, middlings, and flour are not presented as no concentration of residues was observed in these commodities.

Concentration factors were calculated using uncorrected residue data provided by the analytical laboratories. Uncorrected values for one test (Carter, OK) showed propiconazole residues in/on whole grain at 0.01 ppm, and calculations using this figure resulted in apparent concentrations in several commodities. However, as this value is far below the LOQ and other tests from the same processing study did not reveal concentration in these commodities, this apparent trend was considered insignificant.

The submitted wheat processing studies are adequate and indicate that propiconazole residues concentrate in wheat bran and aspirated grain fractions, but do not concentrate significantly in shorts, germ, middlings and flour. The average concentration factor for propiconazole residues was 2x in wheat bran and 8.3x in/on aspirated grain fractions. Based upon HAFT residues of 0.08 ppm in/on wheat grain from the proposed use pattern and the average 2x concentration factor for bran, propiconazole residues in bran could be expected to reach 0.16 ppm, which is over the 0.1 ppm tolerance for wheat grain. Similarly, the maximum residues in/on aspirated grain fractions derived from wheat are estimated to be 0.66 ppm based upon the HAFT and the 8.3x concentration factor.

The registrant should propose a tolerance for residues of propiconazole in wheat bran once acceptable wheat grain data are available. Based upon the above data a tolerance of 0.2 ppm may be appropriate for residues of propiconazole in wheat bran.

The wheat processing data also indicate that a tolerance is required for residues in/on aspirated grain fractions and that a 1.0 ppm tolerance would be appropriate for propiconazole residues in/on aspirated grain fractions. However, propiconazole is also registered for use on field corn and soybeans, and no data are yet available on aspirated grain fractions derived from these crops; these data are required. Once these data are available, HED will assess an appropriate tolerance for propiconazole residues in/on aspirated grain fractions.

Table 10. Residues of propiconazole in wheat processed commodities following application of propiconazole to wheat at Feekes growth stage 8 (0.55 lb ai/A) or at both Feekes growth stage 5 and 8 (0.55lb ai/A/application - 5x the proposed maximum rate).

Commodity	Rate (lb ai/A)	Location	Propiconazole Residues (ppm) [a]	Concentration Factor	Average Concentration Factor
MRID 44411206					
Grain	0.55	Carter, OK	0.01	NA	--
		Umatilla, OR	0.03	NA	
	0.55 + 0.55	Pawnee, KS	0.08	NA	
		Walla Walla, WA	0.43	NA	
Aspirated grain fractions	0.55	Carter, OK	0.03	3	11.0
		Umatilla, OR	0.03	≤1	
	0.55 + 0.55	Pawnee, KS	0.97	12.1	
		Walla Walla, WA	4.3	10.0	
Bran	0.55	Carter, OK	0.03	3	1.2
		Umatilla, OR	0.04	1.3	
	0.55 + 0.55	Pawnee, KS	0.11	1.4	
		Walla Walla, WA	0.40	0.9	

(continued)

Table 10. Continued.

Commodity	Rate (lb ai/A)	Location	Propiconazole Residues (ppm) [a]	Concentration Factor	Average Concentration Factor
MRID 44411207					
Grain	0.55	Foster, ND	0.02	NA	--
		Statsman, ND	0.04	NA	
		Caddo, OK	0.04	NA	
		Washita, OK	0.02	NA	
Aspirated grain fractions	0.55	Foster, ND	0.04	2.0	9.6
		Statsman, ND	0.39	9.8	
		Caddo, OK	0.18	4.5	
		Washita, OK	0.48	24.0	
Bran	0.55	Foster, ND	0.03	1.5	2.3
		Statsman, ND	0.10	2.5	
		Caddo, OK	0.08	2.0	
		Washita, OK	0.06	3.0	
Shorts	0.55	Foster, ND	<0.02	≤1	1.3
		Statsman, ND	0.05	1.3	
		Caddo, OK	0.04	≤1	
		Washita, OK	0.02	≤1	

[a] Values were reported by the analytical laboratory for samples where residues were detected at levels <LOQ (<0.05 ppm).

Field Accumulation in Rotational Crops

In conjunction with the above wheat magnitude of the residue study conducted in 1992 (1997, MRID 44411206), the registrant submitted data depicting propiconazole residues in rotational lentils and peas to satisfy requirements for field rotational crop trial data for potential uses in the Pacific Northwest. In three tests in ID, OR and WA, wheat was planted as the primary crop and treated with two foliar applications of propiconazole (3.6 lb/gal EC) at 0.11 lb ai/A/application (1x the proposed label rate) at retreatment intervals of 6-31 days. After wheat harvest, the rotational crops consisting of lentils and peas (both green and dried) were planted on the test plots at 329-376 days posttreatment.

A single control and two treated samples of lentil seeds, forage and hay; dried pea seeds, straw, and vines; and succulent pea seeds and vines were harvested from each test site. Each commodity was harvested 374-468 days following the last propiconazole application to the primary crop, and stored frozen. Lentils and hay samples from the ID test were air dried for 12 days following harvest. Samples were shipped to Syngenta by freezer truck, placed in frozen storage at -20° C, and homogenized with dry ice in preparation for analysis by the contract laboratory. The prepared samples were shipped on dry ice to EPL Bio-Analytical Services and placed in frozen storage prior to analysis. The total time the samples remained frozen from harvest to analysis was ~2-5 months.

Residues of propiconazole were determined using an adequate GC/ECD method AG-454B described above. The validated LOQ for propiconazole in/on lentils and peas and their respective commodities is 0.05 ppm. Residues of propiconazole were <LOQ (0.05 ppm) in/on all matrices harvested from rotational legume crops planted 329-376 days posttreatment. Apparent residues of propiconazole were <0.05 ppm in/on 24 control samples of each lentil and pea matrix. Adequate sample calculations, raw data, and representative chromatograms were provided.

The current propiconazole labels specify an unrestricted plant-back interval of 105 days for all rotational crops, but the plant-back interval in the above study was approximately 1 year.

AGENCY MEMORANDA CITED

DP Barcode:	D195566
Subject:	Propiconazole. 6(a)(2) Data: Over-tolerance Residues in Rice Grain and Processed Fractions.
From:	C. Swartz
To:	B. Sidwell
Dated:	11/2/93
MRID(s):	42915600 and 42915601

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

DP Barcode:	D210742
Subject:	PP#2F04086: Propiconazole in/on Oats Amendment Dated July 15, 1994; Response to CBTS #s 9325/9603.
From:	M. Rodríguez
To:	S. Lewis/D. Greenway/J. Smith
Dated:	3/15/95
MRID(s):	43314201 and 43314202

Petition No.:	5F04591
DP Barcode:	D219664
Subject:	Propiconazole on the berry crop grouping, carrots, and onions (green and dry bulb).
From:	L. Kutney
To:	D. McCall
Dated:	6/12/96
MRID(s):	43786401, 43786402, 43786403, and 43786404

MASTER RECORD IDENTIFICATION NUMBER

The citations for the MRID documents review in this document are presented below.

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 Novartis 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 Ester by Capillary Gas Chromatography: Lab Project Number: AG-629: 572-97: 411925. Unpublished study prepared by Novartis 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: Project Number: ABR-97085: 207-94: 477925. Unpublished study prepared by Novartis 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, F Lentils and Peas, Following Post Foliar Applications of Tilt: Lab Project Number: ABR-95062: 29-92: 411124. Unpublished study prepared by Novartis 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 Novartis Crop Protection, Inc. 314 p. Relates to L0000296.

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Chemical:	**Propiconazole**
PC Code:	**122101**
HED File Code	**11000 Chemistry Reviews**
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