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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: 7/31/06

Subject: **Propiconazole.** Petitions for Tolerances on Field, Vegetable and Fruit Crops. Summary of Analytical Chemistry and Residue Data. Petition Numbers: 2F6371, 6E4788, 7E4860, and 8E4931.

DP Numbers:	D238458, 238468, 238583, 238597, 238598, 247313, 312277, 313199, 313201	Decision Nos.:	
PC Code:	122101	MRID(s):	43640401, 43655612, 43655613, 44338101, 44416501, 44548402, 44757207, 44757208, 44757210, 45080807, 45080809, 45080810, 45080811, 45215806, 45275801, 45542401, 45778901, 46473001, 46576302, 46576301 46475301, 46159401
40 CFR	180.434	Chemical Class:	Triazole-Type Fungicide

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Executive Summary

Propiconazole is a triazole-type fungicide (Group 3) that provides broad spectrum disease control on a variety of crops. Tolerances in/on plant and animal commodities are currently established for the combined residues of propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole, and its metabolites determined as 2,4-dichlorobenzoic acid (2,4-DCBA) and expressed as parent [40 CFR §180.434]. Tolerances on plant commodities range from 0.1 ppm on several commodities to 40 ppm in/on grass hay and straw, and tolerances on animal commodities range from 0.05 ppm in milk to 2.0 ppm in liver and kidney of livestock.

Syngenta Crop Protection (Syngenta) and Interregional Research Project No. 4 (IR-4) have submitted several petitions supporting new or amended uses on various crops for propiconazole, formulated as a 3.6 lb/gal emulsifiable concentrate (EC) or a 45% wettable powder (WP). The proposed uses are for broadcast foliar applications using ground or aerial equipment at rates ranging from 0.11 to 0.28 lb ai/A/application. For tree nuts, the proposed use is for up to four foliar applications at 0.225 lb ai/A, for a total of 0.90 lb ai/A, with a 60-day preharvest interval (PHI). For bush and cane berries and cranberries, the proposed uses are for 4 or 5 foliar applications at 0.17 lb ai/A, for totals of 0.68-0.84 lb ai/A, with PHIs of 30 or 45 days. For carrots, leaf petiole vegetables, dry peas and beans, sugar beets and strawberries, the proposed uses are for 3 or 4 broadcast foliar applications at 0.11 lb ai/A, for totals of 0.34 or 0.45 lb ai/A, with PHIs of 0 to 21 days. For mint, the proposed use is for two broadcast foliar applications at 0.113 lb ai/A, for a total of 0.225 ai/A, with a PHI of 30 days. For soybeans, the proposed use is for two broadcast foliar applications at 0.169 lb ai/A at up to growth stage R6, for a total of 0.338 ai/A, with a PHI of 30 days. For rice, the proposed use is for a single application or split applications at heading totaling ~0.30 lb ai/A, with a PHI of 35 days. For other cereal grains, the proposed uses are for 2 to 4 broadcast foliar applications at 0.113 lb ai/A up to heading or grain development, for totals of 0.22 or 0.45 ai/A, with PHIs of 14-45 days. In conjunction with these uses, Syngenta and IR-4 are proposing permanent tolerances for propiconazole residues in/on various plant commodities at levels ranging from 0.1 ppm on alfalfa to 32 ppm on soybean hay.

The nature of propiconazole residues in plants and animals is adequately understood based on the available peanut, wheat, grape, rice, celery, carrot, goat, and poultry metabolism studies. A major metabolic pathway in plants appears to be hydroxylation (primarily of the beta-carbon) of the n-propyl group on the dioxolane ring of the cis/trans isomers of propiconazole. These metabolites appear to readily form sugar conjugates. The majority of TRR was found in the stalks, such as peanut stalk, wheat forage and straw, grape leaves, and celery stalks. The HED MARC concluded that for plants and animals, residues of propiconazole and all its metabolites containing the 2,4-dichlorophenyl moiety (2,4-DCBA), including conjugates, are of concern and should be included in the dietary (food) risk assessments, and that propiconazole *per se* should be included in the dietary (water) risk assessments. For tolerance expression, MARC concluded that the current tolerance expression for propiconazole should be amended to include residues of propiconazole *per se* only. This allows for harmonization with the residue definition for Codex.

The free triazole, triazole alanine, and triazole acetic acid are also residues of concern. Since these are common metabolites from several triazole containing pesticides, the risk assessment for triazoles has been assessed separately (HED memo of 2/7/06, M. Doherty, D322215). The cited assessment included all the proposed propiconazole new uses in the subject petitions.

For enforcing the revised tolerances, a GC method using flame ionization detection (Method AG-354) is also available for determining residues of propiconazole *per se* in/on plant commodities, and has an LOQ of 0.05 ppm. In addition, Multiresidue Methods Section 302 can also be used to determine parent propiconazole in both plant and animal matrices.

Samples from the various field trials and processing studies supporting the current petitions were analyzed for combined residues of propiconazole and its 2,4-DCBA containing metabolites using GC/ECD Methods AG-454B and AG-626, which are more recent versions of AG-454A. With the exception of almond hulls, which had a LOQ of 0.1 ppm, the validated LOQ for combined residues was 0.05 ppm in all raw and processed commodities. Each of the methods was validated in conjunction with the field trials and processing studies. In addition, samples from one of the wheat field trials and processing studies were also analyzed for residues of propiconazole, *per se*, using a multiresidue method from the Pesticide Analytical Manual (PAM, Vol. I, Section 302).

Adequate storage stability data are available indicating that residues of propiconazole are stable at ≤-15°C for up to 36 months in peaches, bananas, corn meal, wheat grain, celery, corn oil, and peanut nutmeat, hay, and hulls; 10 months in carrots; and 4-6 months in soybean seed and fodder. Weathered residues of propiconazole and its metabolites were also found to be stable under frozen storage conditions in grass forage, straw, and seed for up to 39 months at -20°C; wild rice and stone fruits for up to 25 months; and peanut hulls and fodder for 25 months at -15°C. These data support most of the samples storage intervals and conditions in the field trials and processing studies submitted with the current petitions. In cases where existing storage stability data are not available, concurrent storage stability data were submitted along with field trials.

Provided that minor changes are made to the proposed use directions, the available field trial data on almonds, bush and cane berries, carrots, celery, corn, cranberries, mint, onions, pecans, rice, sorghum, strawberries and wheat are adequate and support the proposed use patterns for propiconazole (EC or WP) on these crops. The number and geographic distribution of the field trials are adequate, and the appropriate samples were collected. Samples were analyzed using adequate analytical methods and the sample storage intervals are supported by the available storage stability data. Side-by-side field trials were conducted on almond, celery, field corn, and sugar beets to compare residues from the EC and WP formulation. These data show residues are comparable from the two products, with the exception of sugar beet tops at the requested PHI.

Adequate field trial data are also available to support the use of the 45% WP formulation on sugar beets. However, based on the results of the side-by-side tests with the WP and EC formulations, residues in/on tops at the proposed 21-day PHI are likely to be higher for the EC formulation than the WP formulation. Therefore, a complete set of field trial data are required for sugar beet tops reflecting the use of the EC formulation. A conditional registration can be established on sugar beet tops.

For soybeans, after considering all the available soybean field trial data, HED concluded that sufficient residue data are available to support tolerances on soybean forage and hay harvested 30 days following the second of two applications totaling 0.33 lb ai/A (1x rate). Although the petitioner has requested tolerances for soybean forage and hay, the Agency notes that the currently proposed use directions for soybean prohibit the feeding or grazing for forage or hay. HED also considers sufficient residue data are available to support tolerances on soybean seed, even though the PHIs of the soybean seed data varies from 30 to 90 days. Since soybean mature at different times depending on the growing regions, PHI in days can vary from region to region; therefore, provided the label has such language as "do not apply later than the R5 growth stage' or 'apply up to Stage R6", no additional field trials are required for soybean seeds.

For dry peas and beans, however, there are no sufficient field trial data to support the proposed use as only six dry bean field trials are available and no dry pea field trials were conducted. For a subgroup crop tolerance on 6C, a total of 12 dry bean field trials and 5 dry pea field trials are required. In addition, the available dry bean field trials support a PHI of 28 days rather than the 14-day PHI on the proposed label. HED recommends against the establishment of permanent tolerance on subgroup crop 6C until additional field trial data are submitted.

The Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* (tolerance spread sheet) was utilized for determining appropriate tolerance levels on plant commodities. While these tolerance/residue levels are suitable for Tier I dietary risk assessment, they are considered conservative for tolerances in that the field trial data were reported as parent plus all metabolites containing 2,4-DCBA, while the tolerance expression is parent only. HED recommends that the registrant analyze parent and metabolites separately in all future field trials, so that more realistic tolerances can be set in the future.

Adequate processing studies are available for alfalfa (rotational crop), field corn, mint, rice, sorghum, soybean, sugar beet, and wheat. These studies indicate that, with the exception of aspirated grain fractions (AGF), combined propiconazole residues did not concentrate in processed commodities derived from alfalfa, field corn, mint, sorghum, and soybeans, or in polished rice, sugar beet refined sugar, or wheat germ, shorts, middlings and flour. However, combined residues were shown to concentrate in rice hulls (3.8x) and bran (2.9x), sugar beet molasses (7.4x) and dried pulp (4.9x), and wheat bran (3.2x). Considering the highest average field trial (HAFT) residues in the various RACs and the above processing factors, appropriate tolerances for combined propiconazole residues are 20 and 15 ppm for rice hulls and bran, 1.5 and 1.0 ppm for sugar beet molasses and dried pulp, and 0.6 ppm for wheat bran. The recommended tolerance for wheat bran will be translated to bran of barley and rye. With regards to AGF, combined residues were also shown to concentrate by various degrees in AGF derived from field corn (12.8x), sorghum (5.2x), soybeans (32x), and wheat (18x) following late season applications. Considering these AGF concentration factors and the HAFT residues in the respective RACs, the maximum expected residues in AGF are 1.28 ppm for corn, 10.9 ppm for sorghum, 30 ppm for soybean, and 3.2 ppm for wheat. Therefore, the recommended tolerance for propiconazole residues in AGF is 30 ppm based on the soybean data.

The maximum theoretical dietary burdens (MTDB) for combined propiconazole residues were calculated to be 29.0 ppm for beef and 18.5 ppm for dairy cattle, 2.3 ppm for swine and 2.0 ppm for poultry. To estimate maximum combined residues in cattle and swine commodities, the residue levels for the 75-ppm feeding level at 21 days were selected as these residue levels were the highest for the 75-ppm group. This feeding level represents a 2.7x the MTDBs for beef cattle, 4.2x for dairy cattle, and a 32.6x for swine. Maximum combined residues were estimated by dividing the residue values for milk and tissues at the 75-ppm dose level by 2.7 for cattle, 4.2 for milk, and 32.6 for swine. For beef cattle, estimated combined residues at a 1x feeding level are 1.7 ppm for kidney, 1.6 ppm for liver, 0.03 ppm for muscle, 0.05 ppm for fat, and 0.03 pm for milk. For swine, estimated combined residues at a 1x feeding level are 0.14ppm for kidney, 0.13 ppm for liver and <0.005 ppm for muscle and fat. HED recommends that the following tolerance levels be established: For cattle, goat, horses and sheep, kidney and liver at 2.0 ppm; meat and meat byproduct (except kidney and liver) and fat at 0.05 ppm, milk at 0.05 ppm. For hog, kidney and liver at 0.20 ppm, no tolerances are needed for meat, fat, and meat byproduct.

For poultry tissues and eggs, estimated combined residues and parent residues were calculated in the same manner as for cattle and swine. The maximum combined residues in tissues and eggs from the 7.5-ppm dose group in the poultry feeding study were used to estimate residues at the 1x feeding level. The estimated combined residues at the 1x feeding level are all < LOQ. Therefore, tolerances for poultry tissues and eggs are not required as quantifiable levels of propiconazole are unlikely to occur in these commodities [40 CFR 180.6(a) (3)].

Adequate confined rotational crop studies are available indicating that the residues in rotational crops are similar to the primary crops. The confined studies also support the 105-day plant-back interval (PBI) currently listed on product labels for crops without direct uses. Under the current petition, Syngenta has submitted extensive rotational crop field trial data on alfalfa planted following propiconazole-treated wheat and proposed a 0.1 ppm tolerance for inadvertent residues in/on alfalfa. The available alfalfa rotational crop field trials are adequate and will support a 75-day PBI for alfalfa following propiconazole application(s) to primary crops at up to 0.22 lb ai/A/season.

Residue Chemistry Deficiencies

With the exception of the residue data for dry peas and beans, and sugar beet tops, no major deficiencies were noted in the subject petitions that would preclude establishing permanent tolerances for propiconazole on the proposed commodities. Pending the favorable outcome of the aggregate risk assessment, HED recommends establishing permanent tolerances for propiconazole residues at the levels recommended in the Table 9. As insufficient field trial data are available on dry peas and beans (subgroup 6C), HED recommends against establishing permanent tolerances on these commodities at this time until additional field trials are submitted. A conditional registration can be established on sugar beet tops. A human health risk assessment is forthcoming.

- Label directions for the EC and WP formulations must be amended to include the recommended changes listed under the 'Directions for use' section.

- To support the use of the EC formulation on sugar beets, an additional 8 sugar beet field trials are required using a representative EC formulation. As the available data indicate that residues in/on roots are similar for the WP and EC formulations, only residue data on sugar beet tops are required from these trials. HED recommends that registration of the EC on sugar beets be conditional upon the data on tops.

- A total of 12 dry bean field trials and 5 dry pea field trials are required to support the proposed tolerance on the dry pea and bean subgroup 6C. Only five dry bean field trials are available, and they support a 28-day PHI rather than the proposed 14-day PHI. Additional 7 trials on dry beans and 5 trials on dry peas at the proposed rates are needed.

- Since data are available supporting tolerances on soybean forage and hay, the petitioner may delete the "prohibit animal grazing" or "prohibit feeding hay to livestock" on the label.

- The available wheat field trial will only support a maximum use rate of 0.11 lb ai/A prior to the harvest of forage or hay. Label must be revised to specify that no more than 0.11 lbs ai/A be applied before the harvest of forage and hay. If the petitioner intends to support the use of two applications totaling 0.22 lb ai/A prior to harvest of forage and hay, then an additional 8 field trials are required on forage and a complete set of 20 field trials are required for hay.

- The available field corn and sorghum field trial data will only support applications totaling 0.22 lb ai/A prior to the harvest of forage. If the petitioner intends to support total application rate up to 0.44 lb ai/A prior to the harvest of forage, than additional field corn and sorghum forage data will be required to support the higher use rate.

- As propiconazole is one of the triazole producing pesticides, any requests for new uses submitted after September 1, 2005 will require data related to assessing the common metabolites. For detailed information, please refer to HED memo of 4/25/06, M. Doherty, D327788. "Guidance on Residue Chemistry Data Submission".

Background

Propiconazole is a triazole-type fungicide (Group 3) that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. It is formulated as 3.6 lb/gal emulsifiable concentrates (EC) and 45% wettable powder (WP). Propiconazole end-use products are marketed in the United States under the trade names Tilt®, Alamo®, Banner®, and Orbit®. Recently, propiconazole is also registered for use on a variety of crops under the trade names of Stratego™ Twin-Pak™ and Stratego™ , which are end-use products containing a mixture of trifloxystrobin and propiconazole.

Permanent tolerances are currently established for the combined residues of propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole, and its metabolites determined as 2,4-DCBA and expressed in parent equivalents, at levels ranging from 0.1 ppm on numerous plant commodities to 40 ppm in/on grass hay and straw [40 CFR §180.434(a)]. Permanent tolerances are also established for the combined residues of propiconazole and its metabolites determined as 2,4-DCBA at 0.1 ppm in fat, meat, and meat byproducts (except liver and kidney) of livestock, 2.0 ppm in liver and kidney of livestock, and at 0.05 ppm in milk; however, no tolerances have been established for eggs and poultry commodities. Time-limited tolerances are established for combined propiconazole residues in/on a variety of plant commodities at levels from 0.2 ppm in/on sorghum grain to 25 ppm in/on soybean hay [40 CFR §180.434(b)]. In addition, tolerances with regional restrictions have been established for combined propiconazole residues at 0.3 ppm in/on mint tops and 0.5 ppm in/on wild rice [40 CFR §180.434(c)].

Syngenta previously submitted a series of petitions (PP#s 4F3007, 4G3075, 5F4424, 5F4591, and 9F3740) supporting the use of propiconazole, formulated as an EC, on tree nuts, corn, cereal grains, legume vegetables, soybeans, berries, strawberry, sugar beet, carrots and onions. These petitions have been superseded by a single petition (PP#2F6371), which includes new or amended use directions for the above crops. In conjunction with these petitions, Syngenta is proposing the following permanent tolerances as of 7/18/05.

AGF	17.0 ppm
Almond, hulls	8.0 ppm
Crop group 6, Legume vegetables,	1.0 ppm
Crop Group 7, Foliage of legume vegetables	10.0 ppm
Crop Group 7, Forage of legume vegetables	32.0 ppm
Crop Group 13, Berries	1.0 ppm
Crop Group 15, Cereal Grains (except corn, rice and sorghum), forage	3.0 ppm
Crop Group 15, Cereal Grains (except corn, rice and sorghum), and hay	2.0 ppm
Crop Group 15, Cereal Grains (except corn, rice and sorghum), and straw	13.0 ppm
Crop Group 15, Cereal Grains (except corn, rice and sorghum), and bran	2.5 ppm
Crop Group 15, Cereal Grains (except corn, rice and sorghum), and grain	0.5 ppm
Carrot	0.2 ppm
Corn, forage	4.0 ppm
Corn, grain	0.3 ppm
Corn, stover	25.0 ppm

Corn, oil	0.5 ppm
Onion, dry bulb	0.3 ppm
Onion, green	8.0 ppm
Pistachio	0.2 ppm
Rice, bran	28.0 ppm
Rice, grain	7.0 ppm
Rice, hulls	28.0 ppm
Rice, straw	18.0 ppm
Grain sorghum, forage	10.0 ppm
Grain sorghum, grain	2.5 ppm
Grain sorghum, stover	15.0 ppm
Soybean, forage	10.0 ppm
Soybean, hay	32.0 ppm
Soybean, seed	2.0 ppm
Strawberry	1.5 ppm
Sugar beet, dried pulp	2.0 ppm
Sugar beet, roots	0.3 ppm
Sugar beet, tops	10.0 ppm
Sugar beet, molasses	3.0 ppm
Tree nut crop group	0.2 ppm
Milk	0.1 ppm

Syngenta has also submitted petition 5F4498 for establishing Inadvertent/Rotational crop tolerances on alfalfa.

Alfalfa	0.1 ppm

In addition to Syngenta's petition, Interregional Project No. 4 (IR-4) is also supporting three petitions for an unrestricted use of propiconazole on mint (PP#8E4931) and leaf petiole vegetables, subgroup 4B (PP#6E4788), and for the restricted use of propiconazole on cranberries grown in WI and the Pacific Northwest (PP#7E4860). In conjunction with these petitions, IR-4 is proposing the following new or amended tolerances:

Cranberry	1.0 ppm
Crop Subgroup 4-B, Leaf petioles subgroup	5.0 ppm
Mint	3.0 ppm

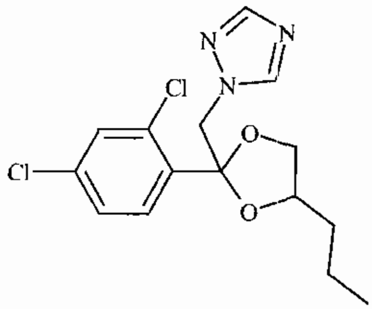
Table 1. Nomenclature of Propiconazole	
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4_triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole
CAS #	60207-90-1
End-use products/EP	3.6 lb/gal ECs (EPA Reg. Nos. 100-617 and 702); 45% WP (EPA Reg. No. 100-780); 1.04 lb/gal EC (EPA Reg. No. 100-1178, MAI with azoxystrobin)

Table 2. Physicochemical Properties of Technical Grade Propiconazole.		
Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK_a)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K_{OW})	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

860.1200 Directions for use

There are currently five active end-use products (EPs) containing propiconazole that are registered to Syngenta for use on feed/food crops. These EPs are marketed under the trade names Tilt® and Orbit™ Fungicides, and include: three 3.6 lb/gal ECs (EPA Reg. Nos. 100-617, 100-702, and 100-737), a 45% WP (EPA Reg. No. 100-780), and a multiple active ingredient (MAI) EC formulation containing 1.04 lb/gal of propiconazole and 0.62 lb/gal of asozystrobin (Quilt™ Fungicide; EPA Reg. No. 100-1178). Proposed or amended use directions for these labels are summarized below in Table 3. Uses are based on an example labels provided for the EC formulations (1/14/05) and the approved labels for the WP (accepted 12/11/03) and EC MAI (accepted 3/8/06).

Table 3. Summary of Directions for Proposed Uses of Propiconazole.

Application Timing, Type and Equipment	Formulation [EPA Reg. No.]	Single rate (lb ai/A)	Max. # of Apps. per Season	Max. Seasonal Rate (lb ai/A)	PHI (days)	Use Directions and Limitations [1]
Almond						
Foliar applications beginning at bud-break Ground or aerial equipment	3.6 lb/gal EC [100-617] 45% WP [100-780]	0.225	4	0.90	NS	Apply in a minimum of 20 or 50 gal/A using aerial and ground equipment, respectively. Minimum RTI is 7 days Do not graze livestock in treated areas or cut treated cover crop for feed
Berries (Bush and Cane berries) and Cranberry						
Foliar applications beginning at bud-break or for cane berries beginning as a delayed dormant application Ground or aerial equipment	3.6 lb/gal EC [100-617] 45% WP [100-780]	0.169	5	0.84	30	Apply in a minimum of 5-10 or 20-50 gal/A using aerial and ground equipment, respectively. The minimum RTI is 7-28 days depending on the disease.
Cranberry (For use Only in Wisconsin and the Pacific Northwest)						
Broadcast foliar applications from bud break to fruit set	3.6 lb/gal EC [100-702]	0.169	4	0.68	45	Minimum RTI is 10 days
Carrots						
Broadcast foliar applications when conditions favor disease development Ground or aerial equipment	3.6 lb/gal EC [100-617] 45% WP [100-780]	0.113	4	0.45	14	Apply in a minimum of 5 or 15 gal/A using aerial and ground equipment, respectively. Minimum RTI is 7 days Application may include spreader-sticker
Celery (Leaf Petiole Vegetables, subgroup 4B)						
Broadcast foliar applications when conditions favor disease development Ground or aerial equipment	3.6 lb/gal EC [100-617] 1.04 lb/gal EC [100-1178] 45% WP [100-780]	0.113	4	0.45	14	Minimum RTI is 7 days Application may include spreader-sticker
Cereals (wheat, barley, rye, triticale and oats)						
Broadcast foliar applications up to Flowering (Feekes Stage 10.5) Aerial or ground equipment, including chemigation	3.6 lb/gal EC [100-617]	0.113	2	0.225	30/35/45	Do not apply after Feekes Stage 10.5 Minimum RTI is 14 days. 30- and 45-day PHIs are specified for forage and hay, respectively, following an application at Feekes Stage 5. A general 35-day PHI is also specified for grazing or harvest of forage, hay and mature wheat.
	1.04 lb/gal EC [100-1178]	0.113	2	0.167	45	Do not harvest wheat for forage and do not graze or feed livestock treated forage or cut green crop of hay or silage
Broadcast foliar applications up to Feekes Stage 8 Aerial or ground equipment, including chemigation	45% WP [100-780]	0.113	1	0.113	40	Do not apply after Feekes Stage 8 Do not apply to oats with 40 days of harvest. Except for oat forage and hay, do not graze or feed livestock treated forage or cut the green crop for hay or silage
Corn (field, seed, pop and sweet)						
Broadcast foliar applications when conditions favor disease development Aerial or ground equipment, including chemigation	3.6 lb/gal EC [100-617] 45% WP [100-780]	0.113	4	0.45	14/30	Minimum RTI is 7 days. A 14-day PHI is specified for sweet corn forage and ears, and a 30-day PHI is specified for forage, grain and stover of field, pop, and seed corn.

Table 3. Summary of Directions for Proposed Uses of Propiconazole.						
Application Timing, Type and Equipment	Formulation [EPA Reg. No.]	Single rate (lb ai/A)	Max. # of Apps. per Season	Max. Seasonal Rate (lb ai/A)	PHI (days)	Use Directions and Limitations [1]
Dry Beans and Peas						
Broadcast foliar applications when conditions favor disease development Aerial or ground equipment	3.6 lb/gal EC [100-617] 45% WP [100-780]	0.113	3	0.338	14	Do not apply to succulent bean varieties Apply in a minimum of 5 or 15 gal/A using aerial and ground equipment, respectively. Minimum RTI is 14 days
Filberts (Hazelnuts)						
Foliar applications beginning at bud break Aerial or ground equipment	3.6 lb/gal EC [100-617]	0.225	4	0.90	NS	For aerial applications, minimum volumes of 5-10 or 20 gal/A are recommended. For ground applications, minimum volumes of 10-50 or 100 gal/A are recommended. Minimum RTI is 14 days Do not graze livestock in treated areas or cut treated cover crop for feed
Onions (green, dry bulb, or seed crop) [2]						
Broadcast foliar applications when conditions favor disease development Aerial or ground equipment	3.6 lb/gal EC [100-617] 45% WP [100-780]	0.225	2	0.45	0 [3]/14	Apply in a minimum of 5 or 15 gal/A using aerial and ground equipment, respectively. Minimum RTI is 7 days PHIs are 0 for green onions and 14 days for dry bulb onions
Peppermint and Spearmint						
Broadcast foliar applications beginning when plants are 2-4 inches in height Equipment not specified	3.6 lb/gal EC [100-617]	0.113	2	0.225	30	Apply in a minimum of 20 gal/A Minimum RTI is 10 days
Pecans						
Foliar applications beginning at emergence of green leaves Aerial or ground equipment	3.6 lb/gal EC [100-617] [100-702] 1.04 lb/gal EC [100-1178] 45% WP [100-780]	0.225	4	0.90	NS	Apply in a minimum of 20 gal/A for aerial applications Minimum RTI is 14 days, Do not apply after shuck split The label for 100-1178 also specifies a 45-day PHI Do not graze livestock in treated areas or cut treated cover crop for feed
Pistachios						
Foliar applications beginning at emergence of green leaves Aerial or ground equipment	3.6 lb/gal EC [100-617] 45% WP [100-780]	0.225	4	0.90	NS	Apply in a minimum of 20 gal/A for aerial applications and 50-100 gal/A for ground applications Minimum RTI is 14 days Do not graze livestock in treated areas or cut treated cover crop for feed
Rice (Do not use in CA)						
Broadcast foliar application(s) after tillering Ground or aerial equipment	3.6 lb/gal EC [100-617] 1.04 lb/gal EC [100-1178] 45% WP [100-780]	0.28	1	0.338	35	Apply aerially in a minimum of 5-20 gal/A. Minimum RTI is 10 days The label for the 1.04 lb/gal EC prohibits applications after head emergence. Do not apply to stubble or ratoon crop. Do not use in rice fields where crayfish farming will be practiced or drain water from treated fields into ponds used for crayfish farming. Do not use water drained from treated fields to irrigate other crops water
		0.169	2			

Table 3. Summary of Directions for Proposed Uses of Propiconazole.

Application Timing, Type and Equipment	Formulation [EPA Reg. No.]	Single rate (lb ai/A)	Max. # of Apps. per Season	Max. Seasonal Rate (lb ai/A)	PHI (days)	Use Directions and Limitations [1]
Sorghum						
Broadcast foliar applications beginning at or just prior to flowering Aerial or ground equipment	3.6 lb/gal EC [100-617] 45% WP [100-780]	0.113	4	0.45	21/30	Apply in a minimum of 5 or 15 gal/A using aerial and ground equipment, respectively. PHIs are 30 days for forage and 21 days for grain and stover Minimum RTI is 5 days
Soybeans						
Broadcast foliar applications beginning at first appearance of disease until to pod fill (Stage R5) Ground and aerial equipment	3.6 lb/gal EC [100-617] 1.04 lb/gal EC [100-1178] 45% WP [100-780]	0.169	2	0.338	30	Apply in a minimum of 5 and 15 gal/A using aerial and ground equipment, respectively. Minimum RTI is 14 days Do not graze or feed soybean forage or hay
Strawberries						
Broadcast foliar applications before disease levels reach 5% Aerial or ground equipment	3.6 lb/gal EC [100-617] 45% WP [100-780]	0.113	4	0.45	0	Apply in a minimum of 5 or 15 gal/A using aerial and ground equipment, respectively. Minimum RTI is 7 days
Sugar beets						
Broadcast foliar applications beginning at first appearance of disease Equipment not specified	3.6 lb/gal EC [100-617] 45% WP [100-780]	0.113	3	0.338	21	Minimum RTI is 10 days
Tree Nut Crops						
Foliar application at unspecified timing Ground and aerial equipment	3.6 lb/gal EC [100-617] 45% WP [100-780]	0.225	4	0.90	60	Apply in a minimum of 20 for aerial applications, or 50-100 gal/A for ground applications. Minimum RTI is not specified.

1 Labels include a 24-hour restricted entry interval. Under general use directions, the following rotational crop restriction is listed: do not replant within 105 days of propiconazole application to preceding crop, unless the second crop appears on the label. In addition, minimum application volumes are 5 and 10 gal/A for aerial and ground applications, respectively, unless otherwise specified. For specified crops, ground applications may include chemigation through center pivot, solid set, hand move, or moving wheel irrigation.

2 Use on dry bulb onions includes garlic, dry bulb onions and dry bulb shallots, and the use on green onions includes green onions, leeks, spring onions or scallions, Japanese bunching onions, green shallots, and green eschalots.

3 For crops with 0-day PHIs (green onions and strawberry), entry within the 24-hour REI requires use of PPE.

RTI = retreatment interval
NS = not specified.

- Use directions for tree nuts (almonds, filberts, and pistachios) should be amended to specify a minimum PHI of 60 days, with the exception of pecans. A specific PHI is not required for pecans as applications to pecans are prohibited after shuck split, and the available pecan field trial data support applications up to shuck split, which is a distinct growth stage. The available almond and pecan field trial data support minimum RTIs of 7 or 14 days and concentrated or dilute application volumes. The use directions for filberts must be clarified to list single minimum volumes for ground and aerial applications.

- Use directions for cranberry should be separated from directions for other berries on all labels. The available cranberry residue data support up to four foliar applications of propiconazole at 0.169 lb ai/A/application, from bud-break through early fruit development, at minimum RTIs of 14 days, for a maximum of 0.68 lb ai/A/season, with 45-day PHI. The use on cranberries should be restricted to Regions 5 and 12.

- Use directions should be standardized between wheat, barley, rye, triticale and oats. The available wheat field trial data will support applications to these cereal grains at up to Feekes Growth Stage 10.5 at a rate of 0.11 lb ai/A/application, for a maximum of 0.22 lb ai/A/season. The data support a minimum RTI of 14 days and PHIs of 30 days for forage, 45 days for hay, and 40 days for grain and straw. In addition, the available field trial data will only support application(s) at up to 0.11 lb ai/A prior to the harvest of forage or hay. Unless the petitioner intends to provide additional data on forage and hay supporting use of rates up to 0.22 lb ai/A, the labels should be amended to specify a maximum total application rate of 0.11 lb ai/A on wheat, barley, oats or rye harvested for forage or hay.

- For both field corn and sorghum, the available field trial data will only support applications totaling 0.22 lb ai/A prior to the harvest of forage. Labels should be amended to specify a maximum total application rate of 0.22 lb ai/A on field corn and sorghum harvested for forage.

- For dry peas and beans, delete these uses.

- The minimum RTI for applications to mint should be changed from 10 to 14 days, and the use directions should specify the types of application equipment allowed (ground and/or aerial).

- Base on the rice field trial data, the minimum RTI for spilt applications to rice should be changed from 10 to 14 days.

- Although label directions for soybeans prohibit the feeding or grazing of forage or hay, tolerances have been proposed for soybean forage and hay and adequate data are available for these commodities. Therefore, this feeding restriction can be removed from the label.

- The available strawberry field trial data support a minimum application volume of 50 gal/A rather than 5 gal/A.

- Base on the available alfalfa rotational crop data, labels can be amended to include at 75-day plant-back interval for the rotation of alfalfa following primary crops treated with up to a total seasonal rate of 0.22 lb ai/A of propiconazole.

860.1300 Nature of the Residue – Plants.

Propiconazole RED, DP Barcode D329394, Y. Donovan, 6/15/06
45206201.der (carrot metabolism)

The nature of propiconazole residues in plants is adequately understood. Initial metabolism studies on peanuts, wheat, grapes and rice were summarized in the Phase 4 Review and indicated that the metabolite profile was similar in both the primary and rotational crops; however, complete quantitative data were not available from these studies. Additional studies have since been conducted on celery, wheat, and carrots that were deemed completely adequate. Together these data indicate that the major metabolic pathway in plants appears to involve hydroxylation of the n-propyl group on the dioxolane ring of the cis/trans isomers of propiconazole, with subsequent conjugation to sugars. A possible alternative pathway involves reductive deketalization of the dioxolane ring and sugar conjugation of the resulting metabolite. The alkyl bridge between the phenyl and triazole rings is metabolized and free 1*H*-1,2,4-triazole is released. The free triazole is readily conjugated with the amino acid, serine/alanine, forming triazole aniline which is further metabolized to triazole acetic acid possibly through the intermediate formation of triazole lactic acid. The free triazole, triazole alanine, and triazole acetic acid are also residues of concern. Since these are common metabolites from several triazole containing pesticides, the risk assessment for triazoles has been assessed separately (HED memo of 2/7/06, M. Doherty, D322215). The cited assessment included all the proposed propiconazole new uses in the subject petitions.

Based on these studies, HED concluded that the residues of concern for dietary risk assessment (food) should include propiconazole and all its metabolites containing the 2,4-DCBA moiety, including conjugates, as virtually all the residue data have been generated using a common moiety method that converts parent and all of the metabolites of concern to 2,4-DCBA. However, only residues of propiconazole *per se* should be included in water for purposes of the dietary risk assessment. The tolerance expression should also be amended to include only propiconazole *per se* because 1) there are a number of pesticides that have 2,4-DCBA as common metabolite, and an enforcement agency may not be able to determine if residues are due to misuse of propiconazole or the proper use of other pesticides containing 2,4-DCBA; 2) propiconazole *per se* can be detected by FDA multiresidue methods; and 3) inclusion of only parent allows harmonization with the residue definition for the Codex MRLs. Although HED also considers free triazole to be a residue of concern in plants, issues pertaining to triazole residues are addressed in a separate document.

860.1300 Nature of the Residue – Livestock.

Propiconazole RED, DP Barcode D329394, Y. Donovan, 6/15/06

The nature of propiconazole residues in livestock is adequately understood based on the acceptable goat and poultry metabolism studies. In one ruminant study, three lactating goats received [phenyl-^{14}C]propiconazole at 67-92 ppm for four consecutive days in the feed. The dosing levels correspond to 1.7-2.3x the MTDB for dairy cattle. The parent (1.7-13.9% TRR), and metabolites CGA-118244 (9.4-34% TRR), and CGA-91305 (15.9-31.3% TRR) were identified in the organic extract of tissues; metabolites CGA-118244 (23% TRR) and CGA-91305 (24% TRR) were also identified in milk. In addition, an unknown was quantified (6.2-31.1% TRR) in goat tissues. In a second ruminant study, a single goat was fed [triazole-^{14}C]propiconazole at 4.53 ppm (0.1x) for 10 days. The TRR in tissues and milk ranged from 0.01 ppm in muscle to 0.96 ppm in liver; TRR in milk were 0.015 ppm. On further analysis of subsamples of milk and liver, sulfate and glucuronide conjugates were found in milk, and conjugation with amino acids was suggested in liver; propiconazole *per se* was not identified in milk or liver.

In the poultry study, four laying hens received [phenyl-^{14}C]propiconazole at 67 ppm for eight consecutive days in feed. The dosing level corresponds to 7.3x MTDB for poultry. The parent (1.4-39.0% TRR), and metabolites CGA-118244 (1.5-50.0% TRR), and CGA-91305 (17.7-78.6% TRR) were identified in the organic extracts of tissues and eggs.

The Agency concluded that parent and all metabolites convertible to 2,4-DCBA are residues of concern for risk assessment, as the analytical method is a common moiety method that detects all residues convertible to 2,4-DCBA. However, for tolerance enforcement purposes, the current tolerance expression should be amended to include only propiconazole *per se.*

860.1340 Residue Analytical Methods.

Propiconazole RED, DP Barcode D329394, Y. Donovan, 6/15/06

Plant commodities: Samples from the various field trials and processing studies supporting the current petitions were analyzed for combined residues of propiconazole and its 2,4-DCBA containing metabolites using GC/ECD Methods AG-454B and AG-626, which are more recent versions of the original tolerance enforcement method (AG-454). Samples from two of the cranberry field trials used a modification to AG-454, in which a nitrogen-phosphorus detector (NPD) was used instead of the ECD. All of these methods are similar common moiety methods in which residues are converted by base hydrolysis and oxidation to 2,4-DCBA, then determined as the 2,4-DCBA methyl ester, and reported in propiconazole equivalents using a conversion factor of 1.79. With the exception of almond hulls, which had a LOQ of 0.1 ppm, the validated LOQ for combined residues was 0.05 ppm in all raw and processed commodities. Each of the methods was validated in conjunction with the field trials and processing studies, and acceptable concurrent method recoveries were obtained for all crop matrices.

In addition to determining combined residues, samples from one of the wheat field trials and processing studies were also analyzed for residues of propiconazole, *per se*, using a GC/NPD method from PAM Vol. I (Method 302 E4 + DG5). This method was also adequately validated in conjunction with the analysis of field trial samples, and the validated LOQ was 0.05 ppm.

In the majority of field trials and processing studies submitted for these petitions, the petitioner reported corrected residue values for samples with procedural recoveries of <100%. However, when available, uncorrected residue data are reported in this review and were used in determining tolerance levels.

For enforcement purposes, residue Method AG-354 is available for determining propiconazole *per se* in/on plant commodities using gas chromatography and flame ionization detection, and the reported LOQ is 0.05 ppm. In addition, Multiresidue Methods Section 302 can also be used to detect parent propiconazole.

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

GLN 860.1360: Multiresidue Methods

The FDA PESTDATA database (PAM Volume I, Appendix I) indicates that propiconazole is completely recovered (>80%) using Multiresidue Methods Section 302. The recovery of propiconazole metabolites CGA-91305, CGA-118244, and 1,2,4-triazole is variable using Section 302. Propiconazole and metabolites CGA-91305, CGA-118244, and 1,2,4-triazole are not recovered using Multiresidue Methods Sections 303 and 304.

860.1380 Storage Stability.

Propiconazole RED, DP Barcode D329394, Y. Donovan, 6/15/06

Adequate storage stability data are available indicating that residues of propiconazole and its metabolites determined as 2,4-DCBA are stable at ≤-15°C for up to 36 months in peaches, bananas, corn meal, wheat grain, celery, corn oil, and peanut nutmeat, hay, and hulls; 10 months in carrots; and 4-6 months in soybean seed and fodder. Weathered residues of propiconazole and its metabolites were also found to be stable under frozen storage conditions in grass forage, straw, and seed for up to 39 months at -20°C; wild rice and stone fruits for up to 25 months; peanut hulls and fodder for 25 months at -15°C; and in extracts of silage-stage corn forage and soybeans for 3 and 8 months, respectively, at 4°C. These storage stability data are adequate to validate the storage intervals and conditions of samples collected from the current field and processing studies. In cases where existing storage stability data are not available, concurrent storage stability data were submitted along with field trials and /or processing studies.

Adequate Storage stability data are also available on animal commodities to support the existing livestock feeding studies.

860.1400 Water, Fish, and Irrigated Crops

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

860.1460 Food Handling

This guideline requirement is not relevant to the current petition as no food handling uses are being proposed for propiconazole.

860.1480 Meat, Milk, Poultry, and Eggs

Propiconazole RED, DP Barcode D329394, Y. Donovan, 6/15/06

The maximum theoretical dietary burdens (MTDB) for combined propiconazole residues were calculated to be 29.0 ppm for beef and 18.5ppm for dairy cattle, 2.3 ppm for swine and 2.0 ppm for poultry.

Table 4. Calculation of Maximum Dietary Burdens of Livestock for Propiconazole Residues.				
Feed Commodity	% Dry Matter [1]	% Diet [1]	Current or Recommended Tolerance (ppm)	Dietary Contribution (ppm)[2]
		Beef Cattle		
Grass, hay [R]	88	50	40	22.7
Corn field, grain [CC]	88	20	0.3	0.07
Rice, bran [R]	88	10	28	3.2
Aspirated grain fractions [CC]	85	5	45	2.65
Soybean seed [PC]	89	15	2.0	0.34
TOTAL		**100**		**29.0**
		Dairy Cattle		
Grass, hay [R]	88	30	40	13.6
Corn, field, stover [R]	83	15	25.0	4.52
Corn, field, grain [CC]	88	40	0.3	0.14
Soybean seed [PC]	89	15	2.0	0.34
TOTAL		**100**		**18.5**
		Poultry		
Wheat grain [CC]	89	60	0.5	0.34
Rice, grain [CC]	88	20	7.0	1.6
Soybean, seed [PC]	89	20	2.0	0.45
TOTAL		**100**		**2.0**
		Swine		
Corn field, grain [CC]	88	60	0.3	0.20
Rice, grain [CC]	88	20	7.0	1.6
Soybean, seed [PC]	89	20	2.0	0.45
TOTAL		**100**		**2.3**

[1] Table 1 (OPPTS Guideline 860.1000).
[2] Contribution = ([tolerance /% DM] X % diet) for beef and dairy cattle; contribution = ([tolerance] X % diet) for poultry and swine.
NA = not applicable

An adequate dairy cattle feeding study is available reflecting dosing with propiconazole at levels equivalent to 15, 75, and 150 ppm in the diet for periods up to 14, 21 and 28 days. Samples of milk were collected daily and tissues samples were collected at study termination. Combined propiconazole residues, determined as 2,4-DCBA and expressed in parent equivalents, were determined using an adequate GC/FID method (AG-359) and an adequate GC/ECD method (AG-517). Combined propiconazole residues in cattle tissues are summarized below in Table 5. For milk, combined residues were nondetectable (<0.01 ppm) at the 15-ppm dose level and were detected at 0.10 and 0.11 ppm at the 75- and 150-ppm dosing levels, respectively.

An adequate laying hen feeding study is also available reflecting dosing with propiconazole at levels equivalent to 7.5, 37.5, and 75 ppm in the diet for periods up to 14, 21 and 28 days. Samples of eggs were collected daily and tissues samples were collected at study termination. Combined propiconazole residues, determined as 2,4-DCBA and expressed in parent equivalents, were determined using an adequate GC/FID method (AG-359) and an adequate GC/ECD method (AG-517). Combined propiconazole residues in poultry tissues are summarized below in Table 6. For whole eggs, combined residues were nondetectable (<0.05

ppm) at the 7.5-ppm feeding level and were detected at 0.18 and 0.37 ppm at the 37.5- and 175-ppm feeding levels respectively.

Table 5. Total Combined Propiconazole Residues in Dairy Cattle Tissues From Feeding Studies Conducted at Dosing Levels Equivalent to 15, 75, and 150 ppm in the Diet (0.4x, 1.9x, and 3.8x MTDB). [1]

Dosing Duration	14 days			21 days			28 days		
Dosing Level (ppm)	15	75	150	15	75	150	15	75	150
Muscle	<0.05	0.11	0.18	<0.05	0.08 [2]	0.13	<0.05	0.05	0.11
Kidney	0.61	3.04	6.48	0.56	4.68 [2]	5.0	0.63	3.68	5.50
Liver	0.5	4.0	4.6	0.81	4.3 [2]	5.3	0.57	2.7	5.6
Fat	<0.05	0.23	0.26	<0.05	0.15 [2]	0.19	<0.05	0.08	0.17

1 Data were obtained from Propiconazole RED, Y. Donovan, 6/15/06.
2 Residue values in shaded cells were used to calculate maximum potential combined residues in ruminants and swine at 1x feeding level

Table 6. Total Combined Propiconazole Residues in Hen Tissues From Feeding Studies Conducted at Dosing Levels Equivalent to 7.5, 37.5, and 75 ppm in the Diet (0.8x, 4.1x, and 8.2x MTDB). [1]

Dosing Duration	14 days			21 days			28 days		
Dosing Level (ppm)	7.5	37.5	75	7.5	37.5	75	7.5	37.5	75
Muscle	<0.05	<0.05	<0.05	<0.05	<0.05	0.07 [2]	<0.05	<0.05	0.06
Liver	<0.1	0.10	0.47 [2]	<0.05	0.08	0.39	0.1	0.16	0.30
Fat	<0.05	<0.05	0.11 [2]	<0.05	<0.05	0.06	<0.05	<0.05	0.05

1 Data were obtained from Propiconazole RED, Y. Donovan, 6/15/06.
2 Residue values in shaded cells were used to calculate maximum potential combined residues in poultry at 1x feeding level.

To estimate maximum combined residues in cattle and swine commodities, the residue levels for the 75-ppm feeding level at 21 days were selected as these residue levels were the highest for the 75-ppm group. This feeding level represents a 2.7x the MTDBs for beef cattle, 4.2x for dairy cattle, and a 32.6x for swine. Maximum combined residues were estimated by dividing the residue values for milk and tissues at the 75-ppm dose level by 2.7 for cattle, 4.2 for milk, and 32.6 for swine. For beef cattle, estimated combined residues at a 1x feeding level are 1.7 ppm for kidney, 1.6 ppm for liver, 0.03 ppm for muscle, 0.05 ppm for fat, and 0.03 pm for milk. For swine, estimated combined residues at a 1x feeding level are 0.14ppm for kidney, 0.13 ppm for liver and <0.005 ppm for muscle and fat. HED recommends that the following tolerance levels be established: For cattle, goat, horses and sheep, kidney and liver at 2.0 ppm; meat and meat byproduct (except kidney and liver) and fat at 0.05 ppm, milk at 0.05 ppm. For hog, kidney and liver at 0.20 ppm, no tolerances are needed for meat, fat, and meat byproduct.

For poultry tissues and eggs, estimated combined residues and parent residues were calculated in the same manner as for cattle and swine. The maximum combined residues in tissues and eggs from the 7.5-ppm dose group in the poultry feeding study were used to estimate residues at the 1x feeding level. The estimated combined residues at the 1x feeding level are all < LOQ. Therefore, tolerances for poultry tissues and eggs are not required as quantifiable levels of propiconazole are unlikely to occur in these commodities [40 CFR 180.6(a)(3)].

860.1500 Crop Field Trials

43655612.der (corn)
43655613.der (celery)
44338101.der (cranberry)
44416501.der (mint)
46473001.der (soybean)
44757207.der1 (sugar beet)
44757208.der1 (wheat)
44757210.der (almond)
45080807.der (sugar beet)
46576301.der (soybean)
45080809.der (corn)
45050811.der1 (rice)
45275801.der (sorghum)
45542401.der (strawberry)

Syngenta and IR-4 have submitted field trials supporting new or amended uses for propiconazole (EC and/or WP) on almonds, celery, field and pop corn, cranberry, mint, rice, sorghum, soybeans, strawberries, sugar beets and wheat. The results from these studies are discussed below and summarized in Table 7. In addition, previously reviewed field trial data on berries, beans (dry), carrots, celery, onions, soybeans, and tree nuts are also summarized below.

Table 7. Summary of Residue Data from Crop Field Trials with Propiconazole (EC and/or WP).

Crop/ Commodity	MRID#	Total Appl. Rate (lb ai/A)	End-use Product	PHI (days)	Combined Residues (ppm) [1] n	Min.	Max.	HAFT[2]	Median[3] (STMdR)	Mean[3] (STMR)	Std. Dev.
Almonds (0.90 lb ai/A total application rate, 60-day PHI)											
Nutmeats	44757210 & 45215806	0.88-0.91 (1x)[4]	45% WP	53-63	12	<0.05	0.07	0.07	0.025	0.035	0.018
			3.6 lb/gal EC		12	<0.05	0.09	0.08	0.025	0.041	0.024
Hull			45% WP	53-63	12	0.57	4.60	4.45	1.20	1.78	1.36
			3.6 lb/gal EC		12	0.67	4.20	4.00	1.85	2.06	1.06
Dry Beans (0.34 lb ai/A total application rate, 14-day PHI)											
Vines	43386501	0.41 (1.2x)	3.6 lb/gal EC	7	10	1.20	7.50	6.20	2.10	3.11	2.17
Hay				23-28	10	0.17	4.90	4.85	1.70	2.11	1.68
Beans				23-31	10	<0.05	0.13	0.12	0.08	0.08	0.04
Vines		0.83 (2.5x)		7	3	1.90	9.90	9.90	4.70	5.50	4.06
Hay				25-28	3	1.10	15.0	15.0	1.80	5.97	7.83
Beans				25-28	3	<0.05	0.10	0.10	0.10	0.08	0.04
Berry Crop Group (0.84 lb ai/A total application rate, 30-day PHI)											
Bush and Cane berries	43786403	0.85 (1x)	3.6 lb/gal EC	30	12	0.14	0.66	0.62	0.35	0.36	0.16
Carrot (0.45 lb ai/A total application rate, 14-day PHI)											
Roots	43786402	0.44 (1x)	3.6 lb/gal EC	13-14	14	<0.05	0.17	0.16	0.10	0.10	0.003
Celery (0.45 lb ai/A total application rate, 14-day PHI)											
Untrimmed stalks	40783301	0.44-0.55 (1-1.3x)	3.6 lb/gal EC	14	20	0.27	4.98	4.98	0.60	1.13	1.28
	43655613	0.44 (1x)	3.6 lb/gal EC	14	2	0.27	0.42	0.35	0.35	0.35	0.11
			45% WP	14	2	0.43	0.51	0.47	0.47	0.47	0.06
Corn, field and pop (0.45 lb ai/A total application rate, 30-day PHI)											
Forage	45080809 & 45080810	0.22 (0.5x)	1.04 lb/gal EC	29-32	36	<0.05	1.90	1.45	0.36	0.45	0.49
Stover		0.42-0.47 (1x)		28-35	48	0.92	19.60	15.9	5.65	6.87	4.75
Grain					48	<0.05	0.15	0.10	0.025	0.037	0.024
Forage	43655613	0.44 (1x)	3.6 lb/gal EC	30-31	4	<0.05	1.26	1.18	0.56	0.60	0.67
			45% WP		4	<0.05	1.66	1.42	0.64	0.74	0.81
Stover		0.44 (1x)	3.6 lb/gal EC	93-118	4	<0.05	2.15	1.93	0.87	0.98	1.11
			45% WP		4	<0.05	2.51	2.35	1.13	1.20	1.34
Grain		0.44 (1x)	3.6 lb/gal EC	93-118	4	<0.05	<0.05	<0.05	0.025	0.025	0.00
			45% WP		4	<0.05	<0.05	<0.05	0.025	0.025	0.00
Cranberry (0.68 lb ai/A total application rate, 45-day PHI)											
Cranberry	44338101	0.66-0.68	3.6 lb/gal	43-44	6	0.18	0.59	0.53	0.23	0.32	0.17

Table 7. Summary of Residue Data from Crop Field Trials with Propiconazole (EC and/or WP).

Crop/ Commodity	MRID#	Total Appl. Rate (lb ai/A)	End-use Product	PHI (days)	Combined Residues (ppm) [1]						
					n	Min.	Max.	HAFT[2]	Median [3] (STMdR)	Mean [3] (STMR)	Std. Dev.
	& 45778901	(1x)	EC								
Mint (0.225 lb ai/A total application rate, 30-day PHI)											
Mint, hay	44416501	0.224-0.227 (1x)	3.6 lb/gal EC	29-30	10	0.06	2.7	2.3	1.1	1.15	0.73
Onions (0.45 lb ai/A total application rate, PHIs 0 day for green onion and 14 days for dry bulb)											
Green whole plant	43786401	0.44 (1x)	3.6 lb/gal EC	0	28	0.57	7.5	5.2	2.1	2.4	0.27
Dry bulb				14	28	<0.05	0.18	0.13	0.03	0.05	0.02
Rice [5] (0.34 lb ai/A total application rate, 35-day PHI)											
Straw	45080811	0.28 (1x)	3.6 lb/gal EC	34-49	32	0.69	17.0	16.5	2.30	4.11	4.62
Grain					32	0.03	5.20	5.05	0.89	1.49	1.55
Straw		0.31 (1x)	1.04 lb/gal EC	35-40	8	0.77	9.50	8.00	2.40	3.46	3.10
Grain					8	0.06	2.50	2.00	0.61	1.01	1.00
Sorghum (0.45 lb ai/A total application rate, PHIs are 30 days for forage and 21 days for grain and stover)											
Forage	45275801	0.22 (0.5x)	3.6 lb/gal EC	0	14	1.8	11.6	10.7	5.4	6.29	2.54
				29-31	24	1.5	8.2	8.1	3.8	4.40	1.92
				37-38 [6]	4	3.8	8.3	7.4	6.5	6.28	1.86
Stover		0.44 (1x)		18-22	24	2.8	11.7	9.2	5.5	5.81	2.25
				28 [6]	4	4.3	14.2	13.5	8.6	8.90	5.29
Grain				18-22	24	0.52	2.3	2.1	0.98	1.14	0.51
				28 [6]	4	1.8	2.4	2.1	2.0	2.05	0.26
Soybean (0.34 lb ai/A total application rate, 30-day PHI)											
Forage	43386502	0.33 (1x)	3.6 lb/gal EC	21-32	28	0.33	5.40	5.20	1.85	2.42	1.64
Hay					28	0.48	21.0	21.0	2.90	4.78	5.29
Seed				41-99	26	0.06	0.80	0.47	0.19	0.22	0.15
Fodder					28	<0.05	6.20	5.40	0.58	1.15	1.48
Seed	46473001	0.32-0.35 [7]	3.6 lb/gal EC	30	8	0.56	1.40	1.40	0.72	0.86	0.34
		0.23-0.25 [7]			8	0.10	0.67	0.63	0.16	0.27	0.23
		0.34-0.36 [7]			8	0.17	0.94	0.90	0.23	0.39	0.32
Seed	46576301	0.24-0.26	1.04 lb/gal EC	19-24	40	<0.10	0.268	0.215	0.05	0.09	0.052
Forage		0.24-0.25		0	40	1.70	12.0	8.43	4.37	4.90	2.32
Hay		0.24-0.25		0	40	2.63	8.43	26.4	12.1	12.74	5.66
Strawberry (0.45 lb ai/A total application rate, 0-day PHI)											
Strawberry	45542401	044 (1x)	3.6 lb/gal EC	0	16	0.07	0.69	0.60	0.32	0.35	0.19
Sugar Beet (0.34 lb ai/A total application rate, 21-day PHI)											
Roots	44757207	0.33 (1x)	45% WP	0	22	<0.05	0.61	0.565	0.025	0.086	0.160
				21-23	22	<0.05	0.08	0.065	0.025	0.035	0.018
Tops		0.33 (1x)		0	22	0.89	5.20	5.05	2.25	2.52	1.17
				21-23	22	0.41	2.90	2.85	0.75	1.10	0.80
Roots	45080807	0.33 (1x)	45% WP	0	8	<0.05	0.42	0.30	0.11	0.14	0.12
				21	8	<0.05	0.23	0.17	0.11	0.13	0.06
Tops				0	8	2.10	6.10	5.20	3.75	4.05	1.26
				21	8	0.74	2.60	2.60	1.50	1.67	0.67
Roots		0.33 (1x)	1.04 lb/gal EC	0	8	<0.05	0.34	0.28	0.11	0.15	0.10
				21	8	0.05	0.23	0.18	0.17	0.14	0.06
Tops				0	8	2.60	8.00	5.65	3.70	4.44	1.86
				21	8	0.77	9.20	7.90	2.85	3.67	2.84

Table 7. Summary of Residue Data from Crop Field Trials with Propiconazole (EC and/or WP).

Crop/ Commodity	MRID#	Total Appl. Rate (lb ai/A)	End-use Product	PHI (days)	Combined Residues (ppm) [1]						
					n	Min.	Max.	HAFT[2]	Median [3] (STMdR)	Mean [3] (STMR)	Std. Dev.
Wheat (0.22 lb ai/A total application rate, PHIs are 30, 45 and 35 days of forage, hay and grain)											
Total Combined Residues											
Forage	44411206	0.22 (1x)	3.6 lb/gal EC	0	24	1.20	10.70	8.70	3.75	4.37	2.29
				30-32	24	0.09	1.70	1.50	0.60	0.70	0.48
Straw				54-91	24	<0.05	4.20	3.85	0.84	0.98	1.04
Grain					24	<0.05	0.08	0.06	0.03	0.03	0.02
Forage	44757208	0.11 (0.5x)	3.6 lb/gal EC	29-32	42	<0.05	1.91	1.58	0.20	0.33	0.35
Hay				43-50	42	<0.05	1.10	1.04	0.23	0.30	0.25
Straw		0.11-0.12 (0.5x)		27-57	42	0.41	6.21	5.32	1.59	2.02	1.25
Grain					42	<0.05	0.13	0.09	0.03	0.04	0.03
Straw		0.22-0.23 (1x)		27-57	42	0.20	8.27	7.49	2.71	3.31	2.17
Grain					42	<0.05	0.20	0.18	0.05	0.07	0.06
Parent Residues [8]											
Forage	44757208	0.11 (0.5x)	3.6 lb/gal EC	29-32	42	<0.05	0.49	0.36	0.025	0.06	0.08
Hay				43-50	42	<0.05	0.20	0.16	0.025	0.04	0.03
Straw		0.11-0.12 (0.5x)		27-57	42	<0.05	1.63	1.62	0.19	0.45	0.51
Grain					42	<0.05	0.03	<0.05	0.025	0.025	0.00
Straw		0.22-0.23 (1x)		27-57	42	<0.05	3.49	3.21	0.25	0.73	0.91
Grain					42	<0.05	0.05	<0.05	0.025	0.025	0.00

1. Unless otherwise indicated, total propiconazole residues were determined as 2,4-DCBA and are expressed in parent equivalents. The method LOQ for propiconazole residues is 0.05 ppm. Residues are not corrected for procedural recoveries. For calculation of the median, mean, and standard deviation, ½LOQ (0.025 ppm) was used for samples with residues <LOQ.
2. HAFT = Highest Average Field Trial.
3. STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.
4. The field trial application rate relative to the maximum proposed use rate is listed in parentheses.
5. The rice field trial data reflect the use of propiconazole (EC) on rice as either a single application during heading at up to 0.28 lb ai/A or a split application during heading totaling 0.31 lb ai/A. Side-by-side tests of the two treatments showed no differences in residue in/on grain and straw between the two treatments.
6. For the sorghum field trials, residue values from sampling intervals later than the proposed PHI will be included in the database used for calculating tolerances, as residue levels at these later intervals were equivalent or higher than residues observed around the proposed PHIs.
7. The three application regimes on soybean were, from top to bottom: 3 applications at 0.11 lb ai/A (totaling 1x rate), 2 applications at 0.11 lb ai/A (totaling 0.67x rate), and 2 applications at 0.17 lb ai/A (totaling 1x rate). Data from the bottom row were used in determining tolerance sine it represent the proposed use pattern.
8. Wheat samples were also analyzed using a method which determined only residues of propiconazole.

Root and Tuber Vegetables Group

Carrot. Field trial data on carrots have been previously reviewed (DP Barcode D219664, L. Kutney, 6/14/96). In a total of 10 field trials conducted during 1994-1995 in CA, FL, MI, NY, OH, TX and WA, propiconazole (3.6 lb/gal EC) was applied to carrots as four broadcast foliar applications at 0.11 lb ai/A/application (1x rate, 7 tests) or 0.22 lb ai/A/application (2x rate, 3 tests), at unspecified RTIs, for totals of 0.44 or 0.88 lb ai/A (1x and 2x seasonal rates). Applications were made in 25 gal of water/A, and included the use of a spreader/sticker at 1% v/v. A single control and single (2x tests) or duplicate (1x tests) treated samples of carrot roots were collected at 13-14 DAT. Samples were stored frozen from collection to analysis for up to 7 months, an interval supported by the available storage stability data. Total residues of propiconazole and its 2,4-DCBA containing metabolites in/on carrots were determined using GC/ECD Method AG-454B, which has a validated method LOQ of 0.05 ppm.

Following four broadcast applications of propiconazole (EC) totaling 0.44 lb ai/A (1x rate), residues were <0.05-0.17 ppm in/on 14 carrot samples harvested 13-14 DAT, with three samples having residues <LOQ. Average and median residues were 0.01 ppm in/on carrots treated at 1x. In the three tests conducted at a 2x rate (0.88 lb ai/A), residues were 0.10-0.17 ppm in/on 3 samples from 14 DAT, and averaged 0.13 ppm.

The carrot field trial data are adequate. Although only seven of the required 8 field trials were conducted at the 1x rate, three additional field trials were conducted at a 2x rate and residues in these tests were all below the recommended tolerance.

Sugar beet. In one set of 11 field trials conducted in 1997 (44757207.der1), propiconazole (45% WP) was applied to sugar beets as three broadcast foliar applications during tuber development at 0.11 lb ai/A/application, for a total of 0.33 lb ai/A/season. Applications were made at retreatment intervals (RTIs) of 9-12 days, with the exception of one site, which had RTIs of 6 and 14 days. At one field site in MN, two additional plots were also treated similarly with three applications of propiconazole (WP) at 0.33 and 0.55 lb ai/A/application (3x and 5x rates), to provide samples for a processing study. Single control and duplicate treated samples of sugar beet roots and tops were harvested from each site at 0 and 21-23 days after the third application (DAT). At two sites, duplicate samples of roots and tops were collected at 0, 7, 14, 21 and 28 DAT to examine residue decline. Sugar beet root and top samples were stored frozen for up to 9.9 months prior to extraction for analysis. Adequate storage stability data are available to support the storage intervals and conditions for the current field trials. Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on sugar beet roots and tops were determined using an adequate GC/ECD method (Method AG-454B). Concurrent recoveries were conducted and the % recoveries are acceptable. Total propiconazole residues in/on sugar beet roots were <0.05-0.61 ppm at 0 DAT and <0.05-0.12 ppm at 21-23 DAT, and total residues in/on tops were 0.89-5.2 ppm at 0 DAT and 0.41-2.9 ppm at 21-23 DAT. Average residues in/on roots and tops were respectively 0.09 and 2.52 ppm at 0 DAT and 0.04 and 1.10 ppm at 21-23 DAT. The highest average field trial (HAFT) residues in/on roots and tops were respectively 0.57 and 5.1 ppm at 0 DAT and 0.08 and 2.9 ppm at 21-23 DAT. In the two residue decline tests, residue levels in/on roots were low and remained relatively steady from 0 to 28 DAT, averaging 0.053 ppm at 0 DAT, 0.064 ppm at 14 DAT, and 0.054 ppm at 28 DAT. However, residues in/on tops declined steadily at longer post-treatment intervals, averaging 2.68 ppm at 0 DAT, 1.15 ppm at 14 DAT and 0.68 ppm at 28 DAT.

The number of trials and the geographic representations are adequate. These field trial data will support the use of propiconazole (WP) on sugar beets as up to three broadcast foliar applications at 0.11 lb ai/A/application, at a minimum RTI of 10 days, for a total of 0.33 lb ai/A/season, with either a 0 or 21 day pre-harvest interval.

In another set of sugar beet field trials conducted in 1998 (45080807.der1), propiconazole was applied to sugar beets in 4 side-by-side tests comparing the use of 45% WP and 1.04 lb/gal EC formulations. In each test, propiconazole (WP or EC) was applied to sugar beets as three broadcast foliar applications during tuber development at 0.11 lb ai/A/application, at retreatment intervals of 10-11 days, for a total of 0.33 lb ai/A/season. Single control and duplicate treated samples of sugar beet roots and tops were harvested from each site at 0 and 21 DAT. Samples were stored frozen from collection to analysis for up to 9.2 months, an interval supported by available storage stability data. Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on sugar beet roots and tops were determined using an adequate GC/ECD method (Method AG-626). Following three applications of the WP formulation totaling 0.33 lb ai/A, total propiconazole residues in/on sugar beet roots ranged from <0.05-0.42 ppm at 0 DAT and <0.05-0.23 ppm at 21 DAT, and total residues in/on tops ranged from 2.10-6.10 ppm at 0 DAT and 0.74-2.60 ppm at 21 DAT. There was no noticeable decline in residues in/on roots between 0 to 21 DAT, but residues did decline in/on tops from 0 to 21 DAT. Following three applications of the EC formulation totaling 0.33 lb ai/A, total propiconazole residues in/on sugar beet roots ranged from <0.05-0.34 ppm at 0 DAT and 0.05-0.23 ppm at 21 DAT, and total residues in/on tops were 2.70-8.0 ppm at DAT and 0.77-9.20 ppm at 21 DAT. Average residues in/on sugar beet roots were similar for both formulations at both 0 and 21 DAT (0.13-0.15 ppm), and average residues in/on sugar beet tops were similar at 0 DAT for the WP (4.05 ppm) and EC (4.44 ppm) formulations. However, average residues in/on tops at 21 DAT were considerably higher for the EC formulation (3.67 ppm) than for the WP formulation (1.67 ppm). This trend toward higher residues from the EC formulation at 21 DAT was evident in 3 out of the 4 field trials.

These data indicate that total propiconazole residues from the WP and EC formulations are similar in/on sugar beet roots harvested at 0 or 21 DAT and in/on sugar beet tops harvested at 0 DAT. However, by 21 days post-treatment, residues in/on tops were substantially higher for the EC formulation than for the WP formulation. Given the differences between the two types of formulations in residue levels on sugar beet tops at 21 DAT, a full set of field trials are required on tops in order to support the use of an EC formulation on sugar beets.

Bulb Vegetables Group

Onion (green and dry bulb). Field trial data on green and dry bulb onions have been previously reviewed (DP Barcode D219664, L. Kutney, 6/14/96). In a total of 9 field trials conducted during 1993 in CA, CO, GA, ID, MI, OR, and TX, propiconazole (3.6 lb/gal EC) was applied to green and dry bulb onions each as two broadcast foliar applications at 0.22 lb ai/A/application (1x rate, 7 tests) or 0.44 lb ai/A/application (2x rate, 2 tests), at RTIs of 7 days, for totals of 0.44 or 0.88 lb ai/A (1x and 2x seasonal rates). Applications included the use of a surfactant at 0.25% v/v. A single control and single (2x tests) or quadruplicate (1x tests) treated samples of green whole plants and dry bulb onions were collected at 14 DAT.

Samples were stored frozen from collection to analysis for up to 14 months, an interval supported by the available storage stability data. Total residues of propiconazole and its 2,4-DCBA containing metabolites in/on green and dry bulb onions were determined using GC/ECD Method AG-454B, which has a validated method LOQ of 0.05 ppm.

Following two broadcast applications of propiconazole (EC) totaling 0.44 lb ai/A (1x rate), residues were 0.57-7.50 ppm in/on 28 samples of green onions harvested at 0 DAT and average residues were 2.4 ppm. In the two 2x rate tests, residues were 3.3 and 5.8 ppm in/on the two samples of green onions at 0 DAT. For the dry bulb onions harvested at 14 DAT, residues were

<0.05-0.18 ppm in/on 28 samples from the 1x tests, with 19 samples having residues <LOQ. Average residues in/on dry bulb onions were 0.05 ppm from the 1x tests. In the two 2x rate tests, residues were <0.05 and 0.41 ppm in/on the two samples of dry bulb onions at 14 DAT. The available onion data will support the proposed use pattern.

Leafy Vegetables (except Brassica vegetables) Group

Celery (leaf petiole vegetables, subgroup 4B). In a series for celery field trials conducted in CA, FL, MI, NY, and TX (PP#8F3674, C. Deyrup, 12/14/88; and PP#0F3869, W. Chin, 8/15/90), a 3.6 lb/gal EC formulation of propiconazole was applied to celery during crop development as 4 or 5 broadcast foliar applications at 0.11 lb ai/A/application, at RTIs of 7-14 days, for a total of 0.44-0.55 lb ai/A/crop (1x-1.2x rate). In four tests, propiconazole (EC) was also applied as 4 broadcast applications at 0.22 lb ai/A, for a total of 0.88 lb ai/A/crop (2x rate). Applications were made using both aerial and ground equipment, and a sticker was included in the tank mix in selected trials. Samples of celery were harvested at 0, 7, and 14 DAT and stored frozen for up to 12 months prior to analysis. Total residues of propiconazole and its 2,4-DCBA metabolites were determined using GC/ECD Method AG-454, which has an LOQ of 0.05 ppm.

Following applications totaling 0.44-0.55 lb ai/A (~1x rate), total propiconazole residues were 0.27-4.98 ppm in/on 20 samples of celery harvested at a PHI of 14 days. Median and average residues were 0.60 and 1.13 ppm, respectively, with a standard deviation of 1.28 ppm. Following applications totaling 0.88 lb ai/A (2x rate), residues were 0.60-2.52 ppm in/on 4 celery samples harvested at 14 DAT. Repeated samplings at 0, 7 and 14 indicated that residues declined at longer post-treatment intervals.

Additional celery field trials were conducted in FL during 1994 (43655613.der) comparing side-by-side applications of propiconazole formulated as a 45% WP and a 3.6 lb/gal EC. Each formulation was applied four times to celery as broadcast foliar applications during crop development at 0.11 lb ai/A/application, at retreatment intervals (RTIs) of 7 days, for a total of 0.44 lb ai/A/season. A single control and duplicate treated samples of whole immature plants were harvested from each plot at 0 days after the final application (DAT), and single control and duplicate treated samples of mature untrimmed stalks (RAC) were harvested from each plot at 14 DAT. Subsamples of trimmed stalks and trimmings were also collected at 14 DAT. Samples were stored frozen from collection to analysis for up to 9.5 months, an interval supported by available storage stability data. Residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on celery were determined using a GC/ECD method (Method AG-454B). Immediately following the final application (0 DAT), residues in/on whole immature plants were 1.5-2.1 ppm for the EC formulation and 1.3-1.5 ppm for the WP formulation. At maturity (14-DAT), residues in/on untrimmed stalks were 0.27-0.42 ppm for the EC formulation and 0.43-0.51 ppm for the WP formulation, with most of the residues being associated with the upper leaves. Residues in/on trimmed stalks at 14 DAT were ≤0.05 ppm for the EC and 0.05-0.07 ppm for the WP, and residues in/on trimmings were 0.41-0.45 ppm for the EC and 0.49-0.83 ppm for the WP. Average residues in/on untrimmed stalks, trimmed stalks, and trimmings were 0.35, 0.04, and 0.43 ppm, respectively, for the EC formulation, and 0.47, 0.06, and 0.66 ppm, respectively, for the WP formulation.

Although the data are limited, residues in/on celery from the EC and WP formulations were similar in this trial. Considering both the original celery field trials and the side-by-side tests, adequate celery field trial data are available to support the proposed use on of propiconazole (EC or WP) on leaf petiole vegetables.

Legume Vegetables Group

Dried Shelled Beans and Peas, except soybean (subgroup 6C). In conjunction with an earlier petition for use on legume vegetables, limited dry bean field trial data were submitted and reviewed under (PP#8F3674, C. Deyrup, 12/14/88). In a single field trial conducted in 1984, propiconazole (3.6 lb/gal EC) was applied to dry beans as three broadcast foliar applications at 0.138 lb ai/A/application, for a total of 0.41 lb ai/A/season (1.2x rate). Duplicate treated samples of mature beans were collected at 25 DAT, and analyzed for combined propiconazole residues using GC/ECD Method AG-454, which has an LOQ of 0.05 ppm. Combined residues in/on beans were 0.14 and 0.08 ppm from the 1.2x rate.

Additional dry bean field trials from 1989 were later submitted and reviewed by the Agency (DP Barcode D210266 and D210295, M. Rodriguez, 3/5/1997). In a series of 5 field trials conducted in ID, CO, ND, NE and MI, propiconazole (3.6 lb/gal EC) was applied to dry bean varieties as three broadcast foliar applications at 0.138 lb ai/A (5 tests) or 0.276 lb ai/A (3 tests), for totals of 0.41 or 0.83 lb ai/A/season (1.2x and 2.5x rates). Samples of vines were collected from each trial at 7 DAT, and samples of hay and mature beans were collected at 23-31 DAT, with most hay and bean samples being collected around 28 DAT. Samples were stored frozen for up to 41 months prior to analysis. Combined residues of propiconazole and its 2,4-DCBA containing metabolites were determined using GC/ECD Method AG-454B, which was adequately validated in conjunction with the analysis of field trial samples. The validated method LOQ is 0.05 ppm, and a LOD was not reported. Following three applications to dry beans at the 1.2x rate, combined propiconazole residues were 1.20-7.50 ppm in/on 10 samples of vines at 7 DAT, 0.17-4.90 ppm in/on 10 samples of hay at ~28 DAT, and <0.05-0.13 ppm in/on 10 samples of seeds at ~28 DAT. Average residues were 3.11 ppm for vines, 2.11 ppm for hay, and 0.08 ppm for seeds. Maximum residues from the 2.5x rate were 9.9, 15, and 0.10 ppm in/on vines, hay and seeds, respectively.

Insufficient field trial data are available to support the purposed use of propiconazole on dry peas and beans as only six dry bean field trials are available and no dry pea field trials were conducted. For a subgroup crop tolerance on 6C, a total of 12 dry bean field trials and 5 dry pea field trials are required. In addition, the available dry bean field trials support a PHI of 28 days rather than the 14-day PHI on the proposed label.

Soybeans. Limited soybean residue data were originally submitted and reviewed under PP#8F3674 (C. Deyrup, 12/14/88), to support a use on legume vegetables. In these studies, propiconazole (3.6 lb/gal EC) was applied to soybeans in 3 field trials as either: three applications at 0.14 lb ai/A, totaling 0.41 lb ai/A (1.2x rate); two applications at 0.16 lb ai/A, totaling 0.33 lb ai/A (1x rate); or three applications at 0.27 lb ai/A, totaling 0.83 lb ai/A (3.7x rate). Applications were made at RTIs of 3-31 days. Samples of hay were collected at 77-105

DAT, and samples of seeds were collected at 64-105 DAT. All samples were analyzed for combined propiconazole residues using GC/ECD Method AG-454, which has an LOQ of 0.05 ppm. Combined residues in/on seeds were 0.15-0.41 ppm from the 1.2x rate, 0.10-0.43 ppm from the 1x rate, and 0.61-0.74 ppm from the 3.7x rate, and combined residues in/on hay were 0.77-3.92 ppm from the 1.2x rate and 0.98-2.05 ppm from the 1x rate. Given the longer PHIs for hay and seed in these studies, these residue data are of limited value in assessing the currently proposed use pattern, which has much shorter PHIs.

More complete soybean field trial data were later submitted by Syngenta and reviewed by the Agency (DP Barcode D210266 and D210295, M. Rodriguez, 3/5/1997. MRID 43386502). In a series of 14 field trials conducted throughout the U.S., propiconazole (3.6 lb/gal EC) was applied to soybeans as two broadcast foliar applications at 0.165 lb ai/A, at RTIs of ~21 days, for a total of 0.33 lb ai/A/season (1x rate). The first application was made at the beginning at pod formation (Stage R3) and the second application was made at pod fill (Stage R5). Duplicate treated samples of forage and hay were collected from each trial at 21-32 DAT, with most samples being collected around 30 DAT. Duplicate treated samples of beans and fodder were collected at 41-99 DAT, with most mature samples being collected around ~50 DAT. At two test sites, forage and hay were also collected at 0, 7, 14, 21 and 30 DAT, to examine residue decline. Samples were stored frozen for up to 41 months prior to analysis, an interval that is supported by the available storage stability data. Combined residues of propiconazole and its 2,4-DCBA containing metabolites in/on soybean commodities were determined using GC/ECD Method AG-454B, which was adequately validated in conjunction with the analysis of field trial samples. The validated method LOQ is 0.05 ppm, and a LOD was not reported. Following two applications at a 1x rate, combined propiconazole residues were 0.33-5.40 ppm in/on forage and 0.48-21.0 ppm in/on hay harvested at ~30 DAT, and residues averaged 2.42 ppm for forage and 4.78 ppm for hay. By ~50 DAT, combine residues were 0.06-0.80 ppm in/on mature seeds and <0.05-6.20 ppm in/on fodder, and residues averaged 0.22 ppm in/on seeds and 1.15 ppm in/on fodder. [Note: fodder residues are included here for informational purposes only, as soybean fodder (straw) is no longer a regulated commodity]. Data from both residue decline trials indicate that residues in/on forage and hay decrease at longer post-treatment intervals.

A total of 20 soybean field trials were conducted during 2003 in EPA Regions 2, 4, and 5. (46576301.der). Each field trial included two treated plots, one for the harvest of forage and hay and the other for the harvest of seed. In the forage and hay plot, a multiple active ingredient EC formulation containing propiconazole at 1.04 lb ai/gal was applied as three broadcast foliar applications beginning at early to mid-flowering (BBCH 60-65 or R1-R2) at 0.075-0.095 lb ai/A/application, at retreatment intervals (RTIs) of 8-11 days, for totals of 0.24-0.25 lb ai/A (0.75x). All applications were made using ground equipment and included the use of a non-ionic surfactant at 0.125% v/v. At each site, soybean forage and hay were harvested at 0 days after the last application (DAT) and seeds were harvested at maturity, 19-24 DAT. At two field sites, forage and hay samples were also harvested at 3, ~5, ~7, and 10 DAT, and seeds were harvested at 18, 21, ~25, ~30, and ~32 DAT to examine residue decline. A single control and duplicate treated samples of each commodity were collected from each test at each interval. Samples were stored frozen from collection to analysis for up to 18 months, an interval supported by available storage stability data. Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on soybean forage, hay and seeds were determined using an adequate GC/MSD method, which is a modification to Method AG-626. Although recoveries from forage and hay were low, averaging 65-68% at all fortification levels, the recoveries were very consistent with low standard deviations (≤7%). Recoveries of propiconazole averaged 82% (±6-15%) from seed. Therefore, the method is deemed adequate for data collection. Combined propiconazole residues ranged from 1.70-12.0 ppm in/on forage and 2.63-27 ppm in/on hay at 0 DAT, and averaged 4.9 ppm in/on forage and 12.7 ppm in/on hay. For mature seeds harvested at 19-24 DAT, combined residues ranged from <0.1-0.27 ppm and averaged 0.09 ppm. The highest average field trial (HAFT) residues were 8.43 ppm for forage, 26.4 ppm for hay, and 0.21 ppm for seeds. Data from the two residue decline trials indicate that combined residues declined slowly in forage and hay from 0 to 10 DAT, but remained relatively steady in seeds from 18 to 33 DAT. **Since these field trials were conducted at 0.75x the maximum rate, the residue data were not used in the tolerance calculation.**

To support a proposed later application timing on soybeans (up to Stage R6), Syngenta also recently submitted data from four soybean field trials conducted in IL, IN and MS during 2003 (46473001.der). In these trials, propiconazole (3.6 lb/gal EC) was applied to soybeans as late-season broadcast foliar applications during pod and seed development. Each field site compared three different application regimes for propiconazole: (1) three applications at 0.11-0.12 lb ai/A from BBCH Stages 71 to 89, for totals of 0.32-0.35 lb ai/A/season (1x rate); (2) two applications at 0.10-0.12 lb ai/A at BBCH stages 77 to 89, for totals of 0.23-0.24 lb ai/A/season (0.67x rate); and (3) two applications at 0.17-0.19 lb ai/A, at BBCH stages 77 to 89 for totals of 0.33-0.36 lb ai/A/season (1x rate). The BBCH growth stages of 71-89 are equivalent to Stages R4-R8. All applications were made using ground equipment at RTIs of 13-18 days, and did not include the use of any adjuvants. Single control and duplicate treated samples of soybean seed were harvested from each test at 30 DAT, and forage and hay samples were not collected. Soybean seed samples were stored frozen for up to 8.5 months prior to extraction for analysis. Combined residues of propiconazole and its 2,4-DCBA containing metabolites in/on soybean seeds were determined using GC/ECD Method AG-626, which was adequately validated in conjunction with the analysis of field trial samples. The validated method LOQ is 0.05 ppm, and a LOD was not reported. Following the two applications totaling 0.33-0.36 lb ai/A (1x rate), combined residues levels in soybean seeds were 0.17-0.94 ppm and averaged 0.39 ppm in/on 8 samples at 30 DAT. No residue decline trials were conducted.

Considering all the available soybean field trial data, HED considers sufficient residue data are available to support tolerances on soybean forage and hay harvested 30 days following the second of two applications totaling 0.33 lb ai/A (1x rate). Although the petitioner has requested tolerances for soybean forage and hay, the Agency notes that the currently proposed use directions for soybean prohibit the feeding or grazing for forage or hay. HED also considers sufficient residue data are available to support tolerances on soybean seed, even though the PHIs of the soybean seed data varies from 30 to 90 days, as long as the label states that "do not apply later than the R5 growth stage' or 'apply up to Stage R6", no additional field trials are required for soybean seeds.

Berries Crop Group

Bush and Cane Berries. Field trial data on blueberry, blackberry, and raspberry have been previously reviewed (DP Barcode D219664, L. Kutney, 6/14/96). In a total of 9 field trials conducted during 1994 in ME, MI, NC, NJ, OR, and WA, propiconazole (3.6 lb/gal EC) was applied to blueberries or cane berries as five foliar applications at 0.17 lb ai/A/application (1x rate, 6 tests) or 0.34 lb ai/A/application (2x rate, 3 tests), at unspecified RTIs, for totals of 0.85 or 1.7 lb ai/A (1x and 2x seasonal rates). Applications were made in a minimum volume of 20 gal/A, and included the use of a spreader/sticker at 1% v/v. A single control and single or duplicate treated samples of berries were collected at 30 DAT. Samples were stored frozen from collection to analysis for up to 5 months, and combined residues of propiconazole and its 2,4-DCBA containing metabolites were determined using GC/ECD Method AG-454B, which was validated in conjunction with the analysis of field trial samples. The validated method LOQ is 0.05 ppm.

Following applications of propiconazole (EC) totaling 0.85 lb ai/A (1x rate), residues were 0.14-0.66 ppm in/on 12 berry samples harvested at 30 DAT, and average residues were 0.36 ppm. In the three tests conducted at a 2x rate (1.7 lb ai/A), residues were 0.27-0.98 ppm in/on 4 samples from 30 DAT, and averaged 0.49 ppm. These field trial data will support the proposed use on bush and cane berries.

Cranberry. The available cranberry data are discussed here under the berry crop group, although cranberry has not yet been officially placed in the expanded berries crop group. A total of three cranberry field trials were conducted, including two in WI during 1995 and one in OR during 1999 (45778901.der and 44338101.der). In each test, propiconazole (3.6 lb/gal EC) was applied to established fields of cranberries as four broadcast foliar applications at 0.156-0.170 lb ai/A/application, for a total of 0.66-0.68 lb ai/A/season. The first two applications were made at bud break and at ~14 days after bud break, and the final two applications were made during fruit development. Retreatment intervals (RTIs) were 13-14 days between the first and second applications, 45-56 days between the second and third applications, and 11-14 days or 78 days between the third and fourth applications. No adjuvants were included in the spray mixes, and all application were made using ground equipment in 18-80 gal/A. One to four control samples and duplicate treated samples of cranberries were harvested from each site at 43 or 44 days after the final application (DAT). Samples were stored frozen from collection to analysis for up to 78 days. This interval is supported by the concurrent storage study indicating that propiconazole is stable at -20°C in cranberries for up to 92 days. The combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on cranberries were determined using either a GC/NPD method (Method AG-454B, modified) for the 1995 tests or a GC/ECD method (Method AAG-626) for the 1999 test. These methods are updated versions of the current tolerance enforcement method. The validated method limit of quantitation (LOQ) is 0.05 ppm, and a limit of detection (LOD) was not reported. Control samples of cranberries were fortified with propiconazole at 0.05, 0.50, and 1.0 ppm and recoveries at each level averaged 74-96%, with standard deviations range from 2-25 %.

Following four applications of propiconazole (EC) totaling 0.66-0.68 lb ai/A, residues were 0.18-0.59 ppm in/on 6 cranberry samples harvested 43-44 DAT, and averaged 0.32 ppm. A residue decline trial was not conducted.

These field trial data support the use of propiconazole (EC) on cranberries with up to four applications at 0.169 lb ai/A/application, for a total of 0.68 lb ai/A/season, minimum RTIs of 14 days and a PHI of 45 days. These data are adequate to support the proposed use on cranberries, restricted to WI and the Pacific NW.

Strawberry. Although strawberry has not yet been officially placed in the expanded berries crop group, the available strawberry data are discussed here under the berry crop group. In 8 field trials conducted throughout the U.S. in 1996 (45542401.der), propiconazole (3.6 lb/gal) was applied to strawberries as four broadcast foliar applications during fruit development at 0.11 lb ai/A/application at retreatment intervals (RTIs) of 6-8 days, for a total of 0.44 lb ai/A/season. All applications were made using ground equipment at volumes of 50-100 gal/A, and no adjuvants were used. Single control and duplicate treated samples of strawberries were harvested from each site on the same day as the final application (0 DAT) and at 3 or 8 DAT at two sites. Samples were stored frozen from collection to analysis for up to 18 months, an interval supported by available storage stability data. Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on strawberries were determined using an adequate GC/ECD method (Method AG-45B). The validated method limit of quantitation (LOQ) is 0.05 ppm, and the limit of detection (LOD) was not reported. The concurrent recovery of propiconazole averaged 77 ± 8% from control samples fortified at 0.05 or 0.50 ppm. Although the raw data (instead of corrected data) were used to report residue values, the data collection method detects parent plus all metabolites containing DCBA, and yet the Agency's tolerance expression for propiconazole will be established at parent only, there fore, tolerances will not under represent the real residue levels.

Following the last of four foliar applications totaling 0.44 lb ai/A, total uncorrected propiconazole residues were 0.07-0.69 ppm in/on 16 samples of strawberries harvested on the day of the final application (0 DAT). Average residues were 0.35 ppm and the highest average field trial (HAFT) residues were 0.60 ppm. Data from both residue decline tests indicated that residues declined on strawberries at longer post-treatment intervals.

The number of trials and the geographic representation of the trials are adequate. These data will support the use of propiconazole (EC) on strawberries as up four broadcast foliar applications at 0.11 lb ai/A/application, at a minimum RTI of 7 days, for a total of 0.44 lb ai/A/season, with a 0-day PHI.

Tree Nuts Crop Group

Pecan. Adequate field trial data on pecans were submitted in conjunction with an earlier petition for use of propiconazole on pecans. (PP#4F3007, A. Smith, 5/15/84). In eight field trials conducted in AL, OK, GA, LA, TX, and NM, propiconazole, formulated as a 3.6 lb/gal EC, was applied to pecans as 6-10 foliar applications at 0.33 lb ai/A/application, beginning a bud break and continuing at 2-week intervals until shuck-split. All tests were conducted using ground equipment, and total application rates were 2-3.3 lb ai/A/season (2-3x rate). Residues in/on all samples of pecan nutmeats were below the method LOQs (<0.05 or <0.1 ppm).

Almond. In five field trials conducted during 1998 and 1999 in CA, propiconazole was applied to almonds in side-by-side tests comparing the use of 45% WP and 3.6 lb/gal EC formulations. Applications were made as dilute sprays (160-207 gal/A) at two sites, as concentrated sprays (10 gal/A) at two sites, and as both dilute (150 gal/A) and concentrated (75 gal/A) sprays at the fifth site. In each test, propiconazole (EC or WP) was applied four times to almonds as foliar applications during nut development at 0.22-0.25 lb ai/A/application, at retreatment intervals (RTIs) of 6-14 days, for a total of 0.88-0.91 lb ai/A/season. All applications were made using ground equipment and adjuvants were not added to the spray mix. Single control and duplicate treated samples of nutmeats and hulls were collected from each test at normal maturity, 53-63 days after the final application (DAT). In one test, duplicate treated samples of nutmeats and hulls were collected at 40, 49, 55, 63, and 68 DAT to examined residue decline. Samples were stored frozen from collection to analysis for up to 10 months, an interval supported by available storage stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on almond nutmeats and hulls were determined using adequate GC/ECD methods (Methods AG-454B and AG-626). The validated method LOQ is 0.05 ppm for nutmeats and 0.10 ppm for hulls, and a LOD was not reported. Although the concurrent recoveries from nutmeat and hulls were generally low (60-80%), the recoveries were relatively consistent. Therefore, the method is deemed adequate for data collection. Although the raw data (instead of corrected data) were used to report residue values, the data collection method detects parent plus all metabolites containing DCBA, and yet the Agency's tolerance expression for propiconazole will be established at parent only, there fore, tolerances will not under represent the real residue levels.

Application volume and formulation type had no apparent effect on residue levels. For samples treated with the WP, combined residues range from <0.05-0.07 ppm in/on 12 samples of nutmeats and 0.57-4.60 ppm in/on 12 samples of hulls, For samples treated with the EC formulation , combined residues range from <0.05-0.09 ppm in/on 12 samples of nutmeats and 0.85-4.20 ppm in/on 12 samples of hulls. For the WP and EC formulations, average residues were respectively 0.035 and 0.041 ppm in/on nutmeats and 1.78 and 2.06 ppm in/on hulls. When data from both formulations are pooled, average residues are 0.038 ppm in/on nutmeats and 1.92 ppm in/on hulls.

In the residue decline test, residues in/on nutmeats declined slightly from an average of 0.07 ppm at 40 DAT to <0.05 ppm by 68 DAT. However, residue levels in/on hulls were variable over time. Given the variability of residues in/on hulls at a single sampling interval (1.92 ± 1.20 ppm; 53-63 DAT), the decline data most likely represent the variability in hulls residues rather than any trend in hull residue levels.

The number of trials and the geographic representation of the trials are adequate. These data will support the use of propiconazole (EC or WP) on almonds as up four foliar applications during nut development at 0.22 lb ai/A/application, at a minimum RTI of 7 days, for a total of 0.88 lb ai/A/season, with a 60-day PHI.

Together the pecan and almond field trial data are sufficient to support the proposed uses on various members of the tree nut crop group.

Cereal Grains and Forage, Fodder, and Straw of Cereal Grains Groups

Corn (field, pop and sweet). Propiconazole (EC and WP) is currently registered for use on field, pop, and sweet corn as multiple foliar applications through silking at up to 0.11 lb ai/A/application, at minimum RTIs of 7 days, for a total of 0.44 lb ai/A/season. Labeled PHIs are 14 days for sweet corn ears and forage, and 30 days for field corn forage. No PHI is specified for mature field, pop or seed corn.

Residue data on field and sweet corn supporting the original use pattern were reviewed under PP#8F3674 (C. Deyrup, 12/14/88). In these studies, propiconazole (3.6 lb/gal EC) was applied to field or sweet corn in 14 tests as five broadcast foliar applications at 0.055-0.11 lb ai/A, for a total of 0.39 lb ai/A/season (~0.9x rate), and in 3 tests as 5-8 foliar applications at 0.055-0.11 lb ai/A, for a total of 0.44 lb ai/A/season (1x rate). Seven trials were also conducted using exaggerate applications at 0.11-0.22 lb ai/A, for totals of 0.77-0.88 lb ai/A/season (1.8-2x rates). In the sweet corn trials, samples of ears and forage were harvested from all tests at 14-38 DAT. In the field corn trials, forage samples were collected at 21-43 DAT, fodder samples were collected at 57-78 DAT, and grain samples were collected at 21-78 DAT. All samples were analyzed for combined propiconazole residues using GC/ECD Method AG-454, which has an LOQ of 0.05 ppm.

In the sweet corn tests conducted at 0.9x and 1.8x rates, combined residues were <0.05-0.06 ppm in/on K+CWHR and 1.27-5.00 ppm in/on forage; maximum forage residues were found at 14 DAT from a 0.9x rate test. In the field corn tests conducted at 0.9-1x rates, combined residues were 0.12-9.30 ppm in/on forage, <0.05 ppm in/on grain, 0.16-4.12 ppm in/on fodder (stover). In the field corn tests conducted at 1.8-2x rates, combined residues were 1.36-14.6 ppm in/on forage, <0.05-0.06 ppm in/on grain, 0.67-8.02 ppm in/on fodder (stover). Based on these data, temporary tolerances have been established at 0.1 ppm in/on corn, field, grain and corn, sweet, K+CWHR, and at 12 ppm in/on corn, field, forage and stover. The 12 ppm tolerance for field corn forage was set at 12 ppm because the maximum residues in field corn forage (9.3 ppm) were observed from a test conducted at 0.9x rate; therefore, the maximum expected residues were assumed to be 10.3 ppm. These tolerances are set to expire on 11/30/08.

43655612.der

In addition to the above corn data, Syngenta has also submitted data from side-by-side tests conducted during 1994 on field and sweet corn (43655612.der), comparing residues resulting from the use of EC and WP formulations. Two tests each were conducted on field and sweet corn. In each test, propiconazole (EC or WP) was applied four times prior to silking as broadcast foliar applications at 0.11 lb ai/A/application, at RTIs of 5-9 days, for a total of 0.44 lb ai/A/season (1x rate). In the field corn tests, samples of forage were collected at 30-31 DAT and 56-63 DAT, and grain and stover were collected at 93 or 118 DAT. In the sweet corn tests, samples of forage were collected at 14 DAT, and samples of mature forage and K+CWHR were collected at 25-35 DAT. All samples were analyzed for combined propiconazole residues using GC/ECD Method AG-454B, which has an LOQ of 0.05 ppm.

In the side-by-side tests, combined residues in/on the various corn commodities were similar for the two formulations. For field corn treated with the EC, residues averaged 0.60 ± 0.67 ppm for forage at ~30 DAT and 0.98 ± 1.11 ppm for mature stover. For the WP formulation, combined residues averaged 0.74 ± 0.81 ppm for forage at ~30 DAT and 1.20 ± 1.34 ppm for mature stover. Combined residues were <LOQ in/on all samples of corn grain, regardless of the formulation used. For sweet corn treated with the EC, residues averaged 0.23 ± 0.15 ppm for forage at 14 DAT and 0.45 ± 0.48 ppm for mature forage. For the WP formulation, residues averaged 0.22 ± 0.10 ppm for forage at 14 DAT and 0.43 ± 0.43 ppm for mature forage. Combined residues were <LOQ in/on all samples of sweet corn ears (K+CWHR) for both formulations.

In the current petition, the maximum single and seasonal use rate on corn are unchanged, but Syngenta is now proposing to allow applications to field, seed and pop corn later in the season, during grain development, and establishing at 30-day PHI for grain and stover of field, pop, and seed corn. Residue data reflecting this later use pattern are described below; no new residue data on sweet corn have been submitted.

45080809 and 45080810.der
In a total of 28 field trials conducted throughout the U.S. during 1998 and 1999, propiconazole (1.04 lb/gal EC) was applied to field corn (24 trials) and popcorn (4 trials). With a few exceptions, each field corn trial included one treated plot for the collection of forage and another plot for the collection of grain and stover, and the four popcorn field trials each had a single treated plot for the collection of only grain and stover. Propiconazole (EC) was applied to the forage plots as two broadcast foliar applications during early vegetative development at a rate of 0.11 lb ai/A/application, for a total of 0.22 lb ai/A. The retreatment interval (RTI) for the forage applications ranged from 3-8 days, but was typically 7 days. For the grain and stover plots, propiconazole (EC) was applied to the corn as four broadcast foliar applications from flowering through grain development at rates of 0.09-0.14 lb ai/A/application, for a total of 0.42-0.47 lb ai/A. The RTIs ranged from 6-9 days, but were typically 7 days. All applications were made using ground equipment in volumes of 5-25 gal/A, and no adjuvants were included in the spray mixtures. At two of the field corn sites, propiconazole was also applied as four broadcast foliar applications during grain development at 0.55 lb ai/A/application, for a total of 2.2 lb ai/A (5x rate). In four of the 1998 field trials, propiconazole was misapplied to the forage and/or stover and grain plots at a reduced rate (0.05-0.06 lb ai/A/application); these field trials were replaced by the subsequent 1999 field trials.

Single control and duplicate treated samples of forage were harvested at 29-32 days after the last treatment (DAT), except in three tests in which forage was collected at 15, 51 or 67 DAT. Single control and duplicate treated samples of corn stover and grain were harvested at 28-35 DAT from all tests, with most samples being collected at 29-30 DAT. To examine residue decline, repeated control and treated samples were also collected at two sites at 0, 9, 16, 23, 30 and 36/37 DAT for forage and stover and at 9, 16, 23, 30 and 36 DAT for grain. Samples were stored frozen from collection to analysis for up to 15.9 months, an interval supported by available storage stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on corn forage, grain and stover were determined using adequate GC/ECD methods (Methods AG-454B and AG-626). The validated method limit of quantitation (LOQ) is 0.05 ppm, and the limit of detection (LOD) was not reported. Concurrent recoveries of propiconazole averaged 93 ± 11% from forage, 89 ± 13 % from stover and 90 ± 15% from grain.

Following the two early-season broadcast foliar applications totaling 0.22 lb ai/A, combined propiconazole residues range from <0.05-1.90 ppm and averaged 0.45 ppm in/on 36 samples of forage harvested at 29-32 DAT. Following the four broadcast foliar applications during flowering through grain development at rates totaling 0.42-0.47 lb ai/A, combined residues range from 0.92-19.6 ppm in/on 48 samples of stover and <0.05-0.15 ppm in/on 48 samples of grain harvested at 28-35 DAT. Average residues were 6.87 in/on stover and 0.037 ppm in/on grain, and the highest average field trial (HAFT) residues were 15.9 ppm in/on stover and 0.10 ppm in/on grain. In the two 5x rate tests, combined residues were 23.2-77 ppm in/on four samples of stover and <0.05-0.062 ppm in/on four samples of grain harvested at 29-30 DAT. Data from the two residue decline trials indicated that residues in/on forage and stover decreased at longer post-treatment intervals. However, residue decline could not be determined in grain as residues in grain were <LOQ in all but two samples from the declined trials.

The number of trials and geographic representation of the trials are adequate. These data support the use of up to four broadcast foliar applications of propiconazole (EC) to field or pop corn through grain development, up to the dent stage (R5 stage), at 0.11 lb ai/A/application, at a minimum RTI of 7 days, for a total of 0.44 lb ai/A/season. The data also support a PHI of 30 days for harvest of forage, grain and stover. However, these most recent data will only support the use of two early-season applications prior to the harvest of forage. **If the petitioner intends to support total use rates of 0.22 lb ai/A to field corn prior to the harvest of forage, then the current residue data on forage indicate that the tolerance for field corn forage could be reduced from 12 ppm to 4.5 ppm.**

Rice. The Agency recently reviewed (DP Barcode D240856, T. Morton, 2/23/05) residue data from eight rice field trials conducted in 1996 reflecting the use of propiconazole (3.6 lb/gal EC) as either a single broadcast foliar application during internode elongation at 0.28 lb ai/A (4 tests) or as a split application at 0.17 lb ai/A/application during internode elongation and again at booting, for a total of 0.34 lb ai/A (4 tests). Combined propiconazole residues were <0.05-0.28 ppm in/on grain and 0.50-1.75 ppm in/on straw at 45 days following the single application at 0.28 lb ai/A, and <0.05-0.07 ppm in/on grain and 0.33-1.62 ppm in/on straw at 45 days following the second of the two split applications.

45080811.der
For the current petition, Syngenta is now proposing that the single or split applications of propiconazole be allowed later in the season, at up to heading. To support this use, Syngenta submitted 16 new rice field trials conducted during 1998 in the major rice producing areas of the U.S. (45080811.der). At each site, propiconazole (3.6 lb/gal EC) was applied to rice as a single broadcast foliar application at 0.28 lb ai/A during heading (1x rate). Four of the trial sites also included another treatment, in which propiconazole (1.04 lb/gal EC) was applied as split broadcast foliar applications around heading at 0.154 lb ai/A/application, at retreatment intervals (RTIs) of 14 days, for a total of 0.31 lb ai/A/season. Single control and duplicate treated samples

of rice straw and grain were harvested from each site at 34-49 days after treatment (DAT), with 14 sites having harvest intervals of 34-37 days. To examine residue decline, additional samples were collected from two test sites at 14, 21, 27-28, 34-38, and 42-45 DAT. Samples were stored frozen from collection to analysis for up to 11.2 months, an interval supported by the available storage stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on rice grain and straw were determined using an adequate GC/ECD method (Method AG-626). Concurrent recoveries from rice straw showed averaged 91 ± 13% and from rice grain 91 ± 7%. The validated method LOQ is 0.05 ppm, and an LOD was not reported.

Following a single application of propiconazole (EC) at 0.28 lb ai/A (1x rate), total propiconazole residues ranged from 0.97-17.0 ppm in/on 32 samples of straw and 0.03-6.50 ppm in/on 32 samples of grain harvested at 34-49 DAT. Average residues were 4.50 ppm for straw and 1.76 ppm for grain. At the four sites where the single application at 0.28 lb ai/A was compared to the split application totaling 0.31 lb ai/A, residues were similar between the two treatments. Average residues in/on grain and straw were 1.34 and 4.27 ppm, respectively, following the single application, and 1.17 and 4.04 ppm, respectively, following the two split applications.

In the two residue decline tests, residues in/on rice grain remained relatively steadily over time, averaging 1.45 ppm at 14 DAT and 1.22 ppm at ~45 DAT. Residues in/on straw showed a slight increase at longer post-treatment intervals, but the trend could not be verified due to the variability in the residue data on straw. Average residues in/on straw were 3.05 ppm at 14 DAT and 4.45 ppm by ~45 DAT. The slight increase in straw residues may be the result of drying down of the foliage as the crop matures. The most recent rice field trials adequate support the proposed 35-day PHI and a minimum RTI of 14 days for the split applications.

Sorghum. Propiconazole (3.6 lb/gal EC) was applied to sorghum in 12 field trials conducted during 1998 (45275801.der). The number of trials and the geographic representation of the trials are adequate. At each field site, separate plots were established for the collection of forage or grain and stover. For the forage plots, propiconazole was applied as two broadcast foliar applications beginning around flower initiation at 0.11 lb ai/A/application, at a retreatment interval (RTI) of 5 days, for a total of 0.22 lb ai/A/season (0.5x seasonal rate). In the grain/stover plots, propiconazole was applied as four broadcast foliar applications at 0.11 lb ai/A/application, beginning at flowering or early grain development, for a total of 0.44 lb ai/A/season. Two test sites also included separate grain/stover plots treated at exaggerated rates of 0.33 or 0.55 lb ai/A/application, for a total of 1.32 or 2.20 lb ai/A/season (reported as 3x and 5x rates). The RTIs for the grain/stover plots ranged from 3-11 days, but were 4-5 days at most test sites. Single control and duplicate treated samples were collected from each plot, with forage samples being harvested at 0 and 29-31 days after the final treatment (DAT) and grain and stover samples being harvested 18-22 DAT. Repeated samples were also collected at two sites to examine residue decline, with forage being sampled at 0, 9, 16, 23, 30 and 37/38 DAT, and grain and stover being sampled at 0, 7, 14, 21 and 28 DAT. Samples were stored frozen for up to 17.1 months prior to extraction for analysis. Adequate storage stability data are available to support the storage intervals and conditions for the current sorghum field trials.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on sorghum forage, stover and grain were determined using an adequate GC/ECD method (Method AG-626, modified), which was adequately validated in conjunction with the analysis of field trial samples. The validated method limit of quantitation (LOQ) is 0.05 ppm, and the limit of detection (LOD) was not reported.

Following two applications totaling 0.22 lb ai/A (0.5x rate),, combined residues in/on forage were 1.80-11.6 ppm in/on 14 samples at 0 DAT and 1.5-8.2 ppm in/on 24 samples at 29-31 DAT, and average residues in/on forage were 6.3 ppm at 0 DAT and 4.4 ppm at 29-31 DAT. Following four applications totaling 0.44 lb ai/A(1x rate), residues were 2.8-11.7 in/on 24 samples of stover and 0.52-2.30 ppm in/on 24 samples of grain harvested at 18-22 DAT, and average residues were 5.8 ppm in/on stover and 1.14 ppm in/on grain. In the exaggerated rate test at 1.32 lb ai/A (3x rate), residues were 12.6 and 15.0 ppm in/on stover and 4.7 and 4.8 ppm in/on grain at 18 DAT. In the two exaggerated rate tests at 2.20 lb ai/A (5x rate), residues were 7.4-30.6 ppm in/on stover and 2.1-7.1 ppm in/on grain at 18-20 DAT.

Data from the two residue decline field trials showed a slight downward trend in residue levels in all three commodities over time, but the decline was erratic in forage and stover and there was a substantial degree of variability in residue levels at each interval. The Agency notes that the combined residues in forage, stover and grain in one of the decline trials were actually higher than the maximum residues observed around the earlier PHI. Maximum residues in forage were 8.2 ppm at 29-31 DAT and 8.3 ppm at 37-38 DAT; maximum residues in stover were 11.7 ppm at 18-22 DAT and 14.2 ppm at 28 DAT; and maximum residues in grain were 2.3 ppm at 18-22 DAT and 2.4 ppm at 28 DAT. As residue levels at these later intervals were equivalent or higher than residues observed around the proposed PHIs, residue values from these sampling intervals will be included in the data base used for calculating sorghum tolerances.

The sorghum field trial data are adequate and support the proposed use pattern, provided that the label is amended to specify a maximum total application rate of 0.22 lb ai/A on sorghum harvested for forage.

Wheat. Previously reviewed residue data and use directions for propiconazole on wheat have allowed for a single application up to heading (Feekes Growth Stage 10.5) at 0.11 lb ai/A. In the current petition, Syngenta is now proposing increasing the use rates for wheat (and barley, rye, triticale, and oats) to include up to two applications at 0.11 lb ai/A up to heading, with a minimum RTI of 14 days. In evaluating the proposed use, this review will only consider the wheat field trial data including the two applications use pattern.

The Agency recently reviewed (DP Barcode D240856, T. Morton, 2/23/05) residue data from 12 wheat field trials conducted in 1992-93 reflecting the use of propiconazole (3.6 lb/gal EC) as two broadcast foliar applications at 0.11 lb ai/A, at Feekes Growth 5 and 8, for a total of 0.22 lb ai/A/season (1x rate). Retreatment intervals were 6-31 days and all applications were made using ground equipment. Single control and duplicate treated samples of wheat forage were harvested from each site 0 and 30-32 DAT, and mature wheat grain and straw were harvested at 54-91 DAT. Wheat hay was not sampled. Samples were stored frozen from collection to analysis for up to 19 months, an interval supported by available storage stability data. Combined residues were determined using GC/ECD Method AG-454B, which was adequately validated in conjunction with the analysis for field trial samples. The validated LOQ is 0.05 ppm, and the LOD was not reported

Following two applications totaling 0.22 lb ai/A (1x rate), combined residues in/on wheat forage harvested at 0 and 30-32 DAT were <1.2-10.7 ppm and 0.09-1.7 ppm, respectively. Combined residues in/on wheat grain and straw harvested at 54-91 DAT <0.05-0.08 ppm and <0.05-4.2 ppm, respectively. Average combined residues were 4.37 ppm in/on forage at 0 DAT, 0.70 ppm in/on forage at ~30 DAT (proposed PHI), 0.98 ppm in/on straw, and 0.03 ppm in/on grain. These field trial data do not adequately support the currently proposed use on wheat as only 12 of the required 20 field trials were conducted, no hay samples were collected, the applications were made earlier in the season (Feekes 5 and 8). However, the forage residue data from the 30-DAT samples do reflect two applications to forage, although the number of tests is insufficient to support a forage tolerance.

More recently, Syngenta has submitted additional wheat field trials more in line with the requested use pattern on wheat (44757208.der1). In a total of 21 field trials conducted throughout the U.S. during 1997, propiconazole (3.6 lb/gal EC) was applied to at least three separate plots of wheat at each site. In two plots at each site, propiconazole was applied as a single broadcast foliar application at 0.11-0.12 lb ai/A (0.5x rate) at either Feekes Growth Stage 5 or FGS 10.5. The early-season application at FGS 5 was used for the collection of forage and hay, and the late-season application at FGS 10.5 was used for collection of grain and straw. In the third plot, propiconazole was applied as two late-season, broadcast foliar applications at booting and heading (Feekes Growth Stages 10 and 10.5), at 0.11-0.12 lb ai/A/application, for a total of 0.22-0.23 lb ai/A (1x rate). This plot was used for the collection of grain and straw samples. All applications were made using ground equipment at spray volumes of 11-25 gal/A, and no adjuvants were included in the tank mixtures. For the plots that received two applications, the RTI was 13-22 days, with most tests having a RTI of 14 days.

Single control and duplicate treated samples of forage were harvested at 29-32 DAT, and hay samples were cut at 43-50 DAT, with most hay samples being cut at 45 DAT. Single control and duplicate treated samples of mature wheat grain and straw were harvested at 27-50 DAT, with most samples being collected around 40 DAT. To examine residue decline, repeated control and treated samples were collected at two sites from 0-37 DAT for forage, 29-59 DAT for hay, and 21-73 DAT for grain and straw. Samples were stored frozen from collection to analysis for up to 16.3 months, an interval supported by available storage stability data.

Combined residues of propiconazole and its 2,4-DCBA containing metabolites were determined using GC/ECD Method AG-454 B, which was adequately validated in conjunction with the analysis of field trial samples. The validated method LOQ is 0.05 ppm for each wheat commodity, but the LOD was not reported. Samples were also analyzed for residues of propiconazole, *per se*, using a GC/NPD method from PAM Vol. I (Method 302 E4 + DG5); this method was also adequately validated in conjunction with the analysis of field trial samples. The method LOQ for propiconazole was 0.05 ppm, and a LOD was not reported.

Following an application at Feekes Growth Stage 5 at 0.11 lb ai/A (0.5x), total combined residues were <0.05-1.91 ppm in/on forage harvested at 29-32 DAT and <0.05-1.10 ppm in/on hay cut at 43-50 DAT, and average combined residues were 0.33 and 0.30 ppm in/on forage and hay, respectively. Residues of parent propiconazole were <0.05-0.49 ppm in/on forage and <0.05-0.20 ppm in/on hay, and averaged 0.06 and 0.04 ppm, respectively.

Following a single application during heading at 0.11-0.12 lb ai/A (0.5x), total combined residues were 0.41-6.21 ppm in/on straw and <0.05-0.13 ppm in/on grain harvested at maturity, 27-57 DAT, and combined residues averaged 2.02 and 0.04 ppm in/on straw and grain, respectively. Residues of parent propiconazole were <0.05-1.63 ppm in/on straw and <0.05 ppm in/on grain, and averaged 0.45 and 0.025 ppm, respectively.

Following two broadcast applications during booting and heading at total rates of 0.22 lb ai/A (1x rate), total combined residues were 0.20-8.27 ppm in/on straw and <0.05-0.20 ppm in/on grain harvested at 27-57 DAT. Combined residues averaged 3.31 and 0.07 ppm in/on straw and grain, respectively. Residues of parent were <0.05-3.49 ppm in/on straw and ≤0.05 ppm in/on grain, and averaged 0.73 and 0.025 ppm, respectively.

The most recent wheat data will support the proposed late-season use pattern for wheat and the PHIs of 30 days for forage, 45 days for hay, and 40 days for grain and straw. Although these data support the use of applications totaling 0.22 lb ai/A prior to harvest of mature grain, the data will only support the use of applications totaling 0.11 lb ai/A, prior to the harvest of either forage or hay. Limited field trial data are available (12 tests) reflecting 1x applications to forage, but no data are available for hay reflecting the 1x rate. Therefore, the label should be amended to specify that only a total of 0.11 lb ai/A may be applied prior to the harvest or grazing of forage and hay. If the petitioner intends to support the use of two applications at 1x prior to harvest of forage and hay, then an additional 8 field trials are required on forage and a complete set of 20 field trials would be required for hay.

Miscellaneous Commodities

Mint. In five field trials conducted during 1995 in Regions 5 and 11 (44416501.der), propiconazole (3.6 lb/gal EC) was applied twice to established fields of mint as broadcast foliar applications at 0.111-0.114 lb ai/A/application at RTIs of 13-14 days, for a total of 0.224-227 lb ai/A/season (1x rate). The initial application was made when plants were 4-8 inches in height, and all applications were made using ground equipment. Duplicate control and treated samples of fresh mint hay were harvested from each site at 29-30 DAT. Samples were stored frozen from collection to analysis for up to 62 days, an interval supported by available storage stability data. Total residues of propiconazole and its DCBA containing metabolites in/on mint were determined using a GC/ECD Method AG-454B, which was adequately validated in conjunction with the analysis of field trial samples. The validated method LOQ is 0.05 ppm, and an LOD was not reported.

Following applications of propiconazole (EC) at rates totaling 0.224-0.227 lb ai/A/season (1x rate), total propiconazole residues were 0.06-2.7 ppm and averaged 1.15 ppm in/on 10 samples of mint hay harvested at 29-30 DAT.

Conclusions The available field trial data on almonds, bush and cane berries, carrots, celery, cranberries, mint, onions, pecans, rice and strawberries are adequate and support the proposed use patterns for propiconazole (EC or WP) on these crops. The number and geographic distribution of the field trials are adequate, and the appropriate samples were collected at the proposed PHIs. Based on available side- by- side studies with almonds, celery, field corn, and sugar beets comparing the EC and WP formulations, the general results are that the residues are similar with the two formulations, with the exception of sugar beet tops where the EC formulation resulted in higher residues. For crops other than almonds, celery, field corn, and sugar beets, data were generated for only the EC formulation. Sugar beets are the only crop for which most of the data reflect the WP formulation. HED concluded that adequate data are available to support use of both formulations on all crops in these petitions with the exception of sugar beets.

The available bush and cane berries field trial data will support a general use on all members of the berry crop group (13); the celery field trial data will support uses on all members of the leafy petioles crop subgroup (4B); and the onion (green and dry bulb) field trial data will support uses on all members of the bulb vegetable crop group (3). The almond and pecan data will support uses on all members of the tree nut crop group (14); however, use directions for all tree nuts, except pecans, should be amended to specify a minimum PHI of 60 days.

Adequate field trial data have previously been reviewed supporting the current use directions on sweet corn. The available field and pop corn field trial data are adequate and support the use of up to four late-season broadcast foliar applications of propiconazole (EC) to field or pop corn through grain development, up to the dent stage (R5 stage), at 0.11 lb ai/A/application, for a total of 0.44 lb ai/A/season. The data support a PHI of 30 days for harvest of forage, grain and stover. However, the most extensive data on field corn forage will only support the use of two early-season applications prior to the harvest of forage. The current time-limited tolerance of 12 ppm on field corn forage can be reduced to 4.5 ppm if the petitioner intends to only support total use rates of 0.22 lb ai/A to field corn prior to the harvest of forage.

The sorghum field trial data are also adequate and support the proposed use pattern, provided that the label is amended to specify a maximum total application rate of 0.22 lb ai/A on sorghum harvested for forage.

There are no sufficient field trial data to support the purposed use on dry peas and beans as only six dry bean field trials are available and no dry pea field trials were conducted. For a subgroup crop tolerance on 6C, a total of 12 dry bean field trials and 5 dry pea field trials are required. In addition, the available dry bean field trials support a PHI of 28 days rather than the 14-day PHI on the proposed label. HED recommends against the establishment of permanent tolerance on subgroup crop 6C until additional field trial data are submitted.

For soybeans, after considering all the available soybean field trial data, HED concluded that sufficient residue data are available to support tolerances on soybean forage and hay harvested 30 days following the second of two applications totaling 0.33 lb ai/A (1x rate). Although the petitioner has requested tolerances for soybean forage and hay, the Agency notes that the currently proposed use directions for soybean prohibit the feeding or grazing for forage or hay.

HED also considers sufficient residue data are available to support tolerances on soybean seed, even though the PHIs of the soybean seed data varies from 30 to 90 days, since soybean mature at different times depending on the growth regions, PHI can vary from region to region, therefore, provided the label has such language as "do not apply later than the R5 growth stage' or 'apply up to Stage R6", no additional field trials are required for soybean seeds.

For sugar beets, adequate field trial data are available to support the use of the 45% WP formulation at the proposed rate. However, based on the results of the side-by-side tests with the WP and EC formulations, residues in/on tops at the proposed 21-day PHI are likely to be higher for the EC formulation than the WP formulation. Therefore, a complete set of field trial data is required for sugar beet tops reflecting the use of the EC formulation.

The available wheat field trial data for grain and straw are adequate and will support the proposed late-season use pattern on wheat, barley, rye and oats; however, the available residue data on forage and hay will only support a maximum use rate of 0.11 lb ai/A prior to the harvest of forage or hay. The use directions must be amended to specify a maximum total application rate of 0.11 lb ai/A on wheat, barley, oats or rye harvested for forage or hay. If the petitioner intends to support the use of two applications totaling 0.22 lb ai/A prior to harvest of forage and hay, then an additional 8 field trials are required on forage and a complete set of 20 field trials are required for hay.

860.1520 Processed Food and Feed

43640401.der5 (rotated alfalfa)	**45080810.der (field corn)**
44548402.der2 (wheat)	**45050811.der2 (rice)**
44757207.der2 (sugar beet)	**45275801.der2 (sorghum)**
44757208.der2 (wheat)	**46576302.der (soybean)**

Alfalfa (rotational crop). In a field trial conducted during 1989 in NE, propiconazole (3.6 lb/gal EC) was applied to a primary crop of wheat as a single broadcast foliar application at flag leaf emergence (Feekes Growth Stage 8) at 0.11, 0.33, or 0.55 lb ai/A (0.5x, 1.5x and 2.5x rates). The wheat was grown to maturity and harvested, and a rotational crop alfalfa was planted 77 DAT. Alfalfa hay was harvested the following spring (380 DAT) and processed into meal and pellets using simulated commercial practices. Prior to analysis, hay, meal and pellets were stored frozen up to 27 months, an interval supported by the available storage stability data.

Total residues of propiconazole and its 2,4-DCBA containing metabolites were determined using GC/ECD Method AG-454 B, which was adequately validated in conjunction with the analysis of field trial samples. The validated method LOQ is 0.05 ppm, and an LOD was not reported.

Following an application of propiconazole (EC) to a primary wheat crop at 0.11 or 0.33 lb ai/A (0.5x or 1.5x), residues were <0.05 ppm in hay, meal and pellets from alfalfa planted at a 77-day PBI. For the application at 0.55 lb ai/A (2.5x), residues were <0.05 ppm in alfalfa hay and meal and 0.06 ppm in pellets, indicating the potential for possible concentration of residue at 1.2x in pellets. However, given the low levels of concentration, a separate tolerance is not required for alfalfa meal.

Corn. In two field trials conducted during 1998, propiconazole (1.04 lb/gal EC) was applied to two plots of field corn at each site as four broadcast foliar applications during grain development at 0.11 or 0.55 lb ai/A/application at RTIs of 5-9 days, for totals of 0.44 or 2.20 lb ai/A/season (1x and 5x rates). All applications were made using ground equipment in volumes of 21-25 gal/A, and no adjuvants were included in the spray mixtures. Single control and treated bulk samples of corn grain were harvested from each test at normal crop maturity, 29 or 30 DAT. The grain was cleaned to generate AGF and then processed using simulated wet- and dry-milling procedures into meal, grits, flour, starch and refined oil. Prior to analysis, the grain and processed fractions were stored frozen for up to 10 months, an interval supported by the available stability data.

Total residues of propiconazole and its 2,4-DCBA containing metabolites were determined using GC/ECD Method AG-454 B, which was adequately validated in conjunction with the analysis of field trial samples. The validated method LOQ is 0.05 ppm, and an LOD was not reported.

Total combined propiconazole residues in/on bulk samples of corn grain harvested at 29 or 30 DAT were <0.05 ppm from the 1x rate tests and 0.062 and 0.081 ppm for the 5x rate tests. Except for AGF, residues in processed fractions were <0.05 ppm in samples from the 1x rate tests. Residues in AGF from the 1x rate tests were 0.159-0.208 ppm from the IL test and 0.173 ppm from the IA test, indicating the potential for concentration of residues in corn grain AGF. However, due to residues being <LOQ in the RAC at 1x, reliable processing factors for AGF from the 1x rate tests could not be calculated.

For the 5x rate tests, residues were also <0.05 ppm in meal, grits, flour and starch and were <0.05-0.097 ppm in refined oil. Processing factors for corn meal, grits, flour and starch were <0.6x-<0.8x and averaged <0.7x, and the processing factors for refined oil were <0.6x-1.6x and averaged 1x. Residues in/on AGF from the 5x tests were 0.250-0.266 ppm in the IL test and 1.04 ppm in the IA test. As the control sample of AGF from the IL test had apparent residues (0.233-0.264 ppm) of similar magnitude to the treated samples, a processing factor was not calculated for AGF from the test in IL. The processing factor for AGF from the 5x test in IA was 12.8x. The maximum theoretical processing factor for corn grain is 25x for corn oil. As the processing factors for meal, flour, grits, starch and refined oil were ≤1x, separate tolerances are not required for these processed commodities. However, a tolerance will be required for AGF. Based on HAFT residues of 0.1 ppm for corn grain and the 12.8x processing factor, the maximum expected in corn grain AGF would be 1.28 ppm.

Mint. Adequate data are available from two mint processing studies (DP Barcode D209468, W. Wassell, 4/25/95). In two field trials, propiconazole (EC) was applied to mint at rates up to 0.34 lb ai/A (1.5x labeled rate). Samples of fresh mint hay were cut 90 DAT, air dried, and distilled to yield mint oil. Samples of mint hay and oil were stored for up to 224 days prior to analysis using an adequate GC/ECD method (AG-454B). Total propiconazole residues were 0.12 ppm in fresh hay from both field trials and were <0.05 and 0.08 ppm in oil from the two sites, for an average processing factor of 0.5x for mint oil. Therefore, a separate tolerance for mint oil is not required.

Rice. In a two field trials conducted during 1998 in AR and LA, propiconazole (3.6 lb/gal EC) was applied to rice as a single broadcast foliar application at heading at 0.28 or 1.40 lb ai/A (0.8x and 4.1x rates) at each site. Rice was grown and harvested at commercial maturity, 35 DAT. Following harvest, whole grain was processed using simulated commercial procedures into polished rice, hulls and bran. Prior to analysis, rice and processed fractions were stored frozen up to 11.1 months, an interval supported by the available storage stability data.

Combined residues of propiconazole and its 2,4-DCBA containing metabolites in/on rice grain, hulls, bran and polished rice were determined using GC/ECD Method AG-626, which was adequately validated in conjunction with the analysis of treated samples. The validated method LOQ is 0.05 ppm for each commodity, and a LOD was not reported.

Following application of propiconazole to rice at 0.28 or 1.40 lb ai/A (0.8x and 4.1x), combined propiconazole residues in/on rice grain at 35 DAT were 0.82 and 0.86 ppm in the two 0.8x tests and 2.4 and 3.7 ppm in the two 4.1x tests. Combined residues were reduced in polished rice by 0.06x-0.19x, and concentrated in rice hulls by 3.0x-4.1x and in bran by 1.7x-3.9x. For all four tests, the average processing factors were 0.12x for polished rice, 3.8x for hulls, and 2.9x for bran. Based on HAFT residues of 5.05 ppm for rice grain and these average processing factors, the maximum expected residues would be 19.2 ppm in hulls and 14.6 ppm in bran. These data indicate that separate tolerances should be established at 20 and 15 ppm for rice hull and bran, respectively.

Sorghum. In two field trials conducted in KS and TX in 1998, propiconazole (3.6 lb/gal EC) was applied to two plots of sorghum at each site as four broadcast foliar applications during grain development at 0.11 or 0.55 lb ai/A/application, for totals of 0.44 or 2.2 lb ai/A/season (1x and 5x rates). All applications were made using ground equipment in volumes of 12-13 gal/A, and included the use of a surfactant at 0.1-0.25% of the spray volume. Single control and treated bulk samples of grain were harvested from each test at normal crop maturity, 18 or 20 DAT. The grain was cleaned to generate AGF and then processed using simulated commercial procedures into flour. Prior to analysis, the grain and processed fractions were stored frozen for up to 15 months, an interval supported by the available stability data.

Combined residues of propiconazole and its 2,4-DCBA containing metabolites were determined using GC/ECD Method AG-626 (modified), which was adequately validated in conjunction with the analysis of treated samples. The validated method LOQ is 0.05 ppm for each commodity, and a LOD was not reported.

Total propiconazole residues in/on bulk samples of sorghum grain harvested at 18-20 DAT were 0.43 or 1.2 ppm following applications at the 1x rate and 2.2 and 6.9 ppm following applications at the 5x rate. For the 1x rate, residues in AGF were 3.39 and 6.5 ppm and residues in flour were 0.06 and 0.48 ppm. For the 5x rates, residues in AGF were 9.2 and 21.3 ppm and residues in flour were 0.22 and 2.6 ppm. The processing factors for AGF were 3.1x-7.9x and averaged 5.2x, and the processing factors for flour were 0.1x-0.4x and averaged 0.3x. Based on the average processing factors and HAFT residues of 2.1 ppm for sorghum grain, the maximum expected residues would be 0.6 ppm in sorghum flour and 10.9 ppm in sorghum AGF.

Soybean. A processing study for soybeans was reviewed in conjunction with the original petition on legume vegetables (PP#8F3674, C. Deyrup,12/14/88, and DP Barcode D210266 and D210295, M. Rodriquez, 3/5/97). Samples of mature soybeans bearing combined residues of 0.40 or 0.61 ppm were processed in hulls, meal, oil and soapstock using simulated commercial practices. Combined residues were 0.026 and 0.31 ppm in/on hulls, 0.40 and 0.75 ppm in meal, <0.05 ppm in refined oil and 0.18 and 0.19 ppm in soapstock. Average processing factors were 0.7x for hulls. 1.1x for meal, <0.1x for refined oil, and 0.4x for soapstock.

In addition, the Agency has more recently reviewed a study on soybean AGF (DP Barcode D246884, T. Morton, 3/10/05). In two tests conducted in 1997, mature samples of soybeans were harvested 45 or 56 days following two foliar applications of propiconazole (3.6 lb/gal EC) at 0.17 lb ai/A/application, with a 14 day RTI, for a total of 0.33 lb ai/A (1x rate). Bulks samples of seed from both tests were cleaned to generate AGF samples, and seeds and AGF samples were analyzed for combined propiconazole residues using GC/ECD Method AG-626, which has an LOQ of 0.05 ppm. Combined residues in/on seeds averaged 0.28 and 0.20 ppm from the two tests, and combined residues in/on AGF averaged 0.27 and 1.5 ppm from the two tests, for processing factors of 1x and 7.5x, respectively. The average processing factor for soybean AGF was 4.3x.

In addition to the above soybean processing data, a soybean processing study is also available reflecting foliar applications later in the growing season of a MAI EC formulation containing propiconazole at 1.04 lb ai/gal. In a field trial conducted during 2003 in MS, the propiconazole MAI EC formulation was applied to soybeans as three broadcast foliar applications during pod development (BBCH 75-77) at 0.398-0.420 lb ai/A/application, at RTIs of 8-9 days, for a total of 1.225 lb ai/A (3.6x maximum rate). Single bulk samples of control and treated seeds were harvested at commercial maturity, 19 DAT. Following harvest, samples of AGF were generated, and seeds were then processed using simulated commercial procedures into hulls, meal, and refined oil. Samples of seed were stored frozen for up to 3 months prior to analysis, and samples of AGF and processed commodities were stored frozen for ≤1 month; these intervals are supported by the available storage stability data.

Combined residues of propiconazole and its 2,4-DCBA containing metabolites were determined using a GC/MSD method, which is a modification to Method AG-626 that uses a MSD instead of ECD for detection of residues. The method is adequately validated in conjunction with the analysis of treated samples. The validated LOQ was 0.5 ppm for all matrices, and the calculated LODs were 0.07 ppm for seeds, 0.4 ppm for hulls, 0.15 ppm for meal and 0.14 ppm for refined oil. An LOD for AGF was not reported.

Following three applications of propiconazole (EC) to soybeans during pod development at rates totaling 1.23 lb ai/A (3.6x rate), combined residues were 1.23-1.32 ppm in/on seeds (RAC) harvested at 19 DAT and were <0.5 ppm in/on hulls, meal and refined oil and 39.4-40.1 ppm in/on AGF. Based on the average combined residues in seeds (RAC) and each processed fraction, the calculated processing factors are 0.2x for hulls, meal, and for refined oil, and 32x for AGF.

Both soybean processing studies indicate that combined propiconazole residues are unlikely to concentrate in hulls, meal and refined oil; therefore, separate tolerances are not required for these commodities. However, both studies also indicate that residues are likely to concentrate in soybean AGF. The difference between the two processing factors for AGF, 4.3x and 32x, was considerable, and most likely reflects the different application timings and harvest intervals for beans in the two studies. In the study with the lower processing factor (4.3x), beans were harvested at 45-56 DAT, and in the study with the higher concentration factor (32x), beans were harvested at 19 DAT. As the petitioner is now proposing a shorter PHI for the harvest of soybeans (30 days), the processing factor from the later study will be more appropriate for estimating soybean AGF residues. Based on HAFT residues of 0.90 ppm for soybean seed and the 32x processing factor, the maximum expected residues would be 30 ppm in soybean AGF.

Sugar beet. In a field trial conducted in MN in 1997, propiconazole (45%WP) was applied to sugar beets as three broadcast foliar applications during root enlargement at either 0.11, 0.33 or 0.55 lb ai/A/application, at a RTI of 10 days, for totals of 0.33, 0.99 and 1.65 lb ai/A/season (1x, 3x and 5x rates). Sugar beets were grown and harvested at commercial maturity, 23 DAT. Following harvest, sugar beet roots from each rate were processed into refined sugar, dried pulp and molasses using simulated commercial procedures. Prior to analysis, samples were stored up to 9.9 months, an interval supported by available storage stability data.

Combined residues of propiconazole and its 2,4-DCBA containing metabolites were determined using GC/ECD Method AG-454B, which was adequately validated in conjunction with the analysis of treated samples. The validated method LOQ is 0.05 ppm for each commodity, and the LOD was 0.02 ppm.

Total residues were 0.03, 0.045 and 0.11 ppm in/on roots treated at the 1x, 3x and 5x rates, respectively. Residues in roots were above the LOQ only in the 5x treatment. For processed fractions from 1x, 3x, and 5x treatments, residues were respectively 0.11, 0.26 and 0.54 ppm in molasses and 0.18, 0.76, and 0.81 ppm in dried pulp. Residues in refined sugar were non-detectable (<0.02 ppm) in all samples. Processing factors from all three tests were <0.2-<0.7x for refined sugar, 6.0-16.9x for molasses, and 3.7-7.4x for dried pulp. With the exception on one for the processing factors for molasses (16.9x from 3x rate test), the processing factors were below the maximum theoretical concentration factor for sugar beets, which is 12.5x. Because residues were above the LOQ in roots from only 5x treatment, the processing factors for refined sugar (<0.2x), molasses (7.4x) and dried pulp (4.9x) from the 5x treatment should be used for determining residues in sugar beet processed fractions. Based on HAFT residues of 0.18 ppm for sugar beet roots and the above processing factors, the maximum expected residues would be <0.05 ppm in refined sugar, 1.33 ppm in molasses, and 0.88 ppm in dried pulp. These data indicate that separate tolerances should be established at 1.5 and 1.0 ppm for sugar beet molasses and dried pulp, respectively.

Wheat. Numerous wheat processing studies are available reflecting one or more applications of propiconazole (EC) to wheat at various growth stages. The Agency previously reviewed (DP Barcode D240856, T. Morton, 2/23/05) a series of wheat processing studies conducted in 1996 and in 1992-93. In the four tests conducted in 1996, propiconazole (EC) was applied to wheat as a single broadcast foliar application at Feekes Growth Stage 8 (flag leaf emergence) at 0.55 lb ai/A (2.5x rate). Mature grain was harvested at 47-68 DAT, and processed into AGF, germ, bran, middlings, shorts, and flour. Total combined residues were determined in all fractions using GC/ECD Method AG-454B, which has a LOQ of 0.05 ppm and a LOD of 0.02 ppm. Residues in/on grain from the four tests were all <LOQ, but were detectable at 0.02-0.04 ppm. Processing factors were all ≤1x for germ, middlings and flour samples, and were <1x-1.3x for shorts, 1.5x-3.0x for bran and 2.0x-24x for AGF. Average processing factors were 1.1x for shorts, 2.3x for bran, and 9.6x for AGF.

In the other four tests conducted in 1992-93, propiconazole (EC) was applied to wheat as either a single broadcast foliar application at Feekes Growth Stage 8 at 0.55 lb ai/A (2.5x rate, 2 tests) or as two foliar applications at 0.55 lb ai/A at both Feekes Growth Stages 5 and 8, for a total of 1.1 lb ai/A (5x rate, 2 tests). Mature grain was harvested at 54-85 DAT, and processed into AGF, germ, bran, middlings, shorts, and flour. Total combined residues were determined in all fractions using GC/ECD Method AG-454B, which has a LOQ of 0.05 ppm. The method LOD was not reported. Residues in/on grain were <LOQ in the two tests which received only a single application (2.5x rate) and were 0.08 and 0.43 ppm in the two tests receiving two applications (5x rate). For the two 5x test, with had quantifiable residues in grain, processing factors were all <1x for germ, shorts, middlings and flour, and were 0.9x and 1.4x for bran and 10x and 12x for AGF. Average processing factors for bran and AGF were 1.2x and 11x, respectively.

In addition to the above studies, Syngenta has submitted several more wheat processing studies reflecting the use of propiconazole at later growth stages, which is the use that the registrant is currently proposing. In two trials conducted in 1996 (44548402.der2), propiconazole (EC) was applied to wheat in four plots at each site as a single broadcast foliar application at booting (Feekes Growth Stage 10) or at heading (Feekes Growth Stage 10.5) at 0.11-0.12 lb ai/A or 0.55-0.62 lb ai/A (0.5x and 2.5x rates). All applications were made using ground equipment in volumes of 15-21 gal/A, and did not include the use of any adjuvants. Single control and treated bulk samples of grain were harvested from each test at normal crop maturity, 63-67 days following the application at booting or 55-57 days following the application at heading. The grain was cleaned to generate AGF and then processed using simulated commercial procedures into wheat germ, bran, middlings, shorts and flour (low grade and patent). Prior to analysis, the grain and processed fractions were stored frozen for up to 4.9 months, an interval supported by the available stability data. Combined residues were determined using GC/ECD Method AG-454B, which was adequately validated in conjunction with the analysis of treated samples. The validated method LOQ is 0.05 ppm for each commodity, and the LOD was 0.02 ppm.

For the tests conducted at the 0.5x rate, total propiconazole residues were <LOQ in/on all samples of grain and all processed fractions, with the exception of AGF. AGF samples from the 0.5x applications were <LOQ in one test and 0.08-0.14 ppm in the remaining three 1x tests, indicating the potential for concentration of residues in AGF. However, reliable processing factors could not be calculated since residues in the RAC were <LOQ.

Residues were also <LOQ in/on grain samples from two of the tests conducted at 2.5x rates; however, in the remaining two 2.5x tests, residues in/on grain were 0.16 ppm at 67 DAT and 0.24 ppm at 57 DAT. In these tests, residues were 1.3-1.4 ppm in AGF, ≤0.06 ppm in germ, 0.05-0.17 ppm in bran, and <LOQ in middlings, shorts and flour. Calculated processing factors for these tests were 5.8-8.1x for AGF, ≤0.3x for germ, 0.3-0.7x for bran, ≤0.2x for middlings,

shorts and flour. Average processing factors were 7.0x for AGF, 0.2x for germ, 0.5x for bran and <0.1x for middlings, shorts and flour.

In the final series of wheat processing studies conducted in 1997 (44757208.der2), propiconazole was applied at the highest use rates and at the latest possible timing. In two trials, propiconazole (EC) was applied to wheat in four separate plots as either a single broadcast foliar application at Feekes Growth Stage 10.5 at 0.11-12 lb ai/A (0.5x rate), or as two broadcast foliar applications around Feekes Growth Stages 10 (booting) and 10.5 (heading) at either 0.11-0.12, 0.33-0.37, or 0.55-0.62 lb ai/A/application, for totals of ~0.22, ~0.66, and ~1.1 lb ai/A/season (1x, 3x and 5x rates). All applications were made using ground equipment in volumes of 19-20 gal/A, and no adjuvants were included in the spray mixture. The RTI was 12 or 16 days for plots receiving two applications. Single control and treated bulks samples of grain were harvested from each test at 36 or 47 DAT. Samples were cleaned to generate AGF and then processed using simulated commercial procedures into wheat germ, bran, middlings, shorts and flour (low grade and patent). Samples were stored up to 9.3 months prior to analysis, an interval supported by available storage stability data.

Combined residues were determined using GC/ECD Method AG-454B, which was adequately validated in conjunction with the analysis of treated samples. The validated method LOQ is 0.05 ppm for each commodity, and the LOD was 0.02 ppm. In addition, samples from these processing studies were also analyzed for residues of propiconazole, *per se*, using a GC/NPD method from PAM Vol. I (Method 302 E4 + DG5). This method was also adequately validated in conjunction with the analysis of treated samples, and the validated method LOQ was 0.05 ppm for all wheat commodities; a LOD was not reported.

Following a single broadcast application to wheat at a 0.5x rate at FGS 10.5, total combined residues were <LOQ in/on mature samples of grain harvested at either 36 or 47 DAT. Following two broadcast applications at approximately Feekes Growth Stages (FGS) 10 and 10.5, combined residues in/on grain were <0.05 and 0.062 ppm from the 1x rate tests, 0.101 and 0.129 ppm from the 3x rate tests, and 0.107 and 0.183 ppm from the 5x rate tests. Within each test, levels of combined residues were typically highest in AGF and then bran, and residues were lowest in flour. Processing factors were calculated only for those tests in which residues were ≥LOQ in/on whole grain. For these tests, average processing factors for total combined residues were 0.9x for germ, 3.2x for bran, 0.7x for middlings, 0.9x for shorts, and <0.3x for flour. The maximum theoretical processing factor for wheat is 8.3x. Processing factors for combined residues in AGF varied considerably between the two test sites, averaging 2.7x at the OK site and 34x at the KS site, for an overall processing factor of 18x.

Regardless of the application timing to wheat, all of the above wheat processing studies indicate that there is the potential for substantial concentration of combined propiconazole residues in wheat AGF and to a lesser extent in bran. Total combined residues were either reduced or concentrated only slightly in germ, shorts, middlings, and flour; therefore, separate tolerances are not required for these wheat commodities. As the final series of processing studies (44757208.der2) reflected the latest proposed application timing and had the highest levels of residues in the RAC, the average processing factors from these tests will be used to estimate maximum potential residues in AGF (18x) and bran (3.2x). Using these processing factors and the HAFT residues in wheat grain (0.18 ppm) reflecting applications at up to Feekes Growth Stage 10.5, the maximum expected combined residues would be 3.2 ppm in wheat AGF and 0.58 ppm in wheat bran.

Conclusions Adequate processing studies, reflecting the measurement of total combined residues, are available for alfalfa (rotational crop), field corn, mint, rice, sorghum, soybean, sugar beet, and wheat. Adequate processing data are also available from one of the wheat processing studies reflecting the measurement of only parent residues.

These studies indicate that, with the exception of AGF, combined propiconazole residues did not concentrate in processed commodities derived from alfalfa, field corn, mint, sorghum, and soybeans, or in polished rice, sugar beet refined sugar, or wheat germ, shorts, middlings and flour. However, combined residues were shown to concentrate in rice hulls (3.8x) and bran (2.9x), sugar beet molasses (7.4x) and dried pulp (4.9x), and wheat bran (3.2x). Therefore separate tolerances are required for these commodities. Considering the HAFT residues in the various RACs and the above processing factors, appropriate tolerances for combined propiconazole residues would be 20 and 15 ppm for rice hulls and bran, 1.5 and 1.0 ppm for sugar beet molasses and dried pulp, and 0.6 ppm for wheat bran.

With regards to AGF, combined residues were shown to concentrate by various degrees in AGF derived from field corn (12.8x), sorghum (5.2x), soybeans (32x), and wheat (13x) following late season applications. Considering these AGF processing factors and the HAFT residues in the respective RACs, the maximum excepted residues in AGF are 1.28 ppm for corn, 10.9 ppm for sorghum, 30 ppm for soybean, and 4.14 ppm for wheat. Therefore, the tolerance for combined propiconazole residues in AGF should be set at 30 ppm based on the soybean data.

860.1650 Submittal of Analytical Reference Standards

An analytical reference standard for propiconazole is available at the EPA National Pesticide Standards Repository.

860.1850/860.1900 Confined and Field Accumulation in Rotational Crops

Propiconazole RED, DP Barcode D329394, Y. Donovan, 6/15/06
43640401.der3 (alfalfa)

The nature of the residue in confined rotational crops is understood. Based on acceptable studies reviewed by EFED, the metabolism of propiconazole in rotational crops is similar to that in primary crops. Plant-back restrictions have been established for propiconazole products registered for use on rotational crops based on the confined rotational crop studies. Labels specify that any food/feed crops not listed on the label should not be planted within 105 days of treatment.

Syngenta has previously proposed tolerances (PP#5F4498) for inadvertent residues on sorghum and alfalfa planted in rotation with propiconazole-treated wheat. However, this petition has been superseded by PP#2F6371, in which Syngenta is now proposing the direct use of propiconazole on sorghum. Once tolerances for the direct use on sorghum are established, rotational crop tolerances on sorghum commodities will no longer be necessary. With regards to alfalfa, Syngenta is still supporting a proposed 0.1 ppm tolerance for alfalfa, based on its rotation with propiconazole-treated wheat, and has submitted field trial data depicting combined residues in/on forage and hay from alfalfa rotated with propiconazole-treated wheat. These data are summarized in Table 8 and discussed below.

Table 8. Summary of Residue Data in Alfalfa Forage and Hay Rotated at a PBI of ~75 days with Propiconazole-Treated Wheat.

Commodity	Total Applic. Rate (lb ai/A)	PBI (days)	DAP [1]	Combined Propiconazole Residues (ppm) [2]						
				n	Min.	Max.	HAFT [3]	Median (STMdR) [4]	Mean (STMR) [4]	Std. Dev.
Fall Forage	0.11 (0.5x) [5]	72-109	60-63	8	<0.05	0.07	0.07	0.05	0.04	0.02
Spring Forage			269-333	10	<0.05	0.07	0.05	0.03	0.04	0.02
Spring Hay				10	<0.05	0.08	0.06	0.04	0.04	0.02
Fall Forage	0.22 (1x)	72-77	60-63	2	<0.05	0.07	0.07	0.05	0.05	0.03
Spring Forage			303-333	2	<0.05	<0.05	0.03	0.03	0.03	0.00
Spring Hay				3	<0.05	0.07	0.07	0.06	0.05	0.02
Fall Forage	0.33 (1.5x)	72-77	60-63	2	<0.05	0.06	0.06	0.04	0.04	0.02
Spring Forage			303-333	2	<0.05	0.07	0.07	0.05	0.05	0.03
Spring Hay				3	<0.05	0.09	0.08	0.06	0.06	0.03
Fall Forage	0.55 (2.5x)	72-77	60-63	2	0.10	0.14	0.14	0.12	0.12	0.03
Spring Forage			303-333	2	<0.05	0.06	0.06	0.04	0.04	0.02
Spring Hay				3	<0.05	0.09	0.09	0.08	0.07	0.04

1 DAP = days after planting. Forage was collected the fall following planting (60-63 DAP) and forage and hay were collected the following spring (269-333 DAP).
2 The LOQ for propiconazole residues in/on alfalfa is 0.05 ppm. The LOD was not reported.
3 HAFT = Highest Average Field Trial.
4 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue. For calculation of the median, mean and standard deviation, 2 the LOQ was used for residues reported at <LOQ.
5 The maximum seasonal application rate is 0.22 lb ai/A for wheat and other small cereal grains (oats, barley, rye).

Alfalfa Five rotational crop field trials were conducted on alfalfa in 1989 in Regions 1, 5 and 11. At each site, propiconazole (3.6 lb/gal EC) was applied at 0.11 lb ai/A to winter wheat in the spring as a single broadcast foliar application at Feekes Growth Stages 7-9. Two of the test sites also had additional plots with application rates at 0.22, 0.33 and 0.55 lb ai/A. These application rates correspond to 0.5x, 1x, 1.5x, and 2.5x the maximum proposed application rate for wheat. All applications were made using ground equipment at volumes of 15-23 gal/A. The wheat was grown to maturity and harvested, and a rotational crop of alfalfa was replanted the same year at PBIs of 72-109 days and was grown using standard agricultural practices. A single control and single or duplicate treated samples of forage were cut in the fall at 60-63 days after planting (DAP), and alfalfa forage and hay samples also collected the following spring at 269-333 DAP. Samples were stored frozen for up to 35 months, an interval supported by available storage stability data.

Residues of propiconazole and its 2,4-DCBA containing metabolites in/on alfalfa forage and forage were determined using GC/ECD Method AG-454 B, which was adequately validated in conjunction with the analysis of field trial samples. The validated method LOQ is 0.05 ppm, and an LOD was not reported.

Following a single application of propiconazole (EC) at 0.11 lb ai/A (0.5x rate) to a primary crop of winter wheat in 5 tests, total propiconazole residues in rotational alfalfa forage and hay from PBIs of 72-109 days were <0.05-0.07 ppm in forage (fall and spring) and <0.05-0.08 ppm in hay. Average residues were 0.04 ppm in both alfalfa forage and hay at the 0.5x rate. At the 1x rate, residues were <0.05-0.07 ppm in forage and hay. At the 1.5x rate, residues were <0.05-0.07 ppm in forage and <0.05-0.09 ppm in hay. At the 2.5x rate, residues were 0.10-0.14 ppm in the initial fall forage and <0.05-0.06 ppm in spring forage and <0.05-0.09 ppm in spring hay.

Conclusions The field rotational crop trials on alfalfa are adequate and will support a 75-day PBI for alfalfa following primary crops treated with propiconazole at rates totaling up to 0.22 lb ai/A/season.

860.1550 Proposed Tolerances

Permanent tolerances are currently established for the combined residues of propiconazole and its 2,4-DCBA containing metabolites at levels ranging from 0.1-40 ppm in/on plant commodities [40 CFR §180.434(a)]. Permanent tolerances are also established for the combined residues of propiconazole and its 2,4-DCBA containing metabolites at 0.1 ppm in fat, meat, and meat byproducts (except liver and kidney) of livestock, 2.0 ppm in liver and kidney of livestock, and at 0.05 ppm in milk; however, no tolerances have been established for eggs and poultry commodities. Time-limited tolerances are established for combined propiconazole residues in/on a variety of plant commodities at levels from 0.2 ppm in/on sorghum grain to 25 ppm in/on soybean hay [40 CFR §180.434(b)]. In addition, tolerances with regional restrictions have been established for combined propiconazole residues at 0.3 ppm in/on mint tops and 0.5 ppm in/on wild rice [40 CFR §180.434(c)]. However, HED has determined that the current tolerance expression for plant and animal commodities is <u>not</u> appropriate and has recommended that the tolerance expression be revised to include only parent.

The tolerances proposed by Syngenta and IR-4 for the current petitions and established tolerances are listed in Table 9, along with the Agency's new recommended tolerance levels. Although HED has recommended changing the tolerance expression to include only parent, the majority of residue data submitted in support of the current petitions were generated using common moiety methods, which do not differentiate between parent and its DCBA containing metabolites. Therefore, the recommended tolerances based on these data will overestimate actual propiconazole residues. The recommended tolerance levels for RACs in the current petitions were determined using recent Agency Guidance (*Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP), with the exception of commodities having substantial (≥15%) numbers of residue values below the method LOQ. For those commodities with large numbers of values <LOQ (corn grain, dry bulb onions, sugar beet roots, tree nuts, and wheat grain), the recommended tolerance was based on the observed maximum residue value. For those commodities for which the tolerance spreadsheet was used to calculate the appropriate tolerance level, the residue data used for the tolerance calculations and the supporting spreadsheet outputs are presented in Appendix II. HED also recommends using the recommended tolerance levels for conducting dietary risk assessment. Although in some cases where uncorrected raw data were used in deriving these tolerances (with average recoveries around 70%), but since this is a tier I DEEM assessment, it will not under estimate the risk.

For purposes of determining tolerances, adequate field trial data are available for alfalfa (rotational crop), almonds, celery, bush and cane berries, carrots, corn (field, pop, and sweet), cranberries, mint, onions, pecans, rice, sorghum, soybean (hay and forage only), strawberries, sugar beet roots, and wheat. The available almond and pecan data will support a crop group tolerance on tree nuts, and separate tolerances pistachios and almond hulls. The celery data will support a subgroup tolerance on leafy petiole vegetables, and the bush and cane berry data will support a crop group tolerance on the berries crop group. In addition, the recommended separate tolerances on green and dry bulb onions will cover the other members of the bulb vegetable crop group.

Based on the different use patterns and resulting residues in/on the various cereal grains, a crop group tolerance is not appropriate for cereal grain and separate tolerances should be established for each member of the crop group with labeled uses. Adequate field trial data are available for corn, rice, sorghum, and wheat. However, tolerances for corn must be separated out for the specific types of corn. The recent field corn data will support the recommended tolerances for field and pop corn commodities and sweet corn stover, and the previously reviewed sweet corn data (PP#8F3674, C. Deyrup, 12/14/88) will support the current tolerance of 0.1 ppm for sweet corn (kernels plus cobs with husks removed) along with a lower tolerance (6 ppm) for sweet corn forage. The most recent wheat field trial data will be used to set wheat tolerances and will also be translated to set new tolerances on barley and rye commodities. As the proposed changes to the label directions will also cover oats, the wheat residue data will also be translated to oats to reassess the existing tolerances on oats.

Although adequate residue data are available to support tolerances on sugar beet roots, additional residue data are required before permanent tolerances can be established for sugar beet tops if the petitioner wants to use EC formulation. HED recommends a conditional tolerance be established on sugar beet tops.

There are no sufficient residue data to establish a permanent tolerance on the dry pea and bean subgroup. HED recommends against the establishment of permanent tolerance on dry peas and beans (subgroup 6C) until additional field trials data are submitted.

Adequate processing studies are available for alfalfa, corn, mint, rice, sorghum, soybeans, sugar beets and wheat. The only processed commodities which shown to have substantial concentrations of combined residues were rice bran (2.9x) and hulls (3.8x), sugar beet molasses (7.4x) and dried pulp (3.9x), and wheat bran (3.2x). Tolerances for these commodities were estimated based on maximum expected residues calculated using HAFT residues and the above processing factors. The tolerances for wheat bran will be translated to barley and rye bran.

The available corn, sorghum, soybean and wheat processing studies all indicated that there is the potential for concentration of combined residues in AGF from all four crops. Following the proposed late season applications, processing factors for AGF were 12.8x for field corn, 5.2x for sorghum, 32x for soybeans, and 13x for wheat (13x). Considering these AGF processing factors and the HAFT residues in the respective RACs, the maximum excepted residues in AGF are 1.28 ppm for corn, 10.9 ppm for sorghum, 30 ppm for soybean, and 4.14 ppm for wheat. Therefore, the tolerance for combined propiconazole residues in AGF should be set at 30 ppm based on the soybean data.

To assess livestock tolerances, total combined residues were estimated for a 1x feeding level using the data on combined residues from the available cattle and poultry feeding studies; For beef cattle, estimated combined residues at a 1x feeding level are 1.7 ppm for kidney, 1.6 ppm for liver, 0.03 ppm for muscle, 0.05 ppm for fat, and 0.03 pm for milk. For swine, estimated combined residues at a 1x feeding level are 0.14ppm for kidney, 0.13 ppm for liver and <0.005 ppm for muscle and fat. HED recommends that the following tolerance levels be established: For cattle, goat, horses and sheep, kidney and liver at 2.0 ppm; meat and meat byproduct (except kidney and liver) and fat at 0.05 ppm, milk at 0.05 ppm. For hog, kidney and liver at 0.20 ppm, no tolerances are needed for meat, fat, and meat byproduct.

For poultry tissues and eggs, estimated combined residues and parent residues were calculated in the same manner as for cattle and swine. The maximum combined residues in tissues and eggs from the 7.5-ppm dose group in the poultry feeding study were used to estimate residues at the 1x feeding level. The estimated combined residues at the 1x feeding level are all < LOQ. Therefore, tolerances for poultry tissues and eggs are not required as quantifiable levels of propiconazole are unlikely to occur in these commodities [40 CFR 180.6(a) (3)].

The Agency notes that these recommended tolerance revisions are relatively conservative, as they are based on combined residues instead of propiconazole, per se.

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for propiconazole in/on various raw agricultural commodities. The Codex MRLs are expressed in terms of propiconazole *per se*, which is the same as the US tolerance expression, recommended by the RED for existing tolerances and for the new uses in the present action. In addition, both Canada and Mexico have established MRLs/tolerances on several commodities which also have U.S. tolerances. To the extent possible, U.S. tolerances have been harmonized with Codex, Canadian, and Mexican MRLs; however, differences in use patterns and the supporting residue data have precluded reducing many tolerances. A comparison of Codex MRLs. Canadian MRLs, and Mexican tolerances and the corresponding U.S. tolerances is presented in Appendix I.

Table 9. Tolerance Summary for Propiconazole			
Crop Commodity	Proposed or (Established) Tolerance (ppm) [6]	**HED Recommended Tolerance (ppm)**	Comments (*Correct Commodity Definition*)
		Tolerances under §180.434(a)	
AGF	17	**30**	Based on the maximum expected residues in AGF from corn (1.28 ppm), sorghum (10.9 ppm), soybeans (44.8 ppm), and wheat (4.14 ppm), the tolerance for AGF should be based on the available soybean data. *Grain, aspirated fractions*
Alfalfa	0.1	**None**	As the tolerance is for rotated alfalfa, it should be established under §180.434(d) for inadvertent residues
Almond, hulls	8.0	**7.0** [1]	Adequate data are available. *Almond, hulls*
Banana	(0.2)	**0.2**	The existing tolerance is adequate
Barley, grain	0.5	**0.3**	Tolerances for barley commodities are based on residue data translated from wheat.
Barley, hay	2.0	**1.4**	
Barley, straw	13	**10**	
Barley, bran	2.5	**0.6**	
Cattle, fat	(0.1)	**0.05**	The recalculated MTDB for beef cattle (28 ppm). Estimated combined residues are: 1.7 ppm in kidney, 1.6 ppm in liver, 0.03 ppm in muscle, 0.05 ppm in fat.
Cattle, kidney	(2.0)	**2.0**	
Cattle, liver	(2.0)	**2.0**	
Cattle, meat	(0.1)	**0.05**	
Cattle, meat byproducts, except liver and kidney	(0.1)	**0.05**	
Celery	(5.0)	**Delete**	Once the tolerance of the leaf petioles subgroup is established the separate tolerance on celery should be deleted
Crop Subgroup 4-B, leaf petioles	5.0	**5.0** [1]	The available residue data on celery will support the 5 ppm tolerance on *Vegetable, leaf petioles, subgroup 4B*
Crop Subgroup 6-C, Dried shelled peas and bean (except soybean)	0.5	**none** [5]	Insufficient residue data to support a tolerance on the *Pea and bean, dried shelled, except soybean, subgroup 6C*
Crop Group 13- Berries Group	1.0	**1.0** [1]	Adequate residue data are available on blueberries, black berries, and raspberries to support a tolerance for *Berry, group 13*
Carrot	0.2	**0.25** [1]	Adequate residue data are available. *Carrot, root*
Corn, field, forage	4.0	**12**	Adequate residue data are available supporting a 30-day PHI for field corn forage following applications totaling 0.44 lb ai/A. *Corn, field, forage*

Table 9. Tolerance Summary for Propiconazole			
Crop Commodity	Proposed or (Established) Tolerance (ppm) [6]	**HED Recommended Tolerance (ppm)**	Comments (*Correct Commodity Definition*)
Corn, sweet, forage	none	**6.0** [3]	A separate tolerance should be established for sweet corn forage. Based on the available sweet corn field trials, in which maximum residues were 5.0 ppm in/on forage from a test conducted at a 0.9x rate, a 6.0 ppm tolerance should be established for residues in/on *Corn, sweet, forage.*
Corn, field, grain	0.3	**0.2** [2]	Adequate residue data are available supporting the reduced 30-day PHI. *Corn, field, grain*
Corn, pop, grain	none	**0.2** [2]	Adequate residue data are available supporting the reduced 30-day PHI. *Corn, pop, grain*
Corn, sweet, K+CWHR	None	**0.1**	Adequate residue data are available supporting the existing tolerance. *Corn, sweet, K+CWHR*
Corn, stover	25	**30** [1]	Adequate residue data are available supporting the reduced 30-day PHI.
Corn, pop, stover	None	**30** [1]	Based on the field corn stover data.
Corn, sweet, stover	none	**30** [1]	Based on the field corn stover data.
Corn, oil	0.5	**None**	Processing factors for corn oil were 0.6x-1.6x and averaged 1x; therefore, a separate tolerance is not required for corn oil
Fruit, stone, group 12	None	**1.0**	Tolerance was reassessed by the Agency (HED memo of propiconazole RED, 6/28/06, Y. Donovan, D329668).
Goat, fat	(0.1)	**0.05**	See comments under cattle.
Goat, kidney	(2.0)	**2.0**	
Goat, liver	(2.0)	**2.0**	
Goat, meat	(0.1)	**0.05**	
Goat, meat byproducts, except liver and kidney	(0.1)	**0.05**	
Grass, forage	(0.5)	**0.5**	The existing tolerances are adequate. The existing tolerances are adequate. (HED memo of propiconazole RED, 6/28/06, Y. Donovan, D329668).
Grass, hay	(0.5)	**0.5**	
Grass, straw	(40)	**40**	
Hog, fat	(0.1)	**Delete**	The recalculated MTDB for swine (2.3 ppm) and estimated residues in liver (0.13 ppm), kidney (0.14 ppm), muscle (<0.005 ppm) and fat (0.005 ppm) at a 1x feeding
Hog, kidney	(2.0)	**0.2**	
Hog, liver	(2.0)	**0.2**	
Hog, meat	(0.1)	**Delete**	

Table 9. Tolerance Summary for Propiconazole			
Crop Commodity	Proposed or (Established) Tolerance (ppm) [6]	HED Recommended Tolerance (ppm)	Comments (*Correct Commodity Definition*)
Hog, meat byproducts, except liver and kidney	(0.1)	**Delete**	level.
Horse, fat	(0.1)	**0.05**	See comments under cattle.
Horse, kidney	(2.0)	**2.0**	
Horse, liver	(2.0)	**2.0**	
Horse, meat	(0.1)	**0.05**	
Horse, meat byproducts, except liver and kidney	(0.1)	**0.05**	
Mint, spearmint, tops	3.0	**3.5** [1]	Adequate data are available.
Mint, peppermint, tops	3.0	**3.5** [1]	Adequate data are available.
Milk	(0.05)	**0.05**	MTDB for dairy cattle is 18.5 ppm. The estimated combined residue on milk at 1x MTDB based on feeding study is 0.03 ppm.
Mushroom	(0.1)	**0.1**	The existing tolerance is adequate.
Oats, forage	10.0	**1.7**	As the proposed changes to the label directions will also cover oats in addition to wheat, the wheat residue data will also be translated to oats to reassess the existing tolerances.
Oats, grain	0.1	**0.3** [2]	
Oats, hay	30.0	**1.4**	
Oats, straw	1.0	**10**	
Onion, bulb	0.3	**0.2** [2]	Adequate residue data are available. Maximum combined residues were 0.18 ppm in/on dry bulb onions. Onion, dry bulb
Onion, green	8.0	**9.0** [1]	Adequate residue data are available. *Onion, green*
Peanut, nut meat	(0.2)	**0.2**	The existing tolerances are adequate.
Peanut, hay	(20)	**20**	
Pecans	(0.1)	**Delete**	Once the tree nut crop group tolerance is established, the separate tolerance for pecans should be deleted
Pineapple	(0.1)	**0.1**	The existing tolerance is adequate.
Pistachio	0.2	**0.1**	Tolerance is based on residue data from almonds and pecans
Rice, bran	28	**15**	Based on HAFT residues of 5.05 ppm for rice grain and an average processing factor of 2.9x for bran, the maximum expected residues in bran would be 14.6 ppm. *Rice, bran*
Rice, grain	7.0	**7.0** [4]	Adequate field trial data are available. *Rice, grain*
Rice, hulls	28	**20**	Based on HAFT residues of 5.05 ppm for rice grain and an average processing factor of 3.8x for hulls, the maximum expected residues in hulls would be 19.2 ppm. *Rice, hulls*

Table 9. Tolerance Summary for Propiconazole			
Crop Commodity	Proposed or (Established) Tolerance (ppm) [6]	**HED Recommended Tolerance (ppm)**	Comments (*Correct Commodity Definition)*
Rice, straw	18	**18** [1]	Adequate field trial data are available. *Rice, straw*
Rye, grain	0.5	**0.3**	Tolerances for rye commodities are based on residue data translated from wheat.
Rye, forage	3.0	**1.7**	
Rye, straw	13	**10**	
Rye, bran	2.5	**0.6**	
Grain sorghum, forage	10	**12** [1]	Adequate field trial data are available for sorghum. *Sorghum, grain, forage: Sorghum, grain;* and *Sorghum, grain, stover*
Grain sorghum, grain	2.5	**3.5** [1]	
Grain sorghum, (stover)	15	**15** [1]	
Sheep, fat	(0.1)	**0.05**	See comments under cattle.
Sheep, kidney	(2.0)	**2.0**	
Sheep, liver	(2.0)	**2.0**	
Sheep, meat	(0.1)	**0.05**	
Sheep, meat byproducts, except liver and kidney	(0.1)	**0.05**	
Soybean, forage	8.0	**11** [1]	Adequate field trial data are available at the 1x rate to support a 30-day PHI for *Soybean, forage* and *Soybean, hay*
Soybean, hay	32	**30** [1]	
Soybean, seed	2.0	**2.0**	Field trial data are available to support *Soybean seed* following applications up to Stage R6.
Strawberry	1.5	**1.3** [1]	Adequate residue data are available. *Strawberry*
Sugar beet, dried pulp	2.0	**1.0**	Based on HAFT residues of 0.18 ppm for roots and a 4.9x processing factor for dried pulp, maximum expected residues in dried pulp would be 0.88 ppm. *Beet, sugar, dried pulp*
Sugar beet, roots	0.3	**0.3** [2]	Adequate residue data are available and indicate that there is no difference in residue levels in/on roots between the WP and EC formulations. Tolerance in based on maximum residues of 0.23 ppm in/on roots *Beet, sugar, roots*

Table 9. Tolerance Summary for Propiconazole			
Crop Commodity	Proposed or (Established) Tolerance (ppm) [6]	**HED Recommended Tolerance (ppm)**	Comments (*Correct Commodity Definition)*
Sugar beet, tops	10	**10** [5]	Adequate residue data are available for the WP formulation and suggest a tolerance level of 4.5 ppm. However, the limited field trial data for the EC formulation indicate that a higher tolerance is required. A tolerance should be set at 10 ppm, with the registration conditioned upon the submission of additional residue data on tops for the EC formulation. *Beet, sugar, tops.*
Sugar beet, molasses	3.0	**1.5**	Based on HAFT residues of 0.18 ppm for roots and a 7.4x processing factor for molasses, maximum expected residues in molasses would be 1.33 ppm. *Beet, sugar, molasses*
Tree nuts crop group	0.2	**0.1** [2]	Adequate residue data are available on pecans and almonds. Tolerance is based on maximum residues of 0.09 ppm for almonds and <0.1 ppm for pecans. *Nut, tree, group 14*
Wheat, bran	2.5	**0.6**	Based on HAFT combined residues of 0.18 ppm for wheat grain and an average 3.2x processing factor for wheat bran, maximum expected residues in bran would be 0.58 ppm. *Wheat, bran*
Wheat, forage	3.0	**1.7** [1]	Adequate residue data are available to support only a single application prior to the harvest of *Wheat, forage*.
Wheat, grain	0.5	**0.3** [2]	Tolerance is based on maximum values of 0.20 ppm for combined residues. *Wheat, grain*
Wheat, hay	2.0	**1.4** [1]	Adequate residue data are available reflecting only a single application prior to harvest of *Wheat, hay*.
Wheat, straw	13	**10** [1]	Adequate residue data are available. *Wheat, straw*
Tolerances under §180.434(c)			
Cranberry	1.0	**1.0**	Adequate residue data are available. Although the tolerance spreadsheet recommends a 0.9 ppm tolerance, a slightly higher 1.0 ppm tolerance was selected to harmonize with the berries crop group. *Cranberry*
Mint, tops (leaves and stems)	0.3	**Delete**	Adequate data are available for all major mint growing regions. The tolerance under

Table 9. Tolerance Summary for Propiconazole			
Crop Commodity	Proposed or (Established) Tolerance (ppm)[6]	**HED Recommended Tolerance (ppm)**	Comments (*Correct Commodity Definition)*
			180.434(c) should be deleted once the new tolerance on mint is established under 180.434(a)
		Tolerances under §180.434(d)	
Alfalfa	0.1	**0.1** [2]	Adequate residue data are available to support a 75-day PBI for alfalfa. Separate tolerances should be established for inadvertent residues in/on *alfalfa, forage* and *alfalfa, hay*, each at 0.1 ppm

1 Tolerance level was calculated using the tolerance spreadsheet and the relevant Agency guidance (see Appendix II).

2 Recommended tolerance is based on maximum residue levels due to the large portion (>15%) of samples having residues <LOQ.

3 The residue data on sweet corn were reviewed under PP#8F3674 (C. Deyrup, 12/14/88).

4 The tolerance spreadsheet recommended a tolerance of 16 ppm for rice grain assuming that the data are distributed lognormally. However, an examination of the plot suggests that the data are not log normal; therefore, a tolerance of 7 ppm was selected using the California Method ($\mu + 3\sigma$). Combined residues in/on rice grain were <0.05-5.20 ppm and averaged 1.49 ppm.

5 Additional residue data are required. Therefore only a conditional, time-limited tolerance is being recommended.

6 Tolerances in parenthesis are currently established under 40 CFR §180.434.

References

DP Barcode: None
Subject: PP#4F3007. CGA-64250 (Tilt) in Pecans. Evaluation of Residue Data and Analytical Method.
From: A. Smith
To: H. Jacoby
Dated: 5/15/84
MRID(s): 00074495, 00074508, 00074509, and 00153327

RCB#: 4279
DP Barcode: None
Subject: PP#8F3674. Propiconazole in or on Celery, Corn, Pineapple, and Legume Vegetables. Evaluation of the Analytical Methodology and Residue Data.
From: C. Deyrup
To: L. Rossi
Dated: 12/14/88
MRID(s): 40783301-40783310

DEB#: 5164, 5165
DP Barcode: None
Subject: PP#9F3740: Propiconazole (Tilt®) in or on Almonds. Petition Review for Establishment of Tolerance(s).
From: M. Nelson
To: H. Jamerson
Dated: 8/24/89
MRID(s): 41021300, 41021301, 41021302

DEB#: 6724
DP Barcode: None
Subject: PP#0F3869: Propiconazole (Tilt®) in or on Celery. Amendment of 3/1/90.
From: W. Chin
To: S. Lewis
Dated: 8/15/90
MRID(s): 41486801 and 41486802

CB#: 7822
DP Barcode: 1-0964
Subject: PP#1F3974. Propiconazole on Grass Seed Screenings, Straw, and Forage. Evaluation of Residue Data and Analytical Methodology.
From: S. Willett
To: S. Lewis and J. Stone
Dated: 6/11/91
MRID(s): 41823301-41823305

DP Barcode: D219664
Subject: PP#5F04591, Propiconazole on the Berry Crop Grouping, Carrots, and Onions (green and dry bulb).
From: L. Kutney
To: D. McCall
Dated: 6/14/96
MRID(s): 43786401-43786404

DP Barcode: D209468
Subject: PP#2E04047. Propiconazole (Tilt® Fungicide) in or on Mint. Amendment submitted on 10/24/94.
From: Y. Donovan
To: H. Jamerson and J. Smith
Dated: 4/25/95
MRID(s): 43424601

DP Barcodes: D210266 and D210295
Subject: PP5F04424 & ID#000100-00618 CGA-64250 Technical: Propiconazole in/on Dry Beans and Soybeans. Evaluation of Reisdue Data and Analytical Methodology.
From: M. Rodriguez
To: D. McCall and S. Robbins
Dated: 3/5/97
MRID(s): 43386501 and 43386502

DP Barcode: D240856
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)
From: T. Morton
To: P. Dobak/S. Lewis
Dated: 2/23/05
MRID(s): 44411201-44411208

DP Barcode: D246884
Subject: Propiconazole (122101): Petition PP#5F04424: Magnitude of the Residue in/on Soybean Aspirated Grain Fractions (GLN 860.1500).
From: T. Morton
To: P. Dobak/S. Lewis
Dated: 3/10/05
MRID(s): 44549101

DP Barcode:	D329394
Subject:	Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Revised Residue Chemistry Considerations.
From:	Y. Donovan
To:	M. Goodis and C. Scheltema
Dated:	6/15/06
MRID(s):	None

Attachments:
Appendix I - International Residue Limits Status
Appendix II - Tolerance Assessment Calculations

Template Version September 2005

Appendix I – International Residue Limits

<table>
<tr><th colspan="4">INTERNATIONAL RESIDUE LIMIT STATUS</th></tr>
<tr><td>Chemical Name 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole</td><td>Common Name: Propiconazole</td><td>X Proposed tolerances
9 Reevaluated tolerance
9 Other</td><td>Date: 7/14/06</td></tr>
<tr><td colspan="2">Codex Status (Maximum Residue Limits)</td><td colspan="2">U. S. Tolerances</td></tr>
<tr><td colspan="2" rowspan="2">X No Codex proposal step 6 or above
9 No Codex proposal step 6 or above for the crops requested</td><td colspan="2">Petition Number: 2F6371, 6E4788, 7E4860, and 8E4931
DP Barcode: D238458
Other Identifier:</td></tr>
<tr></tr>
<tr><td colspan="2" rowspan="2">Residue definition (step 8/CXL): Propiconazole</td><td colspan="2">Reviewer/Branch: Y. Donovan/ RAB4</td></tr>
<tr><td colspan="2">Residue definition:
Tolerances are currently expressed as the combined residues of propiconazole and its metabolites determined as 2,4-DCBA and expressed as parent. However, HED has recommended that the tolerance expression be changed to include only parent.</td></tr>
<tr><td>Crop (s)[1]</td><td>MRL (mg/kg)</td><td>Crop(s)</td><td>Proposed or Established Tolerance (ppm)</td></tr>
<tr><td>Almonds</td><td>0.05</td><td>Tree nuts</td><td>0.10</td></tr>
<tr><td>Banana</td><td>0.1</td><td>Banana</td><td>0.2</td></tr>
<tr><td>Barley</td><td>0.05</td><td>Barley, grain</td><td>0.3</td></tr>
<tr><td>Coffee beans</td><td>0.1</td><td>Not registered use</td><td></td></tr>
<tr><td rowspan="2">Edible offal (mammalian)</td><td rowspan="2">0.05</td><td>Liver and Kidneys of cattle, goats, horses, hogs, and sheep</td><td>2.0</td></tr>
<tr><td>Meat byproducts, except liver and kidney</td><td>0.1</td></tr>
<tr><td>Eggs</td><td>0.05</td><td>Tolerance not required</td><td></td></tr>
<tr><td>Grapes</td><td>0.5</td><td>No registered uses</td><td></td></tr>
<tr><td>Mango</td><td>0.05</td><td>No registered uses</td><td></td></tr>
<tr><td>Meat (from mammals other than marine mammals)</td><td>0.05</td><td>Meat and fat of cattle, goats, horses, hogs, and sheep</td><td>0.1</td></tr>
<tr><td>Milks</td><td>0.01</td><td>Tolerance not required</td><td></td></tr>
<tr><td>Oats</td><td>0.05</td><td>Oats, grain</td><td>0.3</td></tr>
<tr><td>Peanut</td><td>0.05</td><td rowspan="2">Peanut</td><td rowspan="2">0.2</td></tr>
<tr><td>Peanut, whole</td><td>0.1</td></tr>
<tr><td>Pecan</td><td>0.05</td><td>Tree Nuts</td><td>0.10</td></tr>
</table>

Poultry meat	0.05	Tolerance not required	
Rape seed	0.05	No registered uses	
Rye	0.05	Rye, grain	0.3
Stone fruits	1.0	Fruit, Stone, group 12	1.0
Sugar beet	0.05	Beet, sugar, roots	
Sugar beet leaves or tops	0.5	Beet, sugar, tops	10
Sugar cane	0.05	No registered uses	
Wheat	0.05	Wheat Grain	0.3
Limits for Canada		Limits for Mexico	
9 No Limits 9 No Limits for the crops requested		9 No Limits 9 No Limits for the crops requested	
Residue definition: Propiconazole and its metabolites including the 2,4-DCBA moiety		Residue definition: Propiconazole	
Crop(s)	MRL (mg/kg)	Crop(s)	MRL (ppm)
Liver and kidney of cattle	2	Barley	0.1
Apricots, cherries, peaches/nectarines, plums	1	Beans	0.5
Dried blueberries	0.15	Walnut	0.1
Asparagus	0.1	Banana	0.2
Barley, oats, wheat	0.05	Wheat	0.1
Blueberries	0.02		
blackberries, loganberries and raspberries	0.7 proposed		
Notes/Special Instructions:			

Appendix II - Tolerance Assessment Calculations.

The Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* (draft, May 9, 2005) was utilized for determining appropriate tolerance levels on almond hulls, celery (leaf petiole vegetables), bush and cane berries, cranberries, field corn forage and stover, mint, green onions, rice grain and straw, sorghum forage, stover and grain, soybean seed, hay and forage, strawberries, and wheat forage, hay and straw. Combined propiconazole residue levels in these commodities were readily quantifiable, and with the exception of carrots, less than 15% of the residue values were below the LOQ. As the majority of the residue values for almonds, corn grain, dry bulb onions, pecans, sugar beet roots, and wheat grain were <LOQ, the tolerance spreadsheet was not used to calculate tolerances on these commodities. Tolerances for these commodities were estimated based on the maximum observed residues values: **Almond nutmeat and pecan at 0.1 ppm, corn grain at 0.2 ppm, dry bulb onion at 0.2 ppm, wheat grain at 0.3 ppm.**

The datasets used to establish tolerances consisted of field trial data representing applications of the appropriate formulations at ~1x maximum proposed maximum use rates. As specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP, the field trial application rates were within 25% of the maximum label application rate, and the PHIs were consistent with the appropriate stage of maturity and the proposed PHI for each commodity. The residues values used to calculate the tolerances are provided in Tables II-1 through II-13. Tolerance value for soybean seeds was estimated using samples collected at intervals of 41-99 day and 30-day PHI (Figures II-19 and -20). Although the PHIs for these soybean seeds varies, based on HED's ChemSAC minutes of 06/07/2006, soybean seed mature at different times depending on their growth regions, HED considers the soybean data are adequate as long as the applications were made before R6 growth stage (or not later than R5 growth stage). Soybean seed data from the 0.75x rate were not used since these data are not within the 25% of maximum application rate

The datasets were entered into the tolerance spreadsheet and visual inspection of the lognormal probability plots indicates that the datasets are reasonably lognormal, and with the exceptions of the data sets for carrots, celery, rice straw, wheat straw and mint. For the remaining commodities, the results from the approximate Shapiro-Francia test statistic confirmed that the assumption of lognormality should not be rejected. Although the Shapiro-Francia test statistic indicated that the rice grain data are log normal (Figures II-27 and -28), the recommended tolerance of 16 ppm is inordinately high considering the maximum and average residues in/on rice were 5.20 and 1.49 ppm, respectively. **Therefore, the California Method was used to select a tolerance of 7.0 for rice grain. In addition, the calculated tolerance for cranberries was 0.9 ppm, but a tolerance of 1.0 ppm was selected in order to harmonize with the other berries.**

For the remaining commodities, the calculated tolerance levels are **7 ppm for almond hulls, 5 ppm for leaf petiole vegetables (subgroup 4B), 1.0 ppm for berries (group 13), 4.5 ppm for field corn forage, 30 ppm for field corn stover, 3.5 ppm for mint, 9 ppm for green onions, 18 ppm for rice straw, 12 ppm for sorghum forage, 3.5 ppm for sorghum grain, 15 ppm for sorghum stover, 0.8 ppm for soybean seed, 11 ppm for soybean forage, 30 ppm for soybean hay, 1.3 ppm for strawberry, 1.7 ppm for wheat forage, 1.4 ppm for wheat hay, and 10 ppm for wheat straw.**

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For wheat field trials, residue data were reported both as parent only, and parent plus metabolites. Tolerance spread sheet calculations were perform for both sets of data (Table II-11 and Table II-12. Figures II-37 through 44). Since residue data for the rest of the crops were reported as parent plus metabolites, for the purpose of consistency, HED determined that data set of parent plus metabolites should be used to determine tolerance levels for wheat commodities.

Table II-1.	**Combined Propiconazole Residue Data on Carrots.**
Regulator:	**EPA**
Chemical:	**Propiconazole**
Crop:	**Carrots**
PHI:	**14 days**
App. Rate:	**0.44 lb ai/A**
Submitter:	**Syngenta**
MRID Citation:	**MRID 43786402**
	Total Combined Propiconazole Residues
	0.025
	0.025
	0.06
	0.08
	0.14
	0.17
	0.12
	0.12
	0.1
	0.14
	0.1
	0.16
	0.025
	0.07
Values at ½LOQ are in **bold**.	

Figure II-1. Lognormal probability plot of propiconazole field trial data for carrots following four broadcast foliar applications at 1x rate.

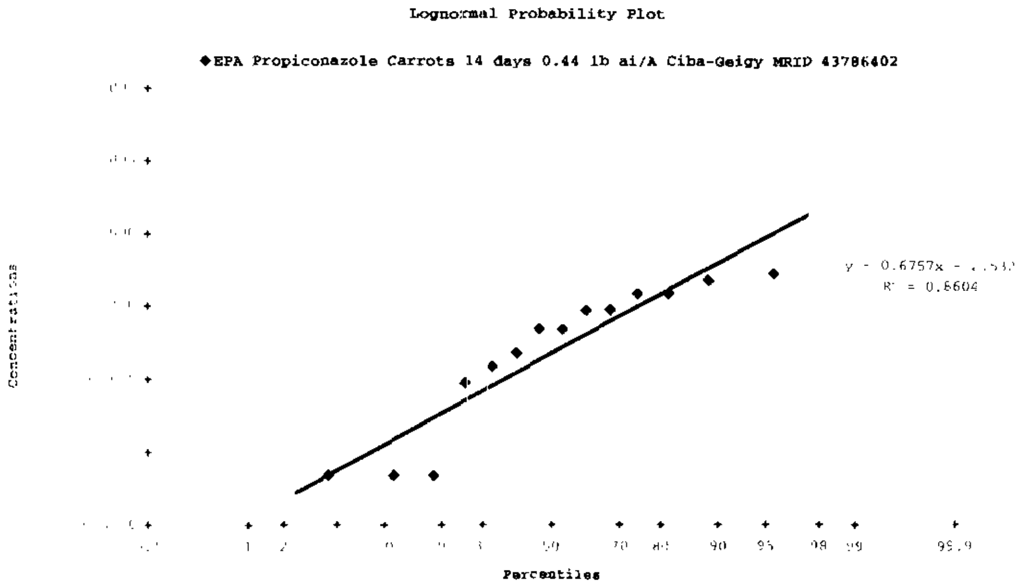

Figure II-2. Tolerance spreadsheet summary of propiconazole field trial data for carrots following four broadcast foliar applications of propiconazole (EC).

	Regulator:	EPA	
	Chemical:	Propiconazole	
	Crop:	Carrots	
	PHI:	14 days	
	App. Rate:	0.44 lb ai/A	
	Submitter:	Ciba-Geigy	
	MRID Citation:	MRID 43786402	
	n:	14	
	min:	0.03	
	max:	0.17	
	median;	0.10	
	average:	0.10	
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	0.20 (0.25)	0.25 (0.30)	0.25 (--)
EU Method I Log Normal	0.25 **(0.50)**	**0.40** (1.0)	0.70 (--)
EU Method II Distribution-Free		0.30	
California Method $\mu + 3\sigma$		**0.25**	
UPLMedian95th		**0.70**	
Approximate Shapiro-Francia Normality Test		0.8604 0.05 >= p-value > 0.01 : Reject lognormality assumption	

Table II-2. Combined Propiconazole Residue Data on Sugar beets using WP formulation.		
Regulator:	**EPA**	
Chemical:	**Propiconazole**	
Crop/Commodity:	**sugar beet roots**	**sugar beet tops**
PHI:	**21-23 days**	
Total App. Rate:	**0.33 lb ai/A**	
Submitter:	**Syngenta**	
MRID Citation:	**44757207 & 45080807**	
	Total Combined Propiconazole Residues	
	0.025	0.57
	0.070	0.89
	0.060	0.67
	0.025	0.54
	0.070	0.76
	0.050	0.56
	0.025	0.41
	0.025	0.46
	0.025	1.20
	0.025	1.10
	0.025	0.50
	0.025	0.44
	0.050	2.90
	0.080	2.80
	0.025	0.54
	0.025	0.85
	0.025	1.30
	0.025	2.30
	0.025	2.20
	0.025	2.00
	0.025	0.50
	0.025	0.73
	0.025	1.30
	0.110	1.30
	0.100	1.70
	0.180	1.90
	0.100	2.60
	0.230	2.60
	0.150	0.74
	0.110	1.20
Values at ½LOQ are in **bold**.		

Figure II-3. **Lognormal probability plot of propiconazole field trial data for sugar beet tops following four broadcast foliar applications at 1x rate.**

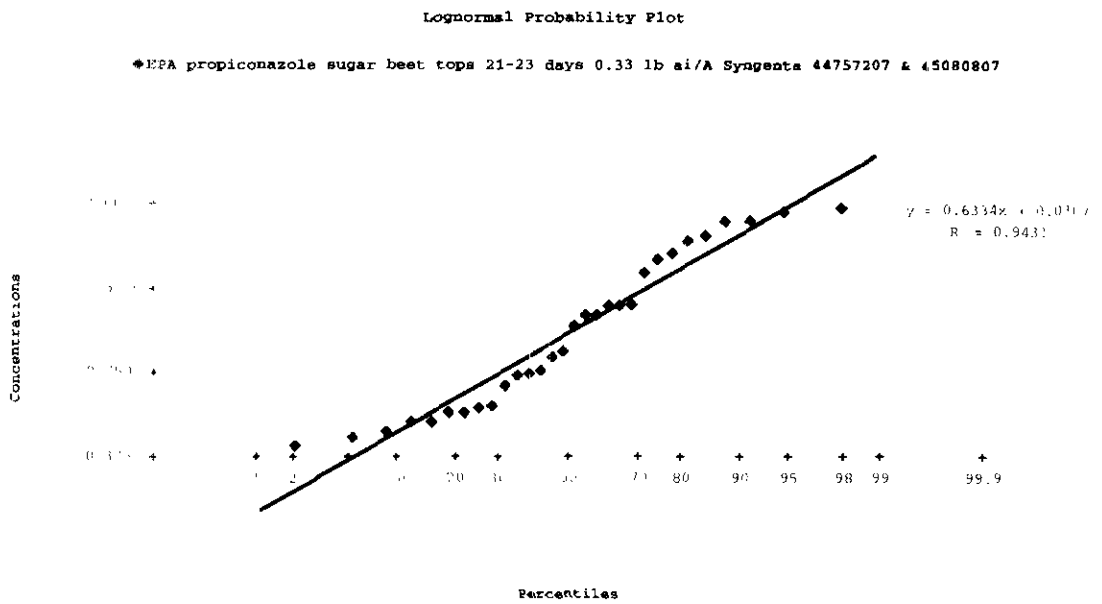

Figure II-4. **Tolerance spreadsheet summary of propiconazole field trial data for sugar beet tops following three broadcast foliar applications of propiconazole (WP).**

Regulator:	EPA
Chemical:	propiconazole
Crop:	sugar beet tops
PHI:	21-23 days
App. Rate:	0.33 lb ai/A
Submitter:	Syngenta
MRID Citation:	44757207 & 45080807
n:	30
min:	0.41
max:	2.90
median:	1.00
average:	1.25

	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	3.0 (3.5)	3.5 (4.0)	4.0 (--)
EU Method I Log Normal	3.0 **(4.5)**	**5.0** (8.0)	8.0 (--)
EU Method II Distribution-Free		4.0	
California Method $\mu + 3\sigma$		**4.0**	
UPLMedian95th		**6.0**	
Approximate Shapiro-Francia Normality Test		0.9431 p-value > 0.05 : Do not reject lognormality assumption	

Table II-3. Combined Propiconazole Residue Data on Onions using EC formulation.		
Regulator:	**EPA**	
Chemical:	**Propiconazole**	
Crop/Commodity:	**Onions, green**	**Onion, dry bulb**
PHI:	**0 days**	**14 days**
Total App. Rate:	**0.45 lb ai/A**	
Submitter:	**Ciba-Geigy (Syngenta)**	
MRID Citation:	**43786401**	
	Total Combined Propiconazole Residues	
	2.6	**0.025**
	3.2	**0.025**
	3.2	**0.025**
	4.3	**0.025**
	2	**0.025**
	2.5	**0.025**
	2.6	**0.025**
	4.3	0.07
	0.57	**0.025**
	0.79	**0.025**
	0.87	0.08
	0.89	0.09
	3.2	**0.025**
	3.9	**0.025**
	6.1	**0.025**
	7.5	0.06
	0.78	**0.025**
	1.2	**0.025**
	1.7	**0.025**
	1.9	**0.025**
	1.5	**0.025**
	1.8	**0.025**
	2.1	**0.025**
	2.5	0.07
	1.1	0.08
	1.2	0.09
	1.4	0.18
	2.2	0.18
Values at ½LOQ are in **bold**.		

Figure II-5. Lognormal probability plot of propiconazole field trial data for green onions following two broadcast foliar applications at 1x rate.

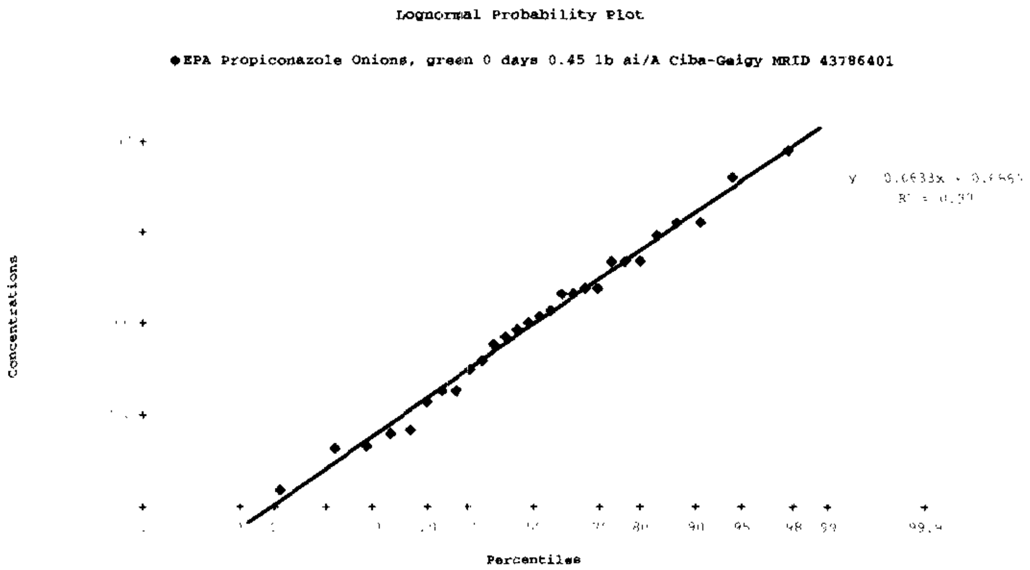

Figure II-6. Tolerance spreadsheet summary of propiconazole field trial data for green onions following two broadcast foliar applications of propiconazole (EC).

	Regulator:	EPA	
	Chemical:	Propiconazole	
	Crop:	Onions, green	
	PHI:	0 days	
	App. Rate:	0.45 lb ai/A	
	Submitter:	Ciba-Geigy	
	MRID Citation:	MRID 43786401	
	n:	28	
	min:	0.57	
	max:	7.50	
	median;	2.05	
	average:	2.43	
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	6.0 (7.0)	7.0 (8.0)	8.0 (--)
EU Method I Log Normal	6.0 **(9.0)**	**9.0** (15)	15 (--)
EU Method II Distribution-Free	7.0		
California Method $\mu + 3\sigma$	**8.0**		
UPLMedian95th	**12**		
Approximate Shapiro-Francia Normality Test	0.9900 p-value > 0.05 : Do not reject lognormality assumption		

Table II-4. Combined Propiconazole Residue Data on celery using WP and EC formulations.	
Regulator:	**EPA**
Chemical:	**Propiconazole**
Crop:	**Celery (untrimmed)**
PHI:	**14 days**
App. Rate:	**0.45-0.55 lb ai/A**
Submitter:	**IR-4**
MRID Citation:	**40783301 & 43655613**
	Total Combined Propiconazole Residues
	0.48
	0.94
	0.81
	0.60
	0.71
	0.57
	1.81
	0.65
	0.40
	0.59
	0.28
	0.47
	0.31
	0.27
	0.35
	0.39
	1.46
	2.61
	3.82
	4.98
	0.27
	0.42
	0.51
	0.43

Figure II-7. **Lognormal probability plot of propiconazole field trial data for celery following four broadcast foliar applications at 1x rate.**

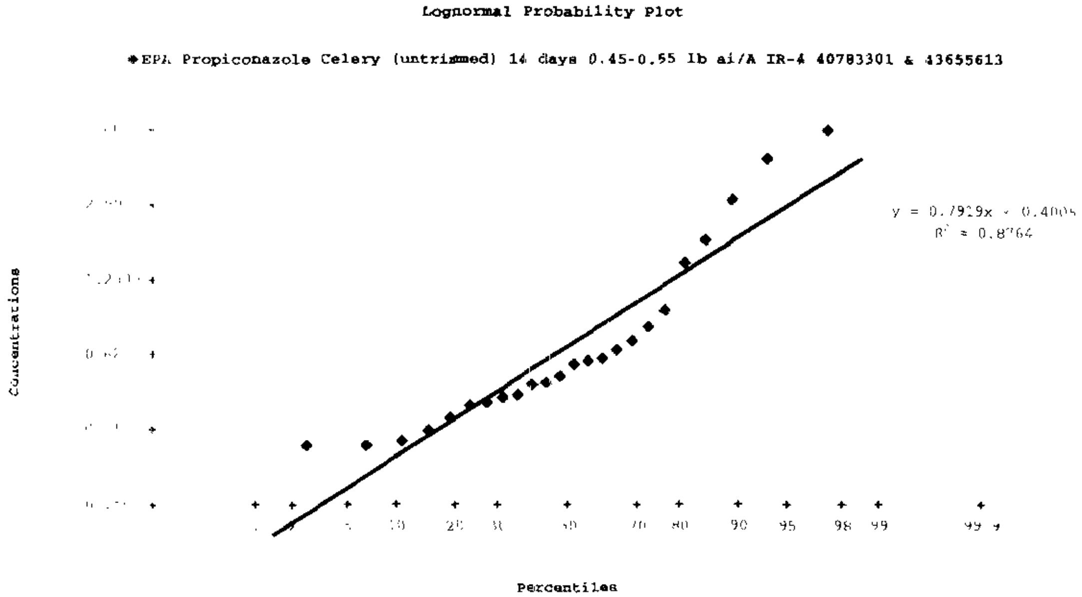

Figure II-8. **Tolerance spreadsheet summary of propiconazole field trial data for celery following four broadcast foliar applications of propiconazole (EC or WP).**

	Regulator: EPA		
	Chemical: Propiconazole		
	Crop: Celery (untrimmed)		
	PHI: 14 days		
	App. Rate: 0.45-0.55 lb ai A		
	Submitter: IR-4		
	MRID Citation: 40783301 & 43655613		
	n: 24		
	min: 0.27		
	max: 4.98		
	median; 0.54		
	average: 1.01		
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	3.0 (4.0)	4.0 (5.0)	5.0 (--)
EU Method I Log Normal	3.0 **(4.5)**	**4.5** (10)	9.0 (--)
EU Method II Distribution-Free	1.9		
California Method μ + 3σ	**5.0**		
UPLMedian95th	**3.5**		
Approximate Shapiro-Francia Normality Test	0.8764 0.05 >= p-value > 0.01 : Reject lognormality assumption		

Table II-5.	Combined Propiconazole Residue Data on various berries using EC formulation.		
Regulator:	**EPA**		
Chemical:	**propiconazole**		
Crop/Commodity:	**Strawberry**	**Cranberry (WI and Pacific NW)**	**Berries (bush and cane berries)**
PHI:	**0 Days**	**43-44 days**	**30 days**
Total App. Rate:	**0.44 lb ai/A**	**0.66-0.68 lb ai/A**	**0.85 lb ai/A**
Submitter:	**Syngenta**	**IR-4**	**Syngenta**
MRID Citation:	**45542401**	**4338101 & 45778901**	**43786403**
	Total Combined Propiconazole Residues		
	0.16	0.18	0.36
	0.15	0.22	0.53
	0.41	0.46	0.22
	0.60	0.59	0.25
	0.38	0.23	0.36
	0.69	0.23	0.45
	0.58		0.66
	0.61		0.57
	0.26		0.28
	0.24		0.34
	0.07		0.14
	0.22		0.18
	0.19		
	0.19		
	0.38		
	0.39		

Figure II-9. **Lognormal probability plot of propiconazole field trial data for strawberries following four broadcast foliar applications at 1x rate.**

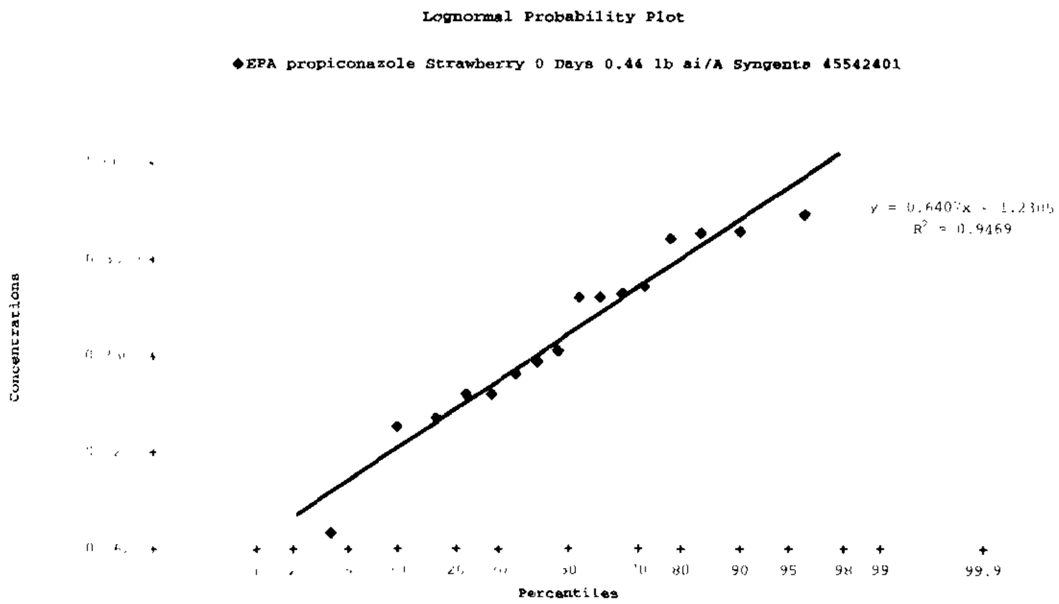

Figure II-10. **Tolerance spreadsheet summary of propiconazole field trial data for strawberries following four broadcast foliar applications of propiconazole (EC).**

Regulator:	EPA
Chemical:	propiconazole
Crop:	Strawberry
PHI:	0 Days
App. Rate:	0.44 lb ai/A
Submitter:	Syngenta
MRID Citation:	45542401
n:	16
min:	0.07
max:	0.69
median;	0.32
average:	0.35

	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	0.70 (0.90)	0.80 (1.1)	1.0 (--)
EU Method I Log Normal	0.90 **(1.5)**	**1.9** (3.0)	2.5 (--)
EU Method II Distribution-Free	1.1		
California Method μ + 3σ	**1.0**		
UPLMedian95th	**2.5**		
Approximate Shapiro-Francia Normality Test	0.9469 p-value > 0.05 : Do not reject lognormality assumption		

Figure II-11. **Lognormal probability plot of propiconazole field trial data for cranberries following four broadcast foliar applications at 1x rate.**

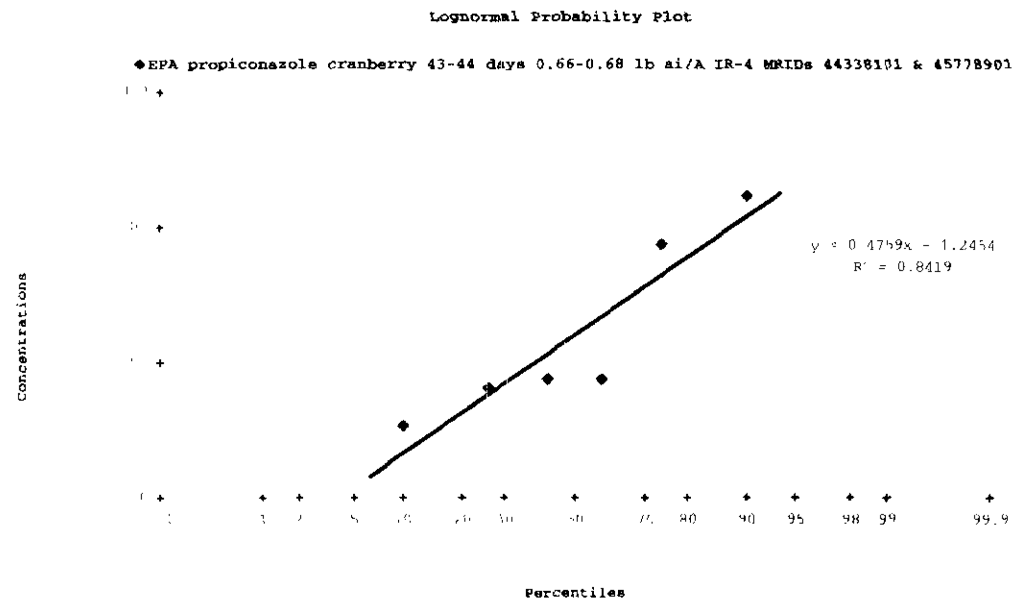

Figure II-12. **Tolerance spreadsheet summary of propiconazole field trial data for cranberries following four broadcast foliar applications of propiconazole (EC).**

	Regulator: EPA		
	Chemical: propiconazole		
	Crop: cranberry		
	PHI: 43-44 days		
	App. Rate: 0.66-0.68 lb ai/A		
	Submitter: IR-4		
	MRID Citation: Ds 44338101 & 45778901		
	n: 6		
	min: 0.18		
	max: 0.59		
	median; 0.23		
	average: 0.32		
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	0.60 (1.0)	0.80 (1.2)	0.90 (--)
EU Method I Log Normal	0.70 **(1.7)**	**0.90** (3.5)	1.3 (--)
EU Method II Distribution-Free	1.0		
California Method $\mu + 3\sigma$	**0.90**		
UPLMedian95th	**3.0**		
Approximate Shapiro-Francia Normality Test	0.8419 p-value > 0.05 : Do not reject lognormality assumption		

Figure II-13. Lognormal probability plot of propiconazole field trial data for bush and cane berries following five broadcast foliar applications at 1x rate.

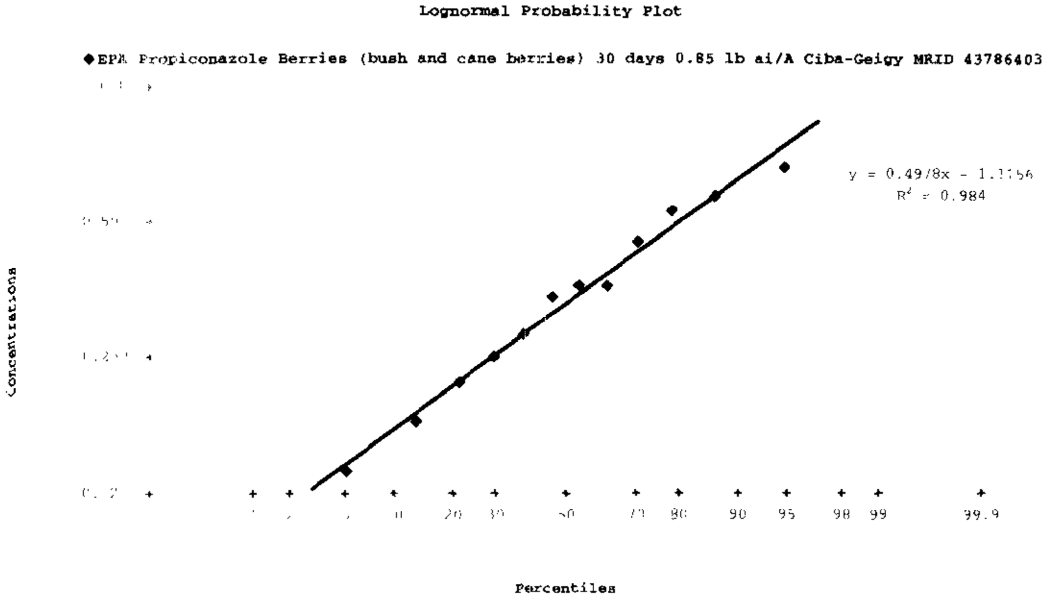

Figure II-14. Tolerance spreadsheet summary of propiconazole field trial data for bush and cane berries following five broadcast foliar applications of propiconazole (EC).

	Regulator: EPA		
	Chemical: Propiconazole		
	Crop: s (bush and cane berries)		
	PHI: 30 days		
	App. Rate: 0.85 lb ai/A		
	Submitter: Ciba-Geigy		
	MRID Citation: MRID 43786403		
	n: 12		
	min: 0.14		
	max: 0.66		
	median: 0.35		
	average: 0.36		
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	0.70 (0.90)	0.80 (1.0)	0.90 (--)
EU Method I Log Normal	0.80 **(1.3)**	**1.0** (2.0)	1.5 (--)
EU Method II Distribution-Free	1.1		
California Method μ + 3σ	**0.90**		
UPLMedian95th	**3.0**		
Approximate Shapiro-Francia Normality Test	0.9840 p-value > 0.05 : Do not reject lognormality assumption		

Table II-6. Combined Propiconazole Residue Data on Soybeans using EC Formulations			
Regulator:	**EPA**		
Chemical:	**Propiconazole**		
Crop:	**Soybean Forage**	**Soybean hay**	**Soybean seeds**
PHI:	**21-32**	**21-32**	**41-99**
App. Rate:	**0.33 lb ai/A**		
Submitter:	**Syngenta**		
MRID Citation:	**MRIDs 43386502**		
	Combined Residues		
	3.30	2.60	0.37
	3.10	3.20	0.23
	2.60	2.20	0.11
	1.00	2.60	0.13
	1.60	0.80	0.10
	0.87	1.70	0.14
	1.20	1.70	0.18
	1.80	1.80	0.34
	3.50	7.70	0.16
	2.20	4.60	0.19
	2.40	2.80	0.37
	3.80	3.30	0.40
	4.90	3.70	0.21
	5.40	5.80	0.25
	0.39	0.48	0.20
	1.90	3.00	0.13
	1.20	2.70	0.11
	0.93	1.60	0.31
	0.63	1.40	0.28
	1.10	4.50	0.12
	1.20	3.40	0.06
	1.60	7.00	0.14
	4.90	12.00	0.19
	5.40	8.80	0.15
	3.70	21.00	0.80
	5.40	21.00	0.14
	1.30	2.00	
	0.33	0.49	
Crop:	**Soybean Forage**	**Soybean hay**	**Soybean seeds**
PHI:			**30**
App. Rate:	**0.33 – 0.36 lb ai/A**		
Submitter:	**Syngenta**		

MRID Citation:	MRIDs 46473001		
	Combined Residues		
			0.19
			0.21
			0.17
			0.23
			0.86
			0.94
			0.23
			0.26

Figure II-15. Lognormal probability plot of propiconazole field trial data for soybean forage following two broadcast foliar applications at 1x rate.

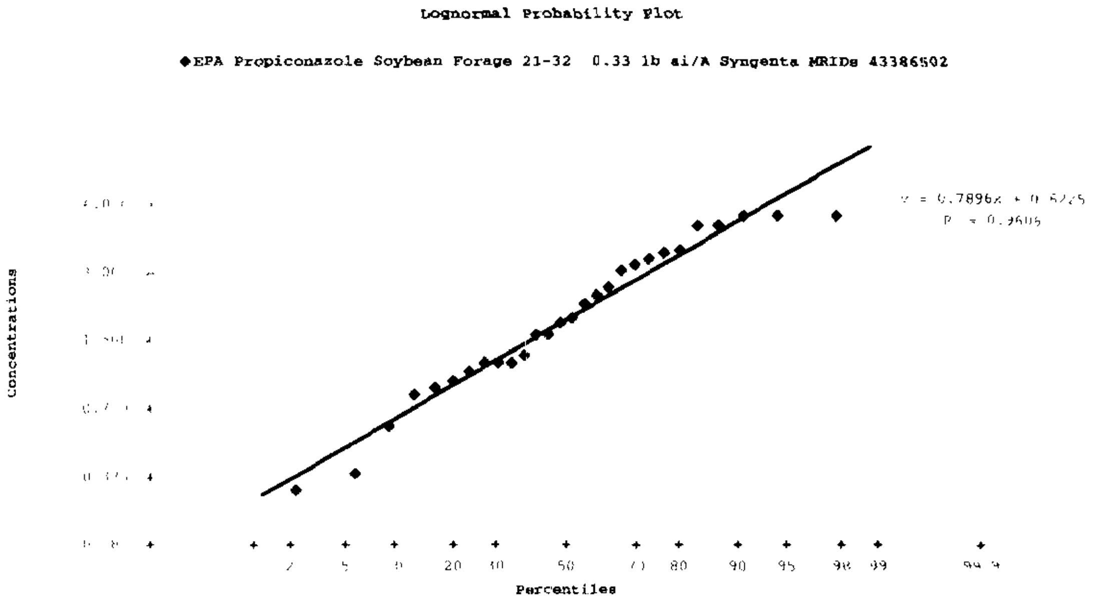

Figure II-16. Tolerance spreadsheet summary of propiconazole field trial data for soybean forage following two broadcast foliar applications of propiconazole (EC).

Regulator:	EPA
Chemical:	Propiconazole
Crop:	Soybean Forage
PHI:	21-32
App. Rate:	0.33 lb ai/A
Submitter:	Syngenta
MRID Citation:	MRIDs 43386502
n:	28
min:	0.33
max:	5.40
median:	1.85
average:	2.42

	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	6.0 (7.0)	7.0 (8.0)	8.0 (--)
EU Method I Log Normal	7.0 **(11)**	**12** (25)	25 (--)
EU Method II Distribution-Free	9.0		
California Method μ + 3σ	**8.0**		
UPLMedian95th	**11**		
Approximate Shapiro-Francia Normality Test	0.9606 p-value > 0.05 : Do not reject lognormality assumption		

Figure II-17. Lognormal probability plot of propiconazole field trial data for soybean hay following two broadcast foliar applications at 1x rate.

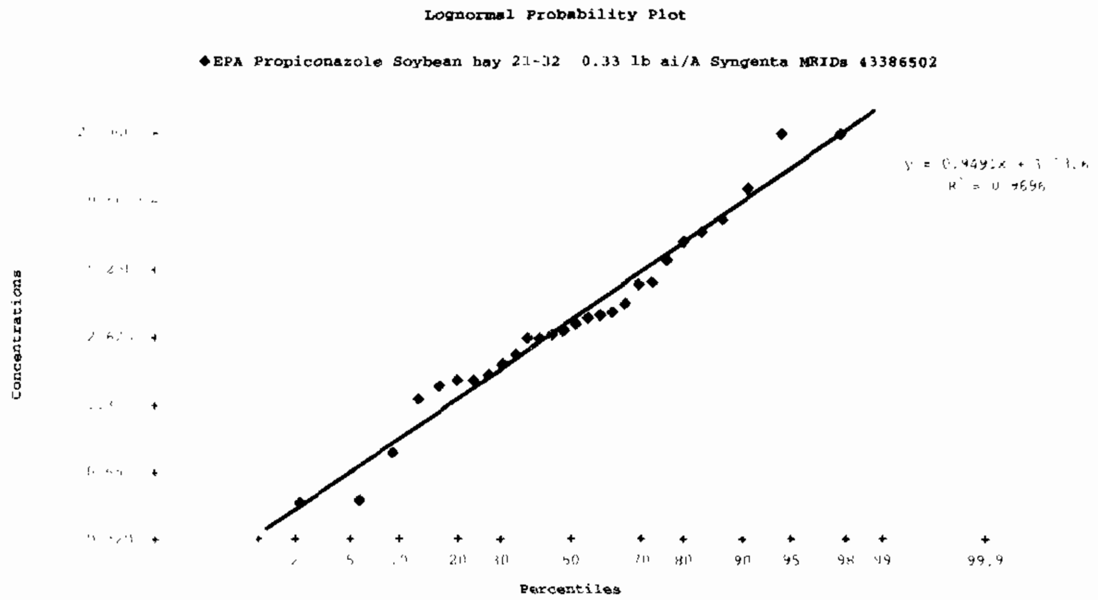

Figure II-18. Tolerance spreadsheet summary of propiconazole field trial data for soybean hay following two broadcast foliar applications of propiconazole (EC).

	Regulator: EPA		
	Chemical: Propiconazole		
	Crop: Soybean hay		
	PHI: 21-32		
	App. Rate: 0.33 lb ai/A		
	Submitter: Syngenta		
	MRID Citation: MRIDs 43386502		
	n: 28		
	min: 0.48		
	max: 21.00		
	median: 2.90		
	average: 4.78		
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	14 (17)	18 (25)	25 (--)
EU Method I Log Normal	15 **(30)**	**30** (60)	60 (--)
EU Method II Distribution-Free	11		
California Method $\mu + 3\sigma$	**25**		
UPLMedian95th	**17**		
Approximate Shapiro-Francia Normality Test	0.9696 p-value > 0.05 : Do not reject lognormality assumption		

Figure II-19. **Lognormal probability plot of propiconazole field trial data for soybean seed following two broadcast foliar applications at 1x rate.**

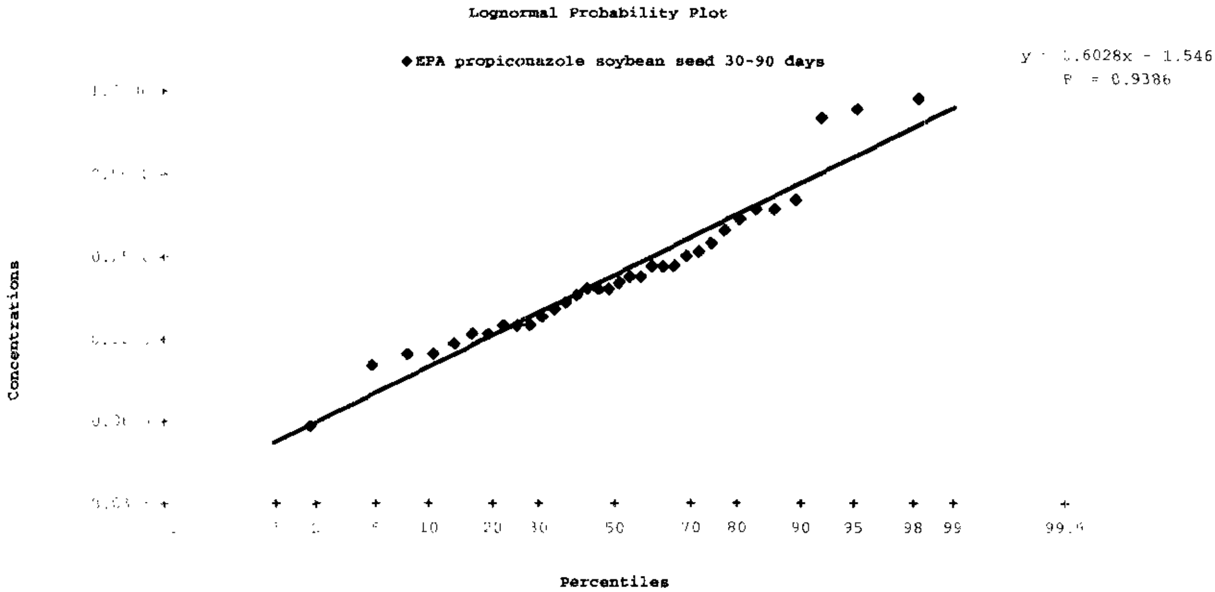

Figure II-20. **Tolerance spreadsheet summary of propiconazole field trial data for soybean seed following two broadcast foliar applications of propiconazole (EC).**

Regulator:	EPA
Chemical:	propiconazole
Crop:	soybean seed
PHI:	30-90 days
App. Rate:	
Submitter:	
n:	34
min:	0.06
max:	0.94
median:	0.20
average:	0.26

	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	0.70 (0.80)	0.80 (0.90)	1.0 (--)
EU Method I Log Normal	0.60 **(0.80)**	**0.90** (1.4)	1.4 (--)
EU Method II Distribution-Free		0.60	
California Method $\mu + 3\sigma$		**0.90**	
UPLMedian95th		**1.1**	
Approximate Shapiro-Francia Normality Test	0.9386 p-value > 0.05 : Do not reject lognormality assumption		

Table II-7. Combined Propiconazole Residue Data on Almond Nutmeat and Hull using EC and WP Formulations.		
Regulator:	**EPA**	
Chemical:	**propiconazole**	
Crop:	**Nutmeats**	**Hulls**
PHI:	**53-63 days**	**53-63 days**
App. Rate:	**0.88-0.91 lb ai/A**	
Submitter:	**Syngenta**	
MRID Citation:	**44757210**	
	Total Combined Propiconazole Residues	
	0.07	0.97
	0.07	0.92
	0.025	1.20
	0.05	1.20
	0.09	1.70
	0.06	1.80
	0.07	1.60
	0.07	1.90
	0.025	4.60
	0.025	4.30
	0.025	4.20
	0.025	3.80
	0.025	1.70
	0.025	1.00
	0.025	1.80
	0.025	1.90
	0.025	0.57
	0.025	0.59
	0.025	0.68
	0.025	0.67
	0.025	2.30
	0.025	2.00
	0.025	2.60
	0.025	2.10
Values at ½LOQ are in **bold**.		

Figure II-21. Lognormal probability plot of propiconazole field trial data for almond hulls following four foliar applications at 1x rate.

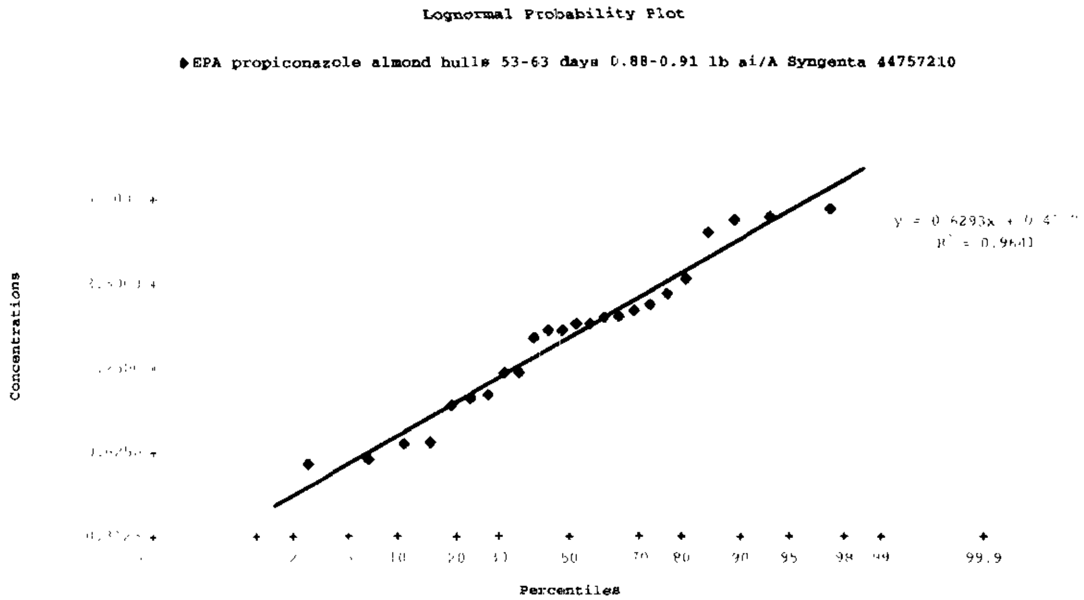

Figure II-22. Tolerance spreadsheet summary of propiconazole field trial data for almond hulls following four foliar applications of propiconazole (EC and WP).

	Regulator:	EPA	
	Chemical:	propiconazole	
	Crop:	almond hulls	
	PHI:	53-63 days	
	App. Rate:	0.88-0.91 lb ai/A	
	Submitter:	Syngenta	
	MRID Citation:	44757210	
	n:	24	
	min:	0.57	
	max:	4.60	
	median;	1.75	
	average:	1.92	
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	4.0 (5.0)	5.0 (6.0)	6.0 (--)
EU Method I Log Normal	4.5 **(7.0)**	**7.0** (12)	11 (--)
EU Method II Distribution-Free	4.5		
California Method μ + 3σ	**6.0**		
UPLMedian95th	**11**		
Approximate Shapiro-Francia Normality Test	0.9641 p-value > 0.05 : Do not reject lognormality assumption		

Table II-8.	**Combined Propiconazole Residue Data on Field and Pop Corn Forage, Stover and Grain using EC Formulation.**		
Regulator:	EPA		
Chemical:	Propiconazole		
Crop:	Corn forage	Corn Stover	Corn grain
PHI:	29-32 days	28-35	28-35
App. Rate:	0.22 lb ai/A	0.42-0.47 lb ai/A	0.42-0.47 lb ai/A
Submitter:	Syngenta		
MRID Citation:	MRIDs 45080809 & 45080810		
	Total Combined Propiconazole Resdiues		
	1.10	12.20	**0.025**
	1.80	19.60	**0.025**
	0.51	3.00	**0.025**
	0.72	1.60	**0.025**
	0.47	0.92	**0.025**
	0.36	0.98	**0.025**
	0.50	6.00	**0.025**
	0.23	5.80	0.150
	0.13	3.20	**0.025**
	0.16	2.30	**0.025**
	0.10	4.70	**0.025**
	0.20	5.70	**0.025**
	0.08	4.90	0.050
	0.025	3.00	0.080
	0.025	3.20	**0.025**
	0.08	3.50	**0.025**
	0.05	2.50	0.080
	0.06	4.40	0.060
	0.35	8.60	**0.025**
	0.44	8.80	**0.025**
	0.71	8.30	0.070
	0.41	10.20	**0.025**
	0.025	9.30	**0.025**
	0.025	6.50	**0.025**
	0.025	6.60	**0.025**
	0.06	8.00	**0.025**
	0.06	6.30	**0.025**
	0.16	5.50	**0.025**
	1.10	3.50	0.060
	1.30	4.70	0.070
	0.43	3.70	**0.025**
	0.63	3.40	**0.025**
	0.78	8.40	**0.025**
	0.39	8.00	**0.025**
	1.90	14.40	0.060
	0.85	15.40	**0.025**
		1.99	**0.025**
		1.52	0.080
		10.60	**0.025**
		17.80	**0.025**
		15.60	**0.025**
		16.60	**0.025**
		12.40	**0.025**

Table II-8.	Combined Propiconazole Residue Data on Field and Pop Corn Forage, Stover and Grain using EC Formulation.		
Regulator:	EPA		
Chemical:	Propiconazole		
Crop:	Corn forage	Corn Stover	Corn grain
PHI:	29-32 days	28-35	28-35
App. Rate:	0.22 lb ai/A	0.42-0.47 lb ai/A	0.42-0.47 lb ai/A
Submitter:	Syngenta		
MRID Citation:	MRIDs 45080809 & 45080810		
	Total Combined Propiconazole Resdiues		
		10.80	**0.025**
		5.60	**0.025**
		2.90	**0.025**
		2.80	**0.025**
		3.90	**0.025**
Values at ½LOQ are in **bold**.			

Figure II-23. Lognormal probability plot of propiconazole field trial data for field corn forage following two foliar applications at 1x rate.

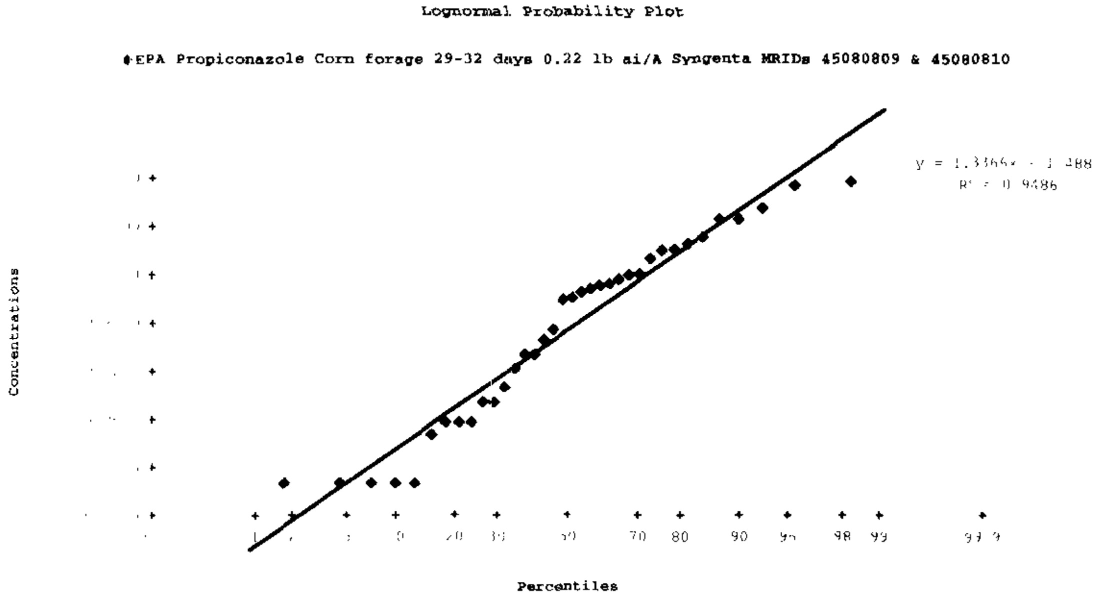

Figure II-24. Tolerance spreadsheet summary of propiconazole field trial data for field corn forage following two foliar applications of propiconazole (EC).

	Regulator:	EPA	
	Chemical:	Propiconazole	
	Crop:	Corn forage	
	PHI:	29-32 days	
	App. Rate:	0.22 lb ai/A	
	Submitter:	Syngenta	
	MRID Citation:	Ds 45080809 & 45080810	
	n:	36	
	min:	0.03	
	max:	1.90	
	median;	0.36	
	average:	0.45	
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	1.3 (1.5)	1.6 (2.0)	2.0 (--)
EU Method I Log Normal	2.5 **(4.5)**	**6.0** (13)	15 (--)
EU Method II Distribution-Free	1.4		
California Method μ + 3σ	**2.0**		
UPLMedian95th	**2.0**		
Approximate Shapiro-Francia Normality Test	0.9486 p-value > 0.05 : Do not reject lognormality assumption		

Figure II-25. **Lognormal probability plot of propiconazole field trial data for field and pop corn stover following four foliar applications at 1x rate.**

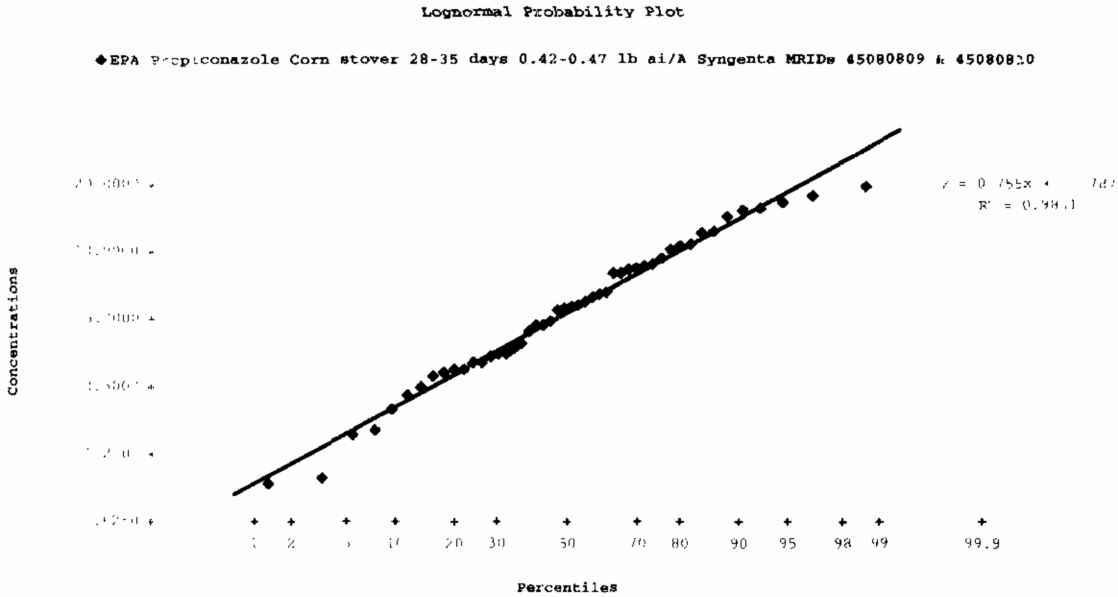

Figure II-26. **Tolerance spreadsheet summary of propiconazole field trial data for field and pop corn stover following four foliar applications of propiconazole (EC).**

	Regulator:	EPA	
	Chemical:	Propiconazole	
	Crop:	Corn stover	
	PHI:	28-35 days	
	App. Rate:	0.42-0.47 lb ai/A	
	Submitter:	Syngenta	
	MRID Citation:	Ds 45080809 & 45080810	
	n:	48	
	min:	0.92	
	max:	19.60	
	median;	5.65	
	average:	6.87	
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	15 (17)	18 (25)	25 (--)
EU Method I Log Normal	19 **(30)**	**35** (50)	55 (--)
EU Method II Distribution-Free		19	
California Method μ + 3σ		**25**	
UPLMedian95th		**30**	
Approximate Shapiro-Francia Normality Test		0.9831 p-value > 0.05 : Do not reject lognormality assumption	

Table II-9. Combined Propiconazole Residue Data on Rice Grain and Straw using EC Formulation.		
Regulator:	**EPA**	
Chemical:	**Propiconazole**	
Crop:	**Rice grain**	**Rice straw**
PHI:	**34-49 days**	**34-49 days**
App. Rate:	**0.28 lb ai/A**	**0.28 lb ai/A**
Submitter:	**Sygenta**	
MRID Citation:	**MRID 45080811**	
	Total Combined Propiconazole Residues	
	0.91	1.5
	1.40	2.1
	3.10	9.0
	2.60	10.2
	2.00	3.3
	1.10	3.4
	0.64	2.3
	0.60	1.9
	0.11	2.6
	0.71	1.4
	3.90	4.0
	3.90	3.2
	4.90	16.0
	5.20	17.0
	0.09	0.7
	0.09	0.7
	0.21	1.9
	0.44	2.6
	0.13	1.4
	0.15	1.1
	0.68	1.3
	0.81	1.3
	1.00	3.3
	0.87	2.1
	0.96	1.7
	0.99	2.5
	0.12	1.6
	0.025	1.5
	3.50	16.0
	4.30	9.2
	1.50	2.4
	0.80	2.3
Values at ½LOQ are in **bold**.		

Figure II-27. Lognormal probability plot of propiconazole field trial data for rice grain following a single foliar application at 1x rate.

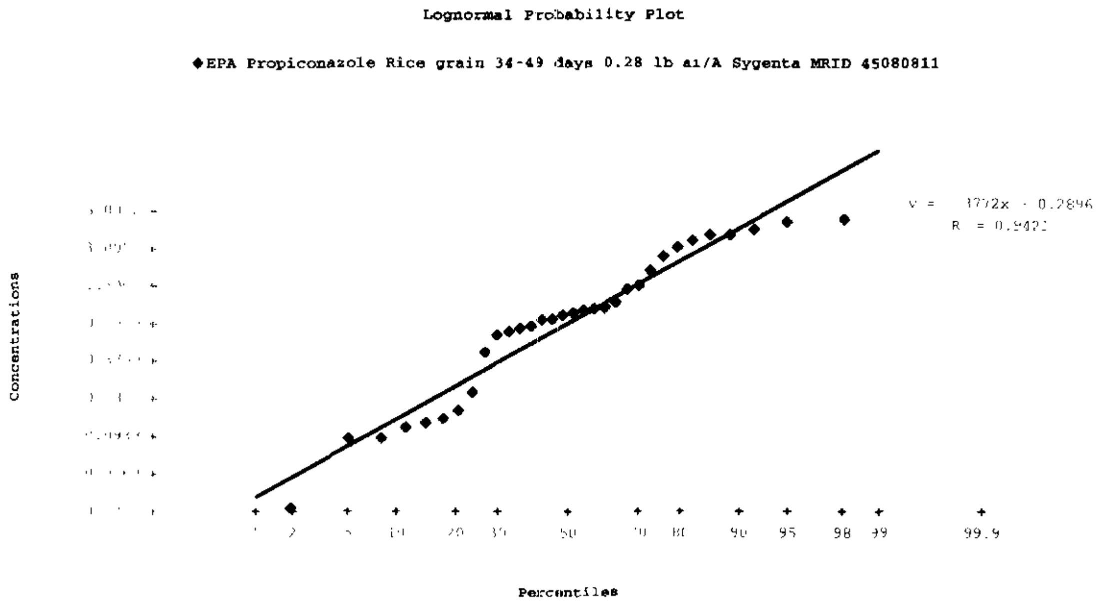

Figure II-28. Tolerance spreadsheet summary of propiconazole field trial data for rice grain following a single foliar applications of propiconazole (EC).

Regulator:	EPA
Chemical:	Propiconazole
Crop:	Rice grain
PHI:	34-49 days
App. Rate:	0.28 lb ai/A
Submitter:	Sygenta
MRID Citation:	MRID 45080811
n:	32
min:	0.03
max:	5.20
median;	0.89
average:	1.49

	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	4.5 (5.0)	6.0 (7.0)	7.0 (--)
EU Method I Log Normal	8.0 **(16)**	**19** (50)	55 (--)
EU Method II Distribution-Free	5.0		
California Method $\mu + 3\sigma$	**7.0**		
UPLMedian95th	**5.0**		
Approximate Shapiro-Francia Normality Test	0.9421 p-value > 0.05 : Do not reject lognormality assumption		

Figure II-29. Lognormal probability plot of propiconazole field trial data for rice straw following a single foliar application at 1x rate.

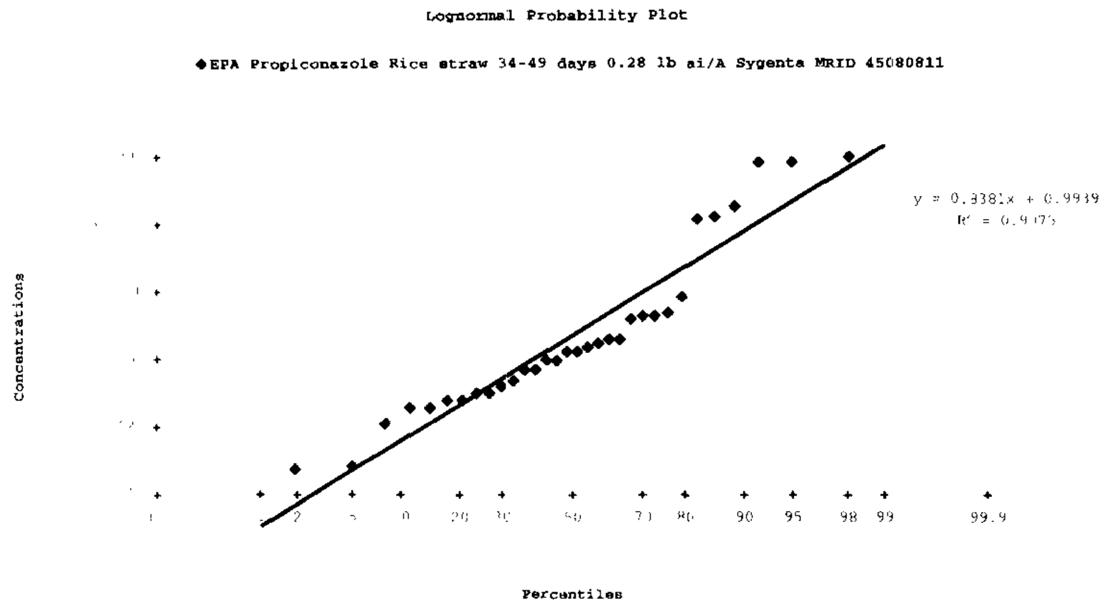

Figure II-30. Tolerance spreadsheet summary of propiconazole field trial data for rice straw following a single foliar applications of propiconazole (EC).

Regulator:	EPA
Chemical:	Propiconazole
Crop:	Rice straw
PHI:	34-49 days
App. Rate:	0.28 lb ai/A
Submitter:	Sygenta
MRID Citation:	MRID 45080811
n:	32
min:	0.69
max:	17.00
median;	2.30
average:	4.11

	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	12 (15)	15 (19)	19 (--)
EU Method I Log Normal	12 **(18)**	**20** (40)	40 (--)
EU Method II Distribution-Free	7.0		
California Method $\mu + 3\sigma$	**18**		
UPLMedian95th	**13**		
Approximate Shapiro-Francia Normality Test	0.9075 0.05 >= p-value > 0.01 : Reject lognormality assumption		

Table II-10. Combined Propiconazole Residue Data on Sorghum Forage, Stover and Grain using EC Formulation.			
Regulator:	**EPA**		
Chemical:	**Propiconazole**		
Crop:	**Sorghum forage**	**Sorghum stover**	**Sorghum grain**
PHI:	**29-38 days**	**18-28 days**	**18-28 days**
App. Rate:	**0.22 lb ai/A**	**0.44 lb ai/A**	**0.44 lb ai/A**
Submitter:	**Sygenta**		
MRID Citation:	***MRID 45275801***		
	Total Combined Propiconazole Residues		
	3.7	11.0	1.00
	2.6	5.1	1.00
	5.8	2.8	0.96
	3.0	8.8	0.80
	7.4	6.2	0.52
	4.2	6.1	0.66
	2.8	4.7	0.75
	3.8	5.7	1.40
	5.2	4.2	1.80
	4.8	8.3	2.30
	3.8	6.6	0.79
	3.4	11.7	0.76
	8.0	4.5	1.00
	8.2	4.6	0.86
	5.5	6.0	2.00
	3.8	6.1	2.10
	6.8	4.7	1.60
	6.0	6.5	1.50
	2.6	2.8	0.56
	2.2	5.6	0.58
	5.5	4.7	0.89
	2.7	5.4	0.83
	2.2	3.2	1.30
	1.5	4.2	1.30
	8.3	14.2	1.90
	6.4	12.7	2.10
	6.6	4.3	2.40
	3.8	4.4	1.80

Figure II-31. Lognormal probability plot of propiconazole field trial data for sorghum forage following two foliar applications at 1x rate.

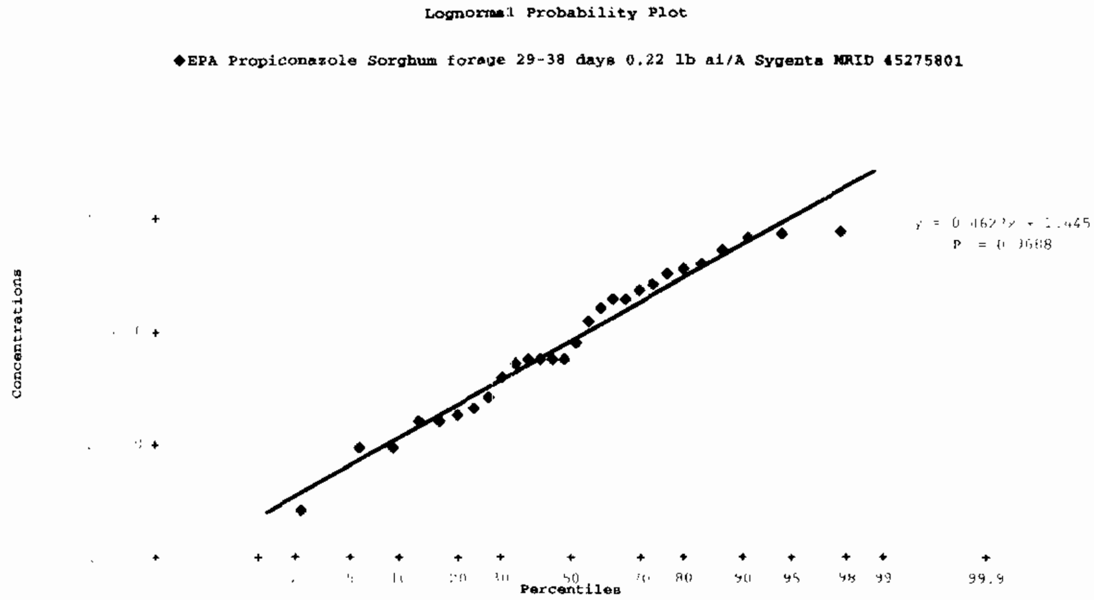

Figure II-32. Tolerance spreadsheet summary of propiconazole field trial data for sorghum forage following two foliar applications of propiconazole (EC).

	Regulator:	EPA	
	Chemical:	Propiconazole	
	Crop:	Sorghum forage	
	PHI:	29-38 days	
	App. Rate:	0.22 lb ai/A	
	Submitter:	Sygenta	
	MRID Citation:	MRID 45275801	
	n:	28	
	min:	1.50	
	max:	8.30	
	median;	4.00	
	average:	4.66	
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	9.0 (10)	10 (11)	11 (--)
EU Method I Log Normal	9.0 **(12)**	**13** (18)	18 (--)
EU Method II Distribution-Free	13		
California Method $\mu + 3\sigma$	**11**		
UPLMedian95th	**25**		
Approximate Shapiro-Francia Normality Test	0.9688 p-value > 0.05 : Do not reject lognormality assumption		

Figure II-33. Lognormal probability plot of propiconazole field trial data for sorghum stover following four foliar applications at 1x rate.

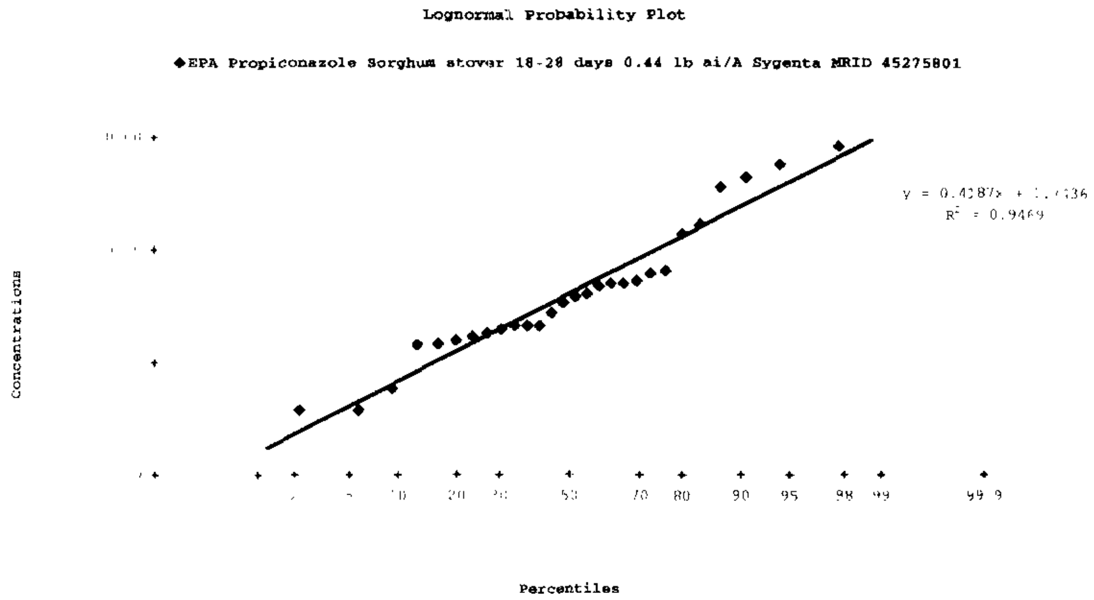

Figure II-34. Tolerance spreadsheet summary of propiconazole field trial data for sorghum stover following four foliar applications of propiconazole (EC).

	Regulator:	EPA	
	Chemical:	Propiconazole	
	Crop:	Sorghum stover	
	PHI:	18-28 days	
	App. Rate:	0.44 lb ai/A	
	Submitter:	Sygenta	
	MRID Citation:	MRID 45275801	
	n:	28	
	min:	2.80	
	max:	14.20	
	median;	5.50	
	average:	6.25	
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	12 (13)	14 (16)	16 (--)
EU Method I Log Normal	12 **(25)**	**16** (25)	25 (--)
EU Method II Distribution-Free		14	
California Method μ + 3σ		**16**	
UPLMedian95th		**35**	
Approximate Shapiro-Francia Normality Test		0.9469 p-value > 0.05 : Do not reject lognormality assumption	

Figure II-35. Lognormal probability plot of propiconazole field trial data for sorghum grain following four foliar applications at 1x rate.

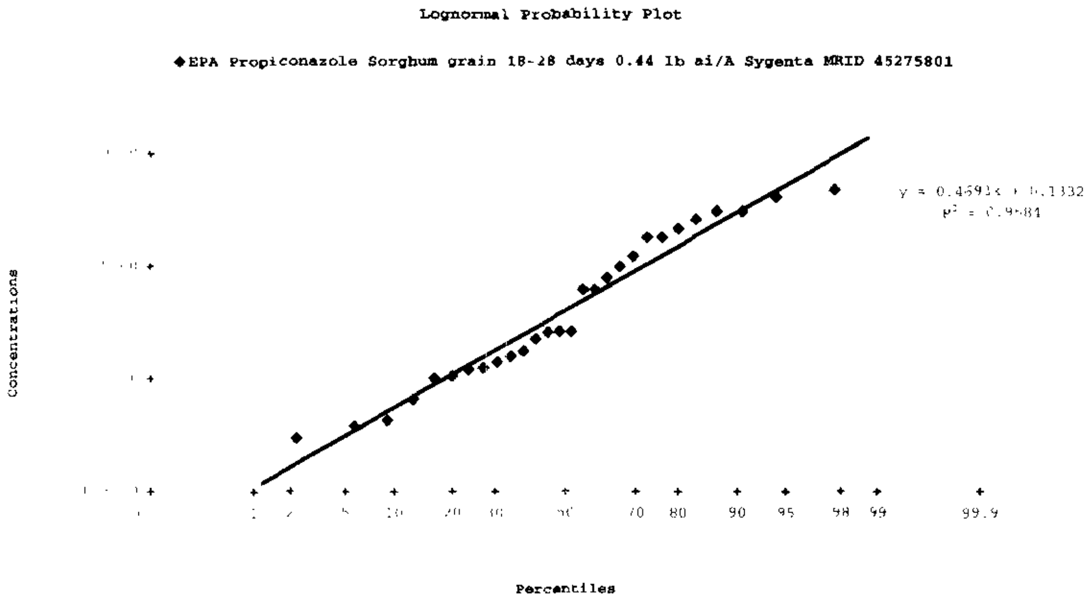

Figure II-36. Tolerance spreadsheet summary of propiconazole field trial data for sorghum grain following four foliar applications of propiconazole (EC).

	Regulator:	EPA	
	Chemical:	Propiconazole	
	Crop:	Sorghum grain	
	PHI:	18-28 days	
	App. Rate:	0.44 lb ai/A	
	Submitter:	Sygenta	
	MRID Citation:	MRID 45275801	
	n:	28	
	min:	0.52	
	max:	2.40	
	median;	1.00	
	average:	1.27	
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	2.5 (3.0)	3.0 (3.5)	3.5 (--)
EU Method I Log Normal	2.5 **(3.5)**	**3.5** (5.0)	5.0 (--)
EU Method II Distribution-Free		4.0	
California Method $\mu + 3\sigma$		**3.5**	
UPLMedian95th		**6.0**	
Approximate Shapiro-Francia Normality Test		0.9584 p value > 0.05 : Do not reject lognormality assumption	

Table II-11. Combined Propiconazole Residue Data on Wheat Forage, Hay, Straw and Grain using EC Formulation.				
Regulator:	**EPA**			
Chemical:	**Propiconazole**			
Crop:	**Wheat forage**	**Wheat hay**	**Wheat straw**	**Wheat grain**
PHI:	**29-32 days**	**43-50 days**	**27-57 days**	**27-57 days**
App. Rate:	**0.11 lb ai/A**	**0.11 lb ai/A**	**0.22-0.23 lb ai/A**	**0.22-0.23 lb ai/A**
Submitter:	**Syngenta**			
MRID Citation:	**MRID 44757208**			
	Total Combined Propiconazole Residues			
	0.48	0.50	7.49	0.06
	0.55	0.37	7.49	**0.025**
	0.19	0.26	3.23	0.05
	0.25	0.27	1.79	**0.025**
	0.13	0.11	3.02	0.07
	0.17	0.14	3.03	0.06
	0.55	0.38	8.27	0.16
	0.44	0.55	5.59	0.20
	0.27	0.22	0.81	0.12
	0.21	0.22	1.05	0.08
	0.13	0.16	1.02	0.05
	0.13	0.16	0.86	0.05
	0.16	0.11	4.74	0.13
	0.12	0.11	5.16	0.13
	0.26	0.47	5.66	**0.025**
	0.22	0.39	6.08	**0.025**
	0.07	0.05	5.38	0.11
	0.07	0.05	4.17	0.07
	0.14	0.41	7.31	0.12
	0.17	0.31	6.63	0.18
	0.20	0.12	0.20	**0.025**
	0.17	0.13	0.24	**0.025**
	0.63	0.75	2.65	**0.025**
	0.66	0.79	2.46	**0.025**
	0.025	0.07	2.45	**0.025**
	0.025	0.05	1.31	0.06
	0.64	0.30	5.73	0.05
	0.59	0.13	3.57	0.07
	0.18	0.14	1.75	**0.025**
	0.14	0.15	1.34	**0.025**
	0.16	0.32	1.14	**0.025**
	0.24	0.40	0.56	**0.025**
	1.24	0.98	2.95	0.06
	1.91	1.10	2.37	**0.025**
	0.20	0.12	2.34	**0.025**
	0.23	0.08	2.01	**0.025**
	0.58	0.48	2.76	0.10
	0.65	0.49	3.36	0.06
	0.25	0.24	0.98	**0.025**
	0.20	0.26	1.57	**0.025**
	0.025	**0.025**	2.42	**0.025**
	0.05	0.05	3.04	**0.025**
Values at ½LOQ are in **bold**.				

Figure II-37. **Lognormal probability plot of propiconazole field trial data (combined residues) for wheat forage following a single foliar application at 1x rate.**

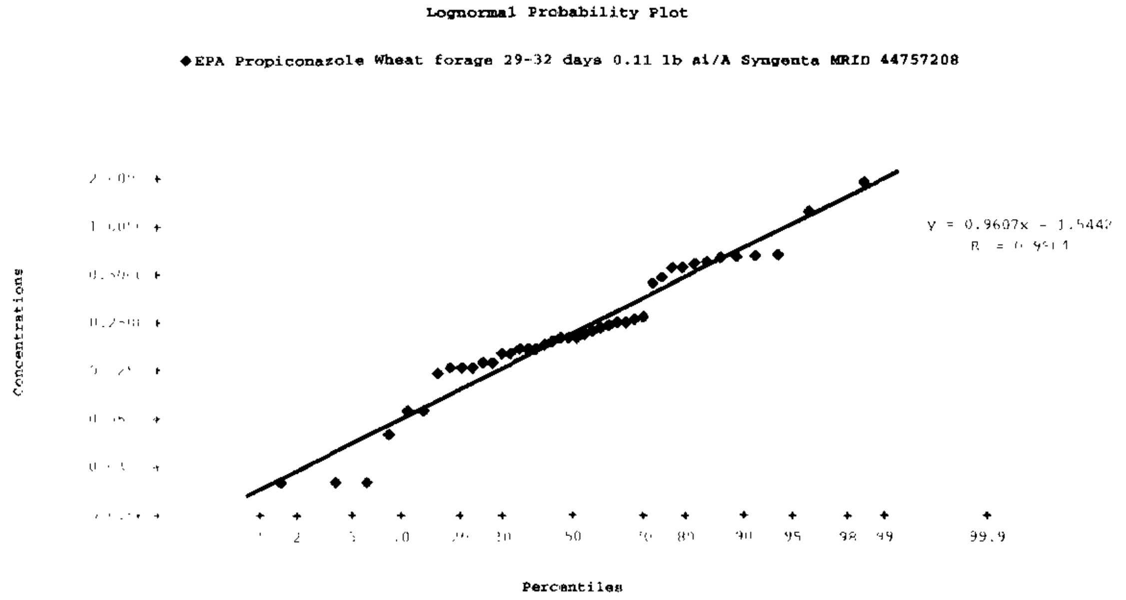

Figure II-38. **Tolerance spreadsheet summary of propiconazole field trial data (combined residues) for wheat forage following a single foliar application of propiconazole (EC).**

	Regulator: EPA		
	Chemical: Propiconazole		
	Crop: Wheat forage		
	PHI: 29-32 days		
	App. Rate: 0.11 lb ai/A		
	Submitter: Syngenta		
	MRID Citation: MRID 44757208		
	n: 42		
	min: 0.03		
	max: 1.91		
	median; 0.20		
	average: 0.33		
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	1.0 (1.1)	1.2 (1.4)	1.5 (--)
EU Method I Log Normal	1.1 **(1.7)**	**2.5** (4.0)	4.5 (--)
EU Method II Distribution-Free	1.0		
California Method $\mu + 3\sigma$	**1.4**		
UPLMedian95th	**1.1**		
Approximate Shapiro-Francia Normality Test	0.9504 p-value > 0.05 : Do not reject lognormality assumption		

Figure II-39. Lognormal probability plot of propiconazole field trial data (combined residues) for wheat hay following a single foliar application at 1x rate.

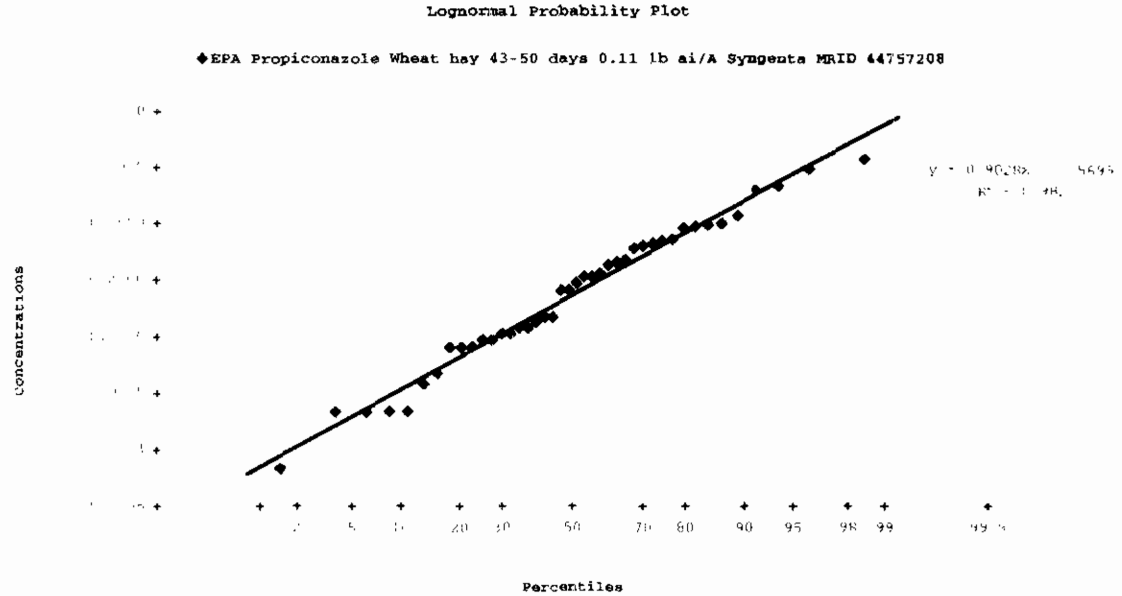

Figure II-40. Tolerance spreadsheet summary of propiconazole field trial data (combined residues) for wheat hay following a single foliar application of propiconazole (EC).

	Regulator:	EPA	
	Chemical:	Propiconazole	
	Crop:	Wheat hay	
	PHI:	43-50 days	
	App. Rate:	0.11 lb ai/A	
	Submitter:	Syngenta	
	MRID Citation:	MRID 44757208	
	n:	42	
	min:	0.03	
	max:	1.10	
	median:	0.23	
	average:	0.30	
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	0.80 (0.90)	0.90 (1.1)	1.1 (--)
EU Method I Log Normal	1.0 **(1.4)**	**1.7** (3.0)	3.5 (--)
EU Method II Distribution-Free	0.90		
California Method μ + 3σ	**1.1**		
UPLMedian95th	**1.3**		
Approximate Shapiro-Francia Normality Test	0.9820 p-value > 0.05 : Do not reject lognormality assumption		

Figure II-41. **Lognormal probability plot of propiconazole field trial data (combined residues) for wheat straw following two foliar applications at 1x rate.**

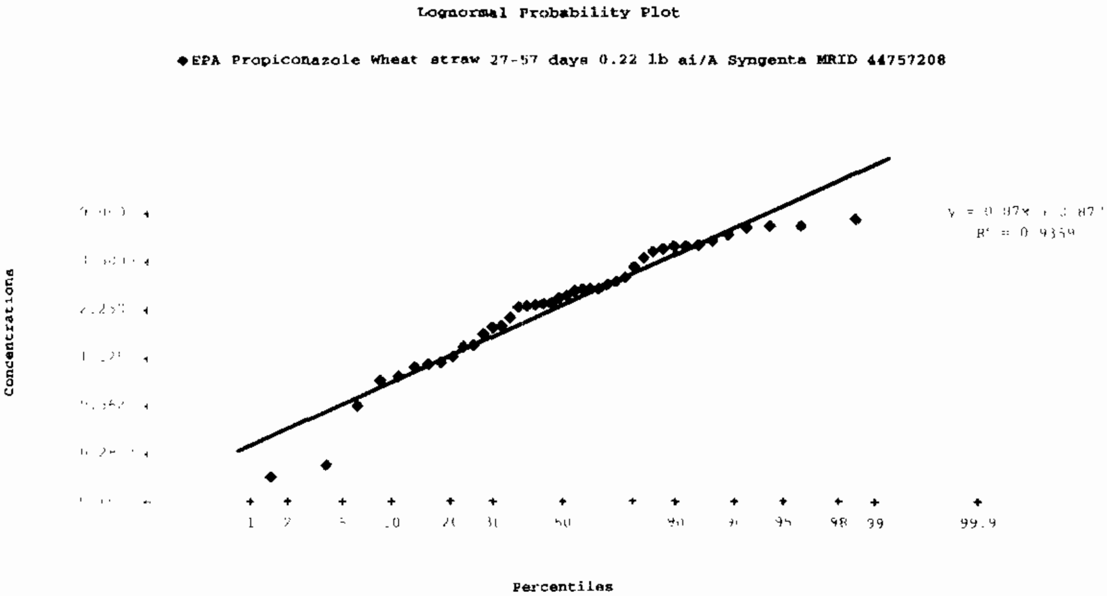

Figure II-42. **Tolerance spreadsheet summary of propiconazole field trial data (combined residues) for wheat straw following two applications of propiconazole (EC).**

	Regulator:	EPA	
	Chemical:	Propiconazole	
	Crop:	Wheat straw	
	PHI:	27-57 days	
	App. Rate:	0.22 lb ai/A	
	Submitter:	Syngenta	
	MRID Citation:	MRID 44757208	
	n:	42	
	min:	0.20	
	max:	8.27	
	median:	2.71	
	average:	3.24	
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	7.0 (8.0)	9.0 (10)	11 (--)
EU Method I Log Normal	11 **(16)**	**19** (35)	40 (--)
EU Method II Distribution-Free	11		
California Method μ + 3σ	**10**		
UPLMedian95th	**15**		
Approximate Shapiro-Francia Normality Test	0.9359 0.05 >= p-value > 0.01 : Reject lognormality assumption		

Table II-12. Parent Residue Data on Wheat Forage, Hay, Straw, and Grain using EC Formulation.				
Regulator:	**EPA**			
Chemical:	**Propiconazole**			
Crop:	**Wheat forage**	**Wheat hay**	**Wheat straw**	**Wheat grain**
PHI:	**29-32 days**	**43-50 days**	**27-57 days**	**27-57 days**
App. Rate:	**0.11 lb ai/A**	**0.11 lb ai/A**	**0.22-0.23 lb ai/A**	**0.22-0.23 lb ai/A**
Submitter:	**Syngenta**			
MRID Citation:	**MRID 44757208**			
	Propiconazole Residues (Parent only)			
	0.090	0.06	1.06	**0.025**
	0.140	0.03	1.13	0.05
	0.025	**0.025**	0.11	**0.025**
	0.025	**0.025**	0.05	**0.025**
	0.025	**0.025**	0.44	**0.025**
	0.025	**0.025**	0.68	**0.025**
	0.090	0.05	2.18	**0.025**
	0.120	0.09	1.92	**0.025**
	0.050	**0.025**	**0.025**	**0.025**
	0.025	**0.025**	**0.025**	**0.025**
	0.025	**0.025**	0.06	**0.025**
	0.025	**0.025**	**0.025**	**0.025**
	0.025	**0.025**	0.72	**0.025**
	0.025	**0.025**	0.91	**0.025**
	0.025	**0.025**	1.77	**0.025**
	0.025	**0.025**	2.63	**0.025**
	0.025	**0.025**	2.22	**0.025**
	0.025	**0.025**	1.64	0.05
	0.025	**0.025**	2.93	**0.025**
	0.025	**0.025**	3.49	**0.025**
	0.025	**0.025**	**0.025**	**0.025**
	0.025	**0.025**	**0.025**	**0.025**
	0.025	0.06	0.15	**0.025**
	0.025	0.06	1.06	**0.025**
	0.025	**0.025**	1.13	**0.025**
	0.025	**0.025**	0.11	**0.025**
	0.050	**0.025**	0.05	**0.025**
	0.060	**0.025**	0.44	**0.025**
	0.025	**0.025**	0.68	**0.025**
	0.025	**0.025**	2.18	**0.025**
	0.025	**0.025**	1.92	**0.025**
	0.025	**0.025**	**0.025**	**0.025**
	0.230	0.11	**0.025**	**0.025**
	0.490	0.20	0.06	**0.025**
	0.025	**0.025**	**0.025**	**0.025**
	0.025	**0.025**	0.72	**0.025**
	0.100	0.05	0.91	**0.025**
	0.120	0.05	1.77	**0.025**
	0.025	**0.025**	2.63	**0.025**
	0.025	**0.025**	2.22	**0.025**
	0.025	**0.025**	1.64	**0.025**
	0.025	**0.025**	2.93	**0.025**

Values at ½LOQ are in **bold**.

Figure II-43. Lognormal probability plot of propiconazole field trial data (parent residues) for wheat straw following two foliar applications at 1x rate.

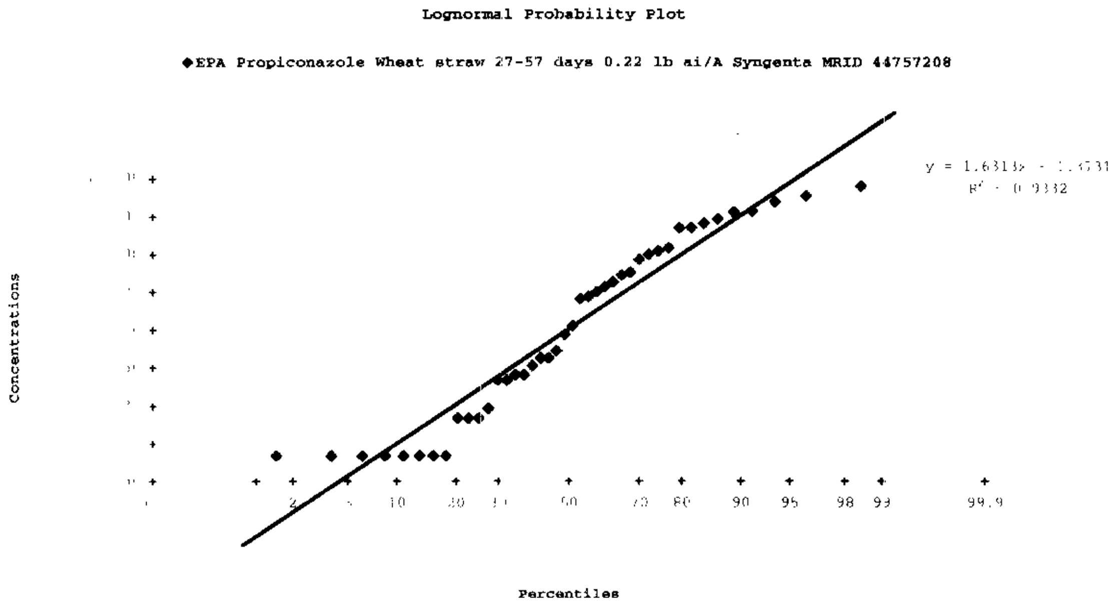

Figure II-44. Tolerance spreadsheet summary of propiconazole field trial data (parent residues) for wheat straw following two applications of propiconazole (EC).

	Regulator: EPA		
	Chemical: Propiconazole		
	Crop: Wheat straw		
	PHI: 27-57 days		
	App. Rate: 0.22 lb ai/A		
	Submitter: Syngenta		
	MRID Citation: MRID 44757208		
	n: 42		
	min: 0.03		
	max: 3.49		
	median; 0.25		
	average: 0.72		
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	2.5 (3.0)	3.0 (3.5)	4.0 (--)
EU Method I Log Normal	4.0 **(9.0)**	**12** (35)	45 (--)
EU Method II Distribution-Free	2.5		
California Method μ + 3σ	**3.5**		
UPLMedian95th	**1.4**		
Approximate Shapiro-Francia Normality Test	0.9332 0.05 >= p-value > 0.01 : Reject lognormality assumption		

Table II-13. Combined Propiconazole Residue Data on Mint using EC formulation.	
Chemical:	**Propiconazole**
Crop:	**Mint Hay**
PHI:	**29-30 days**
App. Rate:	**0.224-0.227 lb ai/A**
Submitter:	**IR-4**
MRID Citation:	**MRID 44416501**
	Total Combined Propiconazole Residues
	1.9
	0.54
	1.1
	1.0
	1.3
	2.7
	0.06
	0.63
	1.2
	1.1

Figure II-45. **Lognormal probability plot of propiconazole field trial data for mint following two broadcast foliar applications at 1x rate.**

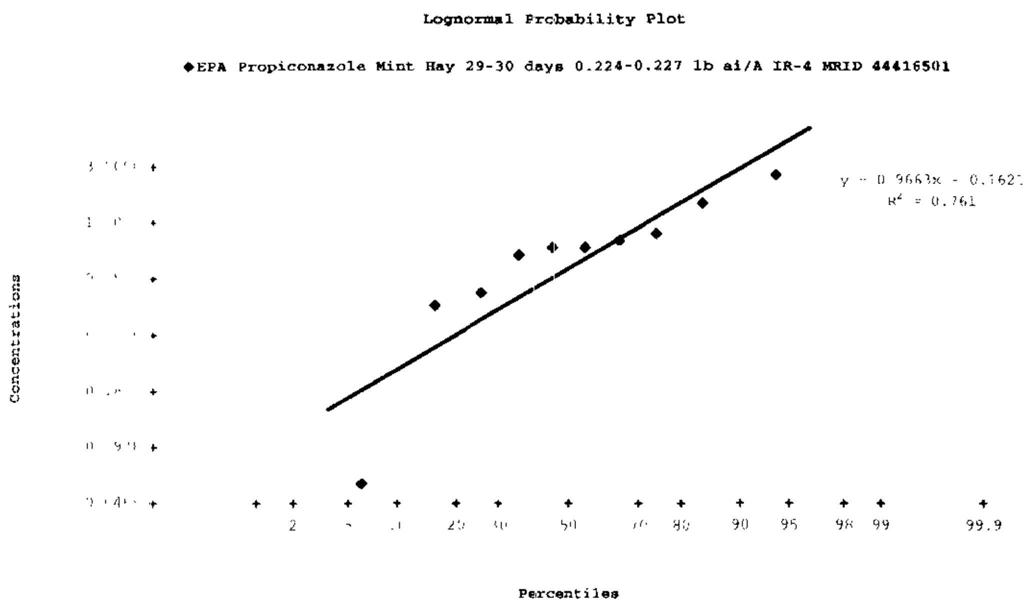

Figure II-46. Tolerance spreadsheet summary of propiconazole field trial data for mint following two broadcast foliar applications of propiconazole (EC).

	Regulator: EPA **Chemical:** Propiconazole **Crop:** Mint Hay **PHI:** 29-30 days **App. Rate:** 0.224-0.227 lb ai/A **Submitter:** IR-4 **MRID Citation:** MRID 44416501 **n:** 10 **min:** 0.06 **max:** 2.70 **median;** 1.10 **average:** 1.15		
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	2.5 (3.5)	3.0 (4.5)	3.5 (--)
EU Method I Log Normal	5.0 **(18)**	**10** (55)	25 (--)
EU Method II Distribution-Free	3.0		
California Method $\mu + 3\sigma$	**3.5**		
UPLMedian95th	**9.0**		
Approximate Shapiro-Francia Normality Test	0.7610 p-value <= 0.01: Reject lognormality assumption		

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED	Date: 07/06/06
	Yan Donovan	
Approved by	Susan Hummel, Chemist, RRB4/HED	Date: 07/06/06
	Susan Hummel	

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 6/27/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

46475301 Purdy, J. (2000) 12 Crop Residue Trials to Determine the Residues of CGA 279202, CGA 64250 and their Significant Crop Metabolites After Application of an Emulsifiable Concentrate Fomulation Containing Both Active Ingredients on Oats. Project Number: CER04406/98, 110899. Unpublished study prepared by Novartis Crop Protection Canada, Inc., Enviro-Test Laboratories and Ag-Quest Inc. 407 p.

EXECUTIVE SUMMARY:

In 12 field trials conducted in Canada during 1999, a multiple active ingredient EC formulation containing propiconazole at 1.04 lb ai/gal was applied to oats as two broadcast foliar applications at 58-71 g ai/ha/application for totals of 120-134 g ai/ha/season. These rates are equivalent to 0.052-0.063 lb ai/A/application and 0.11-0.12 lb ai/A/season. Applications were made to separate plots for either the collection of forage and hay or grain and straw. For the forage and hay plots, the applications were made at around tillering (BBCH 15-26) and flag leaf emergence (BBCH 37-39), at a retreatment interval (RTI) of 8-29 days. For the grain and straw plots, the applications were made around flag leaf emergence (BBCH 37-39) and heading through early flowering (BBCH 58-61), at RTIs of 10-20 days. All applications were made using ground equipment in volumes of 100 L/ha, and did not include the use of any adjuvants. Single control and duplicate treated samples of forage were harvested 29-31 days after treatment (DAT), hay was cut at 44-46 DAT, and grain and straw were harvested 38-83 DAT, with most grain and straw samples being collected from 42-55 DAT. At two sites, additional samples of forage were collected at 21, ~30 and ~37 DAT, and samples of hay were collected at ~37, 45 and ~52 DAT to assess residue decline. Samples were stored frozen for up to 5 months prior to analysis, an interval supported by available storage stability data.

Oat samples were analyzed both for residues of propiconazole, *per se*, and for the combined residues of propiconazole and its metabolites containing 2,4-dichlorobenzoic acid (DCBA), determined as DCBA. Residues of propiconazole were determined using a GC/MS method (REM 130.02), in which residues are extracted with aqueous methanol, partitioned into dichloromethane (DCM), and cleaned up using an alumina column. Residues are then analyzed by GC/MS using select ion monitoring (SIM) with external standards. The method limit of

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quantitation (LOQ) for propiconazole is 0.02 ppm, and the limit of detection LOD was not reported.

Total combined residues were determined using another GC/MS method (REM 3/86), which is similar to the current tolerance enforcement method. For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization. Residues of DCBA are then partitioned into DCM, methylated and analyzed by GC/MS-SIM, using external standards. Total residues are expressed in parent equivalents. The validated method LOQ is 0.04 ppm, and a LOD was not reported. Both methods were adequately validated prior to and in conjunction with the analysis of field trail samples.

The above methods were adequately validated for data collection.

Following two applications at tillering and flag leaf emergence, residues of propiconazole, *per se*, were <0.02-0.22 ppm in/on forage at ~30 DAT and <0.02-0.18 ppm in/on hay cut at ~45 DAT. Following two applications at flag leaf emergence and heading, residues of propiconazole, *per se*, were <0.02-0.022 ppm in/on grain and <0.02-0.43 ppm in/on straw harvested at maturity (38-83 DAT). Average propiconazole residues were 0.051 ppm for forage, 0.049 ppm for hay, 0.011 ppm for grain (<LOQ) and 0.090 ppm for straw. From the same tests, total combined residues were 0.04-1.00 ppm in/on forage, 0.09-2.50 ppm in/on hay, <0.04-0.21 ppm in/on grain, and 0.18-3.10 ppm in/on straw. Average combined residues were 0.44 ppm for forage, 1.02 ppm for hay, 0.10 ppm for grain and 1.09 ppm for straw.

In the two residue decline trails, residues of propiconazole declined over time in both forage and hay sampled from 21-53 DAT. Total combined residues also declined over time in hay, but remained relatively steady in forage.

The number of trials and the geographic representation of the trials are adequate for Canada. Not adequate for U.S. The data support the use of propiconazole (EC) on oats as two broadcast foliar applications at up to 62.5 g ai/ha/application from tillering through heading, for a total of 125 g ai/ha/season. The data support a minimum RTI of 14 days and PHIs of 30 days for forage and 45 days for hay, grain and straw.

<u>STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS</u>:

Under the conditions and parameters used in the study, the oat field trial data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited minor deviations from GLP compliance, pertaining to the collection of weather data, soil data, and the entry and correction of data in reports. None of these deviations affect the overall acceptability of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities, including permanent tolerances of 10 ppm for oat forage, 30 ppm for oat hay, 0.1 ppm for oat grain, and 1.0 ppm for oat straw [40 CFR §180.434(a)].

Syngenta has submitted at petition (PP#2F6371) proposing new tolerances and the use of propiconazole on a variety of cereal grains. The current submission includes residue data from oat field trials conducted in Canada.

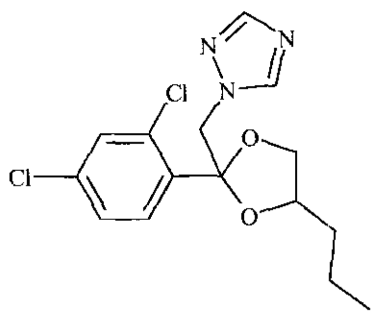
TABLE A.1. Nomenclature of Propiconazole	
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EPs	1.04 lb/gal EC (Stratego 250 EC; MAI containing both propiconazole and trifloxystrobin, each at 1.04 lb ai/gal)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.

Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK_a)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K_{OW})	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Oats was grown and maintained at each test site using typical agricultural practices for the various regions (Table B.1.1). Monthly rainfall and irrigation data were provided for each site, along with temperature data. No usual weather conditions were noted that would have an adverse effect on the field trial data. Information was provided on soil characteristics at each site, along with the maintenance chemicals and other pesticides used.

Four separate plots were established at each field site, two each for the collection of forage and hay or grain and straw (Table B.1.2). Propiconazole (1.04 lb/gal EC) was applied to all plots as two broadcast foliar applications at a target rate of 62.5 g ai/ha/application, for a total of 125 g ai/ha/season. Applications were made approximately at tillering (BBCH 21-29) and flag leaf emergence (BBCH 37-39) for the forage and hay plots, and at flag leaf emergence (BBCH 37-39) and heading (BBCH 58-61) for the grain and straw plots.

TABLE B.1.1. Trial Site Conditions.

Trial Identification (County, State; Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC[2] (meq/g)
Warner, AB 1999	Clay	3.2	7.7	NR
Warner, AB 1999	Clay Loam	3.2	7.7	NR
Rosthern, SK 1999	Clay Loam	5.5	6.0	24.1
Leask, SK 1999	Loam	7.1	7.0	30.4
Lacombe, AB 1999	Loam	8.7	5.9	30.4
Lacombe, AB 1999	Loam	5.4	5.9	24.2
Minto, MT 1999	Loam	5.6	7.7	26.1
Minto, MT 1999	Loam	7.7	7.4	28.9
Ailsa Craig, ON 1999	Silt Loam	3.9	7.7	21.4
London, ON 1999	Loam	4.6	6.6	18.5
Kemptville, ON 1999	Clay Loam	4.4	6.9	26.2
Havelock, NB 1999	Clay Loam	4.9	4.9	21.1

[1] These parameters are optional except in cases where their value affects the use pattern for the chemical.
[2] Cation exchange capacity.

TABLE B.1.2. Study Use Pattern on Oats

Location (County, State; Year) Trial ID	End-use Product [1]	Application Information [2]				
		Method; Timing	Volume (L/ha)	Single Rate [3] (g ai/ha)	RTI (days)	Total Rate [3] (g ai/ha)
Warner, AB 1999 1	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 22-23 and 37-39	100	61.7-62.7	10	123.9, 124.7
		Two broadcast foliar applications at BBCH stages 37-39 and 60	100	61.0-63.4	17	125.4, 123.1
Warner, AB 1999 2	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 22-23 and 37	100	61.1-63.1	10	123.2, 125.1
		Two broadcast foliar applications at BBCH stages 37 and 60	100	61.3-63.0	17	123.3, 125.8
Rosthern, SK 1999 3	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 22-23 and 37-39	100	61.3-63.3	8	124.7, 123.0
		Two broadcast foliar applications at BBCH stages 37-39 and 60-61	100	64.0-65.6	20	129.0, 130.4
Leask, SK 1999 4	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 22-23 and 37-39	100	62.3-67.5	9	126.9, 131.0
		Two broadcast foliar applications at BBCH stages 37-39 and 59-60	100	67.1-71.0	16	128.1, 128.3
Lacombe, AB 1999 5	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 22-23 and 37-39	100	61.9-62.5	10	124.3, 124.4
		Two broadcast foliar applications at 37-39 and 60	100	61.8-62.7	20	124.5, 124.4
Lacombe, AB 1999 6	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 22-23 and 37-39	100	62.4-62.8	11	125.4, 124.6
		Two broadcast foliar applications at BBCH stages 37-39 and 60	100	61.6-62.1	11	123.8, 12.4
Minto, MT 1999 7	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 21-22 and 37	100	62.7-64.2	18	125.6, 127.8
		Two broadcast foliar applications at BBCH stages 37 and 59-60	100	62.7-64.3	14	126.0, 127.4
Minto, MT 1999 8	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 21-22 and 37-39	100	62.3-63.8	15	126.7, 126.1
		Two broadcast foliar applications at BBCH stages 37-39 and 59-60	100	62.7-64.2	13	126.1, 128.0
Alisa Craig, ON 1999 9	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 16-26 and 30-55	100	62.4-71.1	10	133.5, 133.1
		Two broadcast foliar applications at BBCH stages 30-55 and 59-60	100	57.6-65.3	11	122.9, 119.9
London, ON 1999 10	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 15-25 and 32-47	100	60.5-65.1	13	12.51, 127.0
		Two broadcast foliar applications at BBCH stages 32-47 and 50-60	100	60.8-63.2	13	123.1, 125.0
Kemptville, ON 1999 11	1.04 lb/gal EC	Two broadcast foliar applications at 21-25 and 37-45	100	64.5-68.8	9	133.3, 132.9
		Two broadcast foliar applications at BBCH stages 37-45 an 58-60	100	58.9-66.8	14	130.2, 125.7
Havelock, NB 1999 12	1.04 lb/gal EC	Two broadcast foliar applications at 22-23 and 37-60	100	61.5-67.8	29	126.0, 133 0
		Two broadcast foliar applications at BBCH stages 37-60 and 60-69	100	59.7-66.6	10	125.3, 132.1

1. The end-use product was a multiple active ingredient formulation (EC) containing both propiconazole and trifloxystrobin, each at 1.04 lb ai/gal.
2. All applications were made using ground equipment, and no adjuvants were included in the spray mixture.
3. The single application rates of 57.6.0-71.1 g ai/ha are equivalent to 0.051-0.063 lb ai/A, and the total rates of 119.9-133.5 g ai/ha are equivalent to 0.11-0.12 lb ai/A.

TABLE B.1.3.	Trial Numbers and Geographical Locations.		
NAFTA Growing Zones[1]	*Oats*		
	Submitted	Requested	
		Canada	U.S.
1	1	1	1
2	---	---	1
3	---	---	---
4	---	---	---
5	2	1	9
5A	---	1	NA
5B	1	1	NA
6	---	---	1
7	2	2	3
8	---	---	1
9	---	---	---
10	---	---	---
11	---	---	---
12	---	---	---
13	---	---	---
14	6	10	---
Total	12	16	16

NA = not applicable.

B.2. Sample Handling and Preparation

Single control samples and duplicate treated samples of oat forage, hay, grain and straw (~0.5-3 kg/sample) were harvested from each test at 29-31 DAT for forage and 44-46 DAT for hay. Grain and straw samples were harvested at maturity, 29-83 DAT, with most samples being harvested from 42-55 DAT. At two sites, additional samples of forage were collected at 21, 29/31 and 37/38 DAT, and samples of hay were collected at 37/38, 45 and 52/53 DAT to assess residue decline. Samples of forage, grain and straw were frozen shortly after harvest, and samples of hay were allowed to dry under ambient conditions to moisture contents of 10-20% prior to being placed in frozen storage at -10°C. The exact drying intervals for hay were not reported, but the study authors noted that hay from Sites 3 and 4 were dried for 52-57 days, which was longer than normal practices. Samples were stored at -10°C until shipment on dry ice to the analytical laboratory, Enviro-Test Laboratories (Edmonton, AB), where samples were stored at -20°C until analysis.

B.3. Analytical Methodology

Samples were analyzed both for residues of propiconazole, *per se*, and for the combined residues of propiconazole and its DCBA-containing metabolites, determined as DCBA. Residues of propiconazole were determined using a GC/MS method (REM 130.02), and total combined residues were determined using another GC/MS method (REM 3/86). Method REM 3/86 converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For Method REM 130.02, residues were extracted with methanol:water (80:20), salinized, and partitioned into DCM. Residues were then filtered through anhydrous sodium sulfate, concentrated to dryness, and redissolved in hexane. Residues were further purified using an alumina column washed with hexane:methyl t-butyl ether (80:20) and then eluted with methyl t-butyl ether. Residues of propiconazole were then determined by GC/MS using select ion monitoring (SIM) of the m/z 239 and 173 ions with external standards. The method LOQ is 0.02 ppm, and the LOD was not reported.

For Method REM 3/86, oat samples were refluxed in methanol/ammonium hydroxide (80:20) for 30 minutes, concentrated and oxidized by refluxing with basic $KMnO_4$ for 20 minutes. Residues were then acidified, partitioned into DCM, dried through sodium sulfate and concentrated. Residues of DCBA were then methylated with diazomethane, and analyzed by GC/MS-SIM using the m/z 204, 175 and 144 ions with external standards. The method LOQ for each matrix is 0.04 ppm, and the LOD was not reported.

In conjunction with the analysis of field trial samples, the above GC/MS methods were validated using control samples fortified with propiconazole or DCBA at 0.02-0.8 ppm.

C. RESULTS AND DISCUSSION

In 12 field trials conducted in Canada during 1999, propiconazole (1.04 lb/gal EC) was applied to oats as two broadcast foliar applications at 57.6-71.1 g ai/ha/application for totals of 119.9-133.5 g ai/ha/season. Applications were made to separate plots for either the collection of forage and hay or grain and straw. For the forage and hay plots, the applications were made around tillering (BBCH 15-26) and flag leaf emergence (BBCH 37-39), at RTIs of 8-29 days. For the grain and straw plots, the applications were made around flag leaf emergence (BBCH 37-39) and heading through early flowering (BBCH 58-61), at RTIs of 10-20 days. All applications were made using ground equipment in volumes of 100 L/ha, and did not include the use of any adjuvants. Single control and duplicate treated samples of forage were harvested 29-31 DAT, hay was cut at 44-46 DAT, and grain and straw were harvested 38-83 DAT. At two sites, additional samples of forage were collected at 21, ~30 and ~37 DAT, and samples of hay were collected at ~37, 45 and ~52 DAT to assess residue decline.

The GC/MS methods used to determine either residues of propiconazole (REM 130.02) or total combined residues including DCBA-containing metabolites (REM 3/86) in/on hay, forage, grain and straw were adequately validated prior to and in conjunction with the analysis of field trial samples. For Method REM 130.02, method validation recoveries averaged 82-108% from the four matrices, with standard deviations of 5-12%, and concurrent method recoveries averaged 79-95%, with standard deviations of 7-10% (Table C.1). Apparent residues of propiconazole were <LOQ on all control samples. The validated method LOQ for propiconazole is 0.02 ppm, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided.

For Method REM 3/86, method validation recoveries for DCBA averaged 80-99% from the four matrices, with standard deviations of 10-14%, and concurrent method recoveries averaged 90-107%, with standard deviations of 15-22% (Table C.1). Apparent combined residues were <LOQ on all control samples. The validated method LOQ for DCBA is 0.04 ppm, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided.

Samples of oat matrices were stored frozen (<-10°C) for up to 5 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating that the residues of propiconazole and its metabolites are stable at -20° C for up to 38 months in grass forage, straw and seed (DP Barcode D279300, Y. Donovan, 8/18/05). As these matrices are similar to oat matrices, these data will support the storage intervals and conditions for the oat field trials. Although several extracts from straw, used for analysis of DCBA, were stored for >30 days, data are also available from corn forage and soybeans indicating that residues are stable in extracts at 4°C for at least 3 months.

TABLE C.1. Summary of Method Validation and Concurrent Recoveries of Propiconazole from Oat Matrices.

Matrix	Analyte	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Method Validation Recoveries					
Forage	Propiconazole	0.02-0.2	6	109, 107, 85, 81, 86, 95	94 ± 12
	DCBA	0.04-0.8	6	73, 63, 74, 85, 93, 94	80 ± 12
Hay	Propiconazole	0.02-0.2	6	75, 85, 76, 80, 89, 88	82 ± 6
	DCBA	0.04-0.8	6	84, 67, 98, 101, 73, 85	85 ± 13
Grain	Propiconazole	0.02-0.2	6	118, 107, 110, 114, 100, 100	108 ± 7
	DCBA	0.02-0.4	6	97, 88, 81, 97, 115, 117	99 ± 14
Straw	Propiconazole	0.02-0.2	6	96, 91, 87, 93, 99, 98	94 ± 5
	DCBA	0.04-0.8	6	92, 65, 88, 91, 88, 81	84 ± 10
Concurrent Method Recoveries					
Forage	Propiconazole	0.02-0.1	8	97, 82, 82, 71, 80, 89, 75, 90	83 ± 8
	DCBA	0.04-0.5	11	72, 72, 98, 80, 71, 105, 88, 106, 97, 110, 89, 11[1]	90 ± 15
Hay	Propiconazole	0.02-0.2	7	72, 71, 80, 72, 82, 79, 87, 91	79 ± 7
	DCBA	0.04-0.5	11	104, 87, 80, 120, 72, 82, 83, 120, 82, 110, 65, 33[1]	91 ± 19
Grain	Propiconazole	0.02-0.1	6	110, 87, 90, 102, 88, 93	95 ± 9
	DCBA	0.04-0.5	8	73, 84, 118, 131, 115, 131, 111, 89	107 ± 22
Straw	Propiconazole	0.02-0.2	6	102, 82, 89, 77, 74, 92	86 ± 10
	DCBA	0.04-0.5	8	65, 80, 102, 76, 104, 99, 104, 119	94 ± 18

[1] Statistical outlier not included in calculation of average and standard deviation.

TABLE C.2. Summary of Storage Conditions for Oat Matrices.

Matrix	Storage Temperature (°C)	Actual Storage Duration [1] (months)	Interval of Demonstrated Storage Stability (months) [2]
Forage	-20	5	38
Hay			
Grain			
Straw			

1 From harvest to extraction for analysis. Samples were analyzed for parent within 2-12 days of extraction and for total combined residues (DCBA) within 2-38 days of extraction.
2 DP Barcode: D279300, Y. Donovan, 8/18/05.

Following two applications of propiconazole (EC) to oats at tillering and flag leaf emergence at rates totaling 123-134 g ai/ha (0.11-0.12 lb ai/A), residues of propiconazole, *per se*, were <0.02-0.22 ppm in/on 24 samples of forage at ~30 DAT and <0.02-0.18 ppm in/on 24 samples of hay cut at ~45 DAT (Table C.3). Following two applications at flag leaf emergence and heading at rates totaling 120-132 g ai/ha, residues of propiconazole, *per se*, were <0.02-0.022 ppm in/on 24 samples of grain and <0.02-0.43 ppm in/on 24 samples of straw harvested at maturity (38-83 DAT). Average propiconazole residues were 0.051 ppm for forage, 0.049 ppm for hay, 0.011 ppm for grain (<LOQ) and 0.090 ppm for straw (Table C.4.1). Although samples of hay from Sites 3 and 4 were allowed to dry for longer intervals (~50 days) than normal, residues in hay samples from these sites were similar to residues from the remaining ten sites.

From the same tests, total combined residues were 0.04-1.00 ppm in/on forage, 0.09-2.50 ppm in/on hay, <0.04-0.21 ppm in/on grain, and 0.18-3.10 ppm in/on straw. Average combined residues were 0.44 ppm for forage, 1.02 ppm for hay, 0.10 ppm for grain and 1.09 ppm for straw.

In the two residue decline trails, average residues of propiconazole declined in forage from 0.08 ppm at 21 DAT to 0.02 ppm by 37 DAT, and average parent residues declined slightly in hay from 0.04 ppm at 37 DAT to 0.02 ppm at 52 DAT (Table C.4.2; Figure C.1). Average combined residues in forage remained relatively steady at 0.62-0.75 ppm from 21-53 DAT, but average combined residues in hay decreased steadily from 1.43 ppm at 37 DAT to 0.74 ppm by 53 DAT (Figure C.2).

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data

TABLE C.3. Residue Data for Propiconazole and Total Combined Residues on Oat Forage, Hay, Grain and Straw.

Trial ID (County, State; Year)	Zone	Variety	Total Rate (lb ai/A) [1]	Commodity	PHI (days)	Residues (ppm) [2] Propiconazole	Residues (ppm) [2] Total
Warner, AB 1999 1	7	Foothills	123.9, 124.7	Forage	30	0.14, 0.17	0.55, 0.64
				Hay	46	0.18, 0.14	1.4, 0.95
			125.4, 123.1	Grain	40	<0.02, <0.02	0.039, 0.066
				Straw		0.43, 0.18	2.6, 1.4
Warner, AB 1999 2	7	Foothills	123.2, 125.1	Forage	30	0.13, 0.11	0.60, 0.043
				Hay	46	0.12, 0.12	1.1, 1.4
			123.3, 125.8	Grain	42	<0.02, <0.02	<0.04, 0.040
				Straw		0.17, 0.034	0.88, 0.91
Rosthern, SK 1999 3	14	Boyer	124.7, 123.0	Forage	29	0.22, <0.02	0.22, 0.20
				Hay	44	0.023, <0.02	0.93, 0.37
			129.0, 130.4	Grain	42	0.021, 0.021	0.20, 0.19
				Straw		0.19, 0.15	0.97, 0.71
Leask, SK 1999 4	14	Boyer	126.9, 131.0	Forage	21	0.10, 0.15	0.51, 0.52
					29	0.039, 0.062	0.33, 0.44
					37	0.030, 0.019	0.58, 0.41
				Hay	37	0.051, 0.056	1.6, 1.8
					44	0.10, 0.079	1.8, 1.8
					53	0.021, 0.034	1.1, 1.4
			128.1, 128.3	Grain	55	<0.02, <0.02	0.026, 0.068
				Straw		0.029, 0.041	0.34, 0.58
Lacombe, AB 1999 5	14	CDC Boyer	124.3, 124.4	Forage	31	<0.02, <0.02	0.33, 0.36
				Hay	45	<0.02, <0.02	0.87, 0.61
			124.5, 124.4	Grain	56	0.022, <0.02	0.066, 0.032
				Straw		0.11, 0.076	3.1, 2.6
Lacombe, AB 1999 6	14	CDC Boyer	125.4, 124.6	Forage	31	0.064, 0.076	0.72, 0.66
				Hay	44	0.073, 0.064	1.4, 1.0
			123.8, 124.6	Grain	83	<0.02, <0.02	0.084, 0.11
				Straw		<0.02, <0.02	0.39, 0.50
Minto, MT 1999 7	14	AC Assiniboia	125.6, 127.8	Forage	30	0.046, 0.025	0.20, 0.23
				Hay	45	0.041, 0.044	1.4, 1.3
			126.0, 127.4	Grain	38	<0.02, <0.02	0.049, 0.16
				Straw		0.14, 0.098	1.3, 1.0
Minto, MT 1999 8	14	Paisley	126.7, 126.1	Forage	30	<0.02, <0.02	0.18, 0.17
				Hay	45	0.026, 0.026	0.98, 0.65
			126.1, 128.0	Grain	39	<0.02, <0.02	0.028, 0.053
				Straw		0.050, 0.16	1.6, 1.1
Alisa Craig, ON 1999 9	5	Paisley	133.5, 133.1	Forage	21	0.021, 0.036	0.96, 0.99
					31	<0.02, 0.031	0.71, 1.0
					38	<0.02, 0.026	0.77, 0.95
				Hay	38	0.023, 0.029	0.91, 1.4
					45	<0.02, <0.02	0.59, 0.32
					52	<0.02, <0.02	0.18, 0.26
			122.9, 119.9	Grain	55	<0.02, <0.02	0.18, 0.10
				Straw		0.035, 0.034	1.2, 0.78
London, ON 1999 10	5	Paisley	125.1, 127.0	Forage	30	<0.02, <0.02	0.46, 0.42
				Hay	44	<0.02, <0.02	1.3, 1.3
			123.1, 125.0	Grain	49	<0.02, <0.02	0.086, 0.10
				Straw		<0.02, <0.02	0.38, 0.73

TABLE C.3. Residue Data for Propiconazole and Total Combined Residues on Oat Forage, Hay, Grain and Straw.

Trial ID (County, State, Year)	Zone	Variety	Total Rate (lb ai/A) [1]	Commodity	PHI (days)	Residues (ppm) [2]	
						Propiconazole	Total
Kemptville, ON 1999 11	5B	Paisley	133.3, 132.9	Forage	29	<0.02, <0.02	0.37, 0.36
				Hay	44	<0.02, <0.02	0.24, 0.19
			130.2, 125.7	Grain	42	<0.02, <0.02	0.12, 0.21
				Straw		0.040, 0.040	1.1, 1.5
Havelock, NB 1999 12	1	not reported	126.0, 133.0	Forage	30	<0.02, <0.02	0.57, 0.88
				Hay	46	0.033, 0.023	0.094, 2.5
			125.3, 132.1	Grain	57	<0.02, <0.02	0.16, 0.21
				Straw		0.057, 0.054	0.18, 0.26

1 Total rates are equivalent to 0.11-0.12 lb ai/A of propiconazole.

2 Residues of propiconazole, per se, were determined using GC/MS Method REM 130.02, and total combined residues were determined as methyl-DCBA and expressed in parent equivalents using GC/MS Method 3/86. For each matrix, the validated method LOQ is 0.02 ppm for propiconazole, and 0.04 ppm for combined residues. LODs were not reported.

TABLE C.4.1 Summary of Residue Data from Oat Field Trials with Propiconazole (EC)

Commodity	Total Applic. Rate (g ai/ha) [1]	PHI (days)	Residue Levels (ppm) [2]						
			n	Min.	Max.	HAFT[3]	Median (STMdR)[4]	Mean (STMR)[4]	Std. Dev.
Propiconazole Residues									
Forage	123.0-133.5	29-31	24	<0.02	0.220	0.155	0.018	0.051	0.060
Hay		44-46	24	<0.02	0.180	0.160	0.025	0.049	0.050
Grain	119.9-132.1	38-83	24	<0.02	0.022	0.021	0.010	0.011	0.004
Straw			24	<0.02	0.430	0.305	0.052	0.090	0.094
Total Combined Residues									
Forage	123.0-133.5	29-31	24	0.04	1.00	0.86	0.40	0.44	0.24
Hay		44-46	24	0.09	2.50	1.80	0.99	1.02	0.58
Grain	119.9-132.1	38-83	24	<0.04	0.21	0.20	0.09	0.10	0.06
Straw			24	0.18	3.10	2.85	0.94	1.09	0.76

1 Total rates are equivalent to 0.11-0.12 lb ai/A of propiconazole.

2 The validated method LOQs are 0.02 ppm for propiconazole and 0.04 ppm for combined total residues. For calculation of the median, mean and standard deviation, ½LOQ (0.01 or 0.02 ppm) was used for samples with residues <LOQ.

3 HAFT = Highest Average Field Trial.

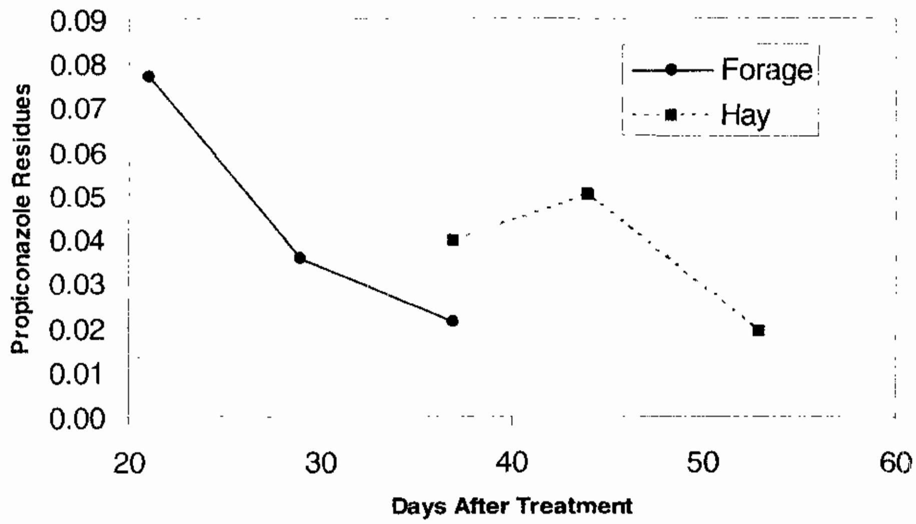
4 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

TABLE C.4.2 Summary of Residue Decline Data from Oat Field Trials with Propiconazole (EC).

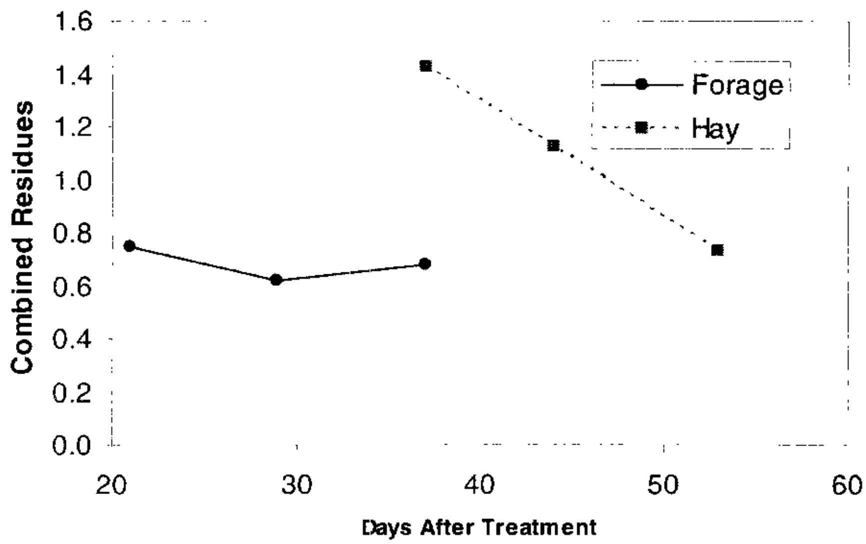
Commodity	Total Applic. Rate (g ai/ha)	PHI (days)	Residue Levels (ppm)[1]						
			n	Min.	Max.	HAFT[2]	Median (STMdR)[3]	Mean (STMR)[3]	Std. Dev.
Propiconazole Residues									
Forage	119.1-131.0	21	4	0.021	0.150	0.125	0.068	0.077	0.060
		29	4	<0.02	0.062	0.051	0.035	0.036	0.021
		37	4	<0.02	0.030	0.025	0.023	0.021	0.009
Hay	119.1-131.0	37	4	0.023	0.056	0.054	0.040	0.040	0.016
		44	4	<0.02	0.100	0.090	0.045	0.050	0.047
		53	4	<0.02	0.034	0.028	0.016	0.019	0.011
Total Combined Residues									
Forage	119.1-131.0	21	4	0.51	0.99	0.98	0.74	0.75	0.27
		29	4	0.33	1.00	0.86	0.58	0.62	0.30
		37	4	0.41	0.95	0.86	0.68	0.68	0.23
Hay	119.1-131.0	37	4	0.91	1.80	1.70	1.50	1.43	0.38
		44	4	0.32	1.80	1.80	1.20	1.13	0.78
		53	4	0.18	1.40	1.25	0.68	0.74	0.61

[1] The validated method LOQs are 0.02 ppm for propiconazole and 0.04 ppm for combined total residues. For calculation of the median mean and standard deviation, ½LOQ (0.01 or 0.02 ppm) was used for samples with residues <LOQ.
[2] HAFT = Highest Average Field Trial.
[3] STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

Figures C.1. Decline of Parent Residues in Forage and Hay.



Figures C.1. Decline of Total Combined Residues in Forage and Hay.



D. CONCLUSION

The oat field trials are adequate and support the use of propiconazole (EC) on oats as two broadcast foliar applications at up to 62.5 g ai/ha/application at up to heading, for a total of 125 g ai/ha/season. The data support a minimum RTI of 14 days and PHIs of 30 days for forage and 45 days for hay, grain and straw.

E. REFERENCES

DP Barcode:	D279300
Subject:	Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From:	Y. Donovan
To:	S. Lewis/J. Guerry
Dated:	8/18/05
MRID:	None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4, HED
Petition Number(s): 2F6371
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, HED/RRB4 Yan Donovan	Date: 5/31/06
Approved by	Susan Hummel, Senior Scientist, RRB4/HED Susan Hummel	Date: 5/31/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B. Durham, NC 27713; submitted 4/28/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

43640401 Ross, J.A. (1994) Propiconazole – Magnitude of Residues in Wheat and Raw Agricultural commodities and Processed Fractions of Rotational Grain Sorghum and Alfalfa Following application of Tilt® 3.6 E to Wheat: Lab Project Number: ABR-92089. Unpublished study prepared by Ciba-Geigy Corporation. 885 p.

EXECUTIVE SUMMARY:

In a field trial study conducted during 1989 in TX, propiconazole (3.6 lb/gal EC) was applied to a primary crop of winter wheat as a single broadcast foliar application in the spring at flag leaf emergence at 0.11, 0.33, or 0.55 lb ai/A (1x, 3x and 5x rates). The wheat was grown to maturity and harvested, and a rotational crop of sorghum was planted 67 days after treatment (DAT). Mature sorghum grain was then harvested 110 days after planting (DAP), 177 DAT. Following harvest, whole grain was processed by dry-milling into flour using simulated commercial practices. Prior to analysis, whole grain and flour were stored frozen up to 35 months, an interval supported by the available storage stability data.

Residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in sorghum grain and processed fractions were determined using a GC/ECD method (Method AG-454 B). This method is an updated version of the current tolerance enforcement method and was adequately validated in conjunction with the analysis of field trial samples. The validated method LOQ is 0.05 ppm, and an LOD was not reported.

Following an application of propiconazole (3.6 lb/gal EC) to a primary crop of winter wheat at 0.11 or 0.33 lb ai/A (1x or 3x), residues were <0.05 ppm in grain and flour from sorghum planted at a 67-day PBI. For the application at 0.55 lb ai/A (5x), residues were <0.05-0.06 ppm in sorghum grain and <0.05 ppm in sorghum flour. The data indicate that residues do not concentrate in flour from sorghum grain grown in rotation with propiconazole-treated wheat. The sorghum processing study are considered adequate.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

C

Under the conditions and parameters used in the study, the rotational sorghum processing data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study authors noted numerous minor deviations from GLP compliance at the test site, including the collection of weather data and descriptions of the field plot. However, these deviations do not impact the validity of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides board spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities, including time-limited tolerances of 0.2 and 1.5 ppm on sorghum grain and stover [40 CFR §180.434(b)].

Syngenta has previously proposed tolerances (PP# 5F4498) for inadvertent residues on sorghum and alfalfa planted in rotation with propiconazole-treated wheat. This petition has been superseded by PP#2F6371, in which tolerances are being requested on a wide variety of crops including wheat and sorghum (DP Barcode D279300, Y. Donovan, 8/18/2005).

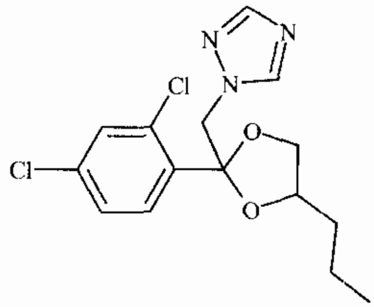
TABLE A.1.	Nomenclature of Propiconazole
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EP	3.6 lb/gal EC (Tilt Fungicide, EPA Reg. No. 100-617)
Regulated Metabolite	None
Common name	N/A
IUPAC name	N/A
CAS #	N/A

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.

Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No.:43698701
pH	4.9 @ 25°C (1% aqueous tdispersion)	MRID No.:43698701
Density	1.289 g/cm3 typical @ 20°C	MRID No.: 43698701
Water solubility (20°C)	0.10 g/L at 20°C	MRID No.: 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. n-hexane = 47 g/L	MRID No.: 42030201
Vapor pressure at 25°C	4.2 x 10^{-7} mm Hg @ 25°C	MRID No.: 41720301
Dissociation constant (pK_a)	1.09	MRID No.: 43698701
Octanol/water partition coefficient Log(K_{OW}) (25 °C)	3.72 @ pH 6.6	MRID No.: 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No.: 40583703

B. EXPERIMENTAL DESIGN

B.1. Application and Crop Information

Propiconazole (EC) was applied to a primary crop of winter wheat at 0.11, 0.33, or 0.55 lb ai/A (Table B.1.1). The wheat was grown to maturity and harvested following common agricultural practices, and a rotational crop of sorghum was planted in each plot at 67 DAT.

TABLE B.1.1. Study Use Pattern on Primary Crop of Winter Wheat.

Location (County, State: Year) Trial ID	End-use Product	Application to Primary Wheat Crop					Tank Mix/ Adjuvants
		Method; Timing	Volume (gal/A)	Rate (lb ai/A)	PBI [1] (days)	Total Rate (lb ai/A)	
Burleson, TX, 1989 0S-FR-203-89	3.6 lb/gal EC	Single broadcast foliar application at Feekes Growth Stage 8	15	0.110	67	0.110	none
				0.330		0.330	
				0.550		0.550	

[1] PBI = plant-back interval.

B.2. Sample Handling and Processing Procedures

Single bulk samples of control and treated sorghum grain were harvested at normal crop maturity, 110 DAP. Samples were shipped frozen via overnight courier to the Food Protein R&D Center, Texas A&M University System, College Station, TX for processing. Grain was processed by dry-milling into flour using simulated commercial practices. After collection, samples were placed in frozen storage and shipped on dry ice to Ciba-Geigy (Greensboro, NC), where samples were stored at -20EC and prepared for analysis. Samples were later shipped frozen the analytical laboratory (EPL-BioAnalytical Services, Harristown, IL), where samples were stored frozen prior to analysis.

B.3. Analytical Methodology

Samples of sorghum grain and flour were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-454B), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, residues are extracted and base hydrolyzed by refluxing for 1 hour with NH_4OH/MeOH (20:80, v/v) and filtered. Residues are concentrated and oxidized to 2,4-DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, sodium meta-bisulfite is added to deactivate the $KMnO_4$, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using diazomethane. Residues are then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and analyzed by GC/ECD, using external standards. The validated method LOQ is 0.05 ppm for residues in/on wheat forage, and an LOD was not reported.

In conjunction with the analysis of field trial samples, the above method was validated using control samples of sorghum grain and flour fortified with propiconazole at 0.05-5.0 ppm.

C. RESULTS AND DISCUSSION

The GC/ECD method (Method AG-454 B) used to determine propiconazole residues in/on sorghum grain and flour was adequately validated in conjunction with the analysis of treated samples. Recoveries averaged 81 ± 19% from control samples of grain fortified with propiconazole at 0.05-0.20 ppm, 71% from grain (processor) fortified at 0.05 and 0.20 ppm, and 78% from flour fortified at 0.05-0.10 ppm. Apparent residues of propiconazole were <LOQ in/on all control samples. The validated method LOQ for propiconazole is 0.05 ppm, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided.

Prior to analysis, sorghum flour and grain were stored frozen for up to 35 months (Table C.2.). Adequate storage stability data are available indicating the weathered residues of propiconazole and its metabolites are stable for up to 38 months at -20° C in grass straw and seed (DP Barcode D210742, 3/15/95, M. Rodriguez). These data will support the storage intervals and conditions for the sorghum processing study.

Following an application of propiconazole (3.6 lb/gal EC) to a primary crop of winter wheat at 0.11 or 0.33 lb ai/A (1x or 3x), residues were <0.05 ppm in grain and flour from sorghum planted at a 67-day PBI (Table C.3). For the application at 0.55 lb ai/A (5x), residues were <0.05-0.06 ppm in sorghum grain and <0.05 ppm in sorghum flour.

TABLE C.1.	Summary of Concurrent Recoveries of Propiconazole from Sorghum Grain and Flour Using GC/ECD Method AG-454 B.			
Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Grain	0.05-0.20	12	81, 79, 70, 59, 86, 55, 72, 83, 89, 83, 90, 130	81 ± 19
Whole Grain (from processor)	0.05, 0.20	2	61, 80	71
Flour	0.05, 0.10	2	73, 83	78

TABLE C.2. Summary of Storage Conditions.			
Matrix (Extract)	Storage Temperature (°C)	Actual Storage Duration (Months) [1]	Interval of Demonstrated Storage Stability (days) [2]
Sorghum flour/whole grain	-20	35	38

[1] From harvest to extraction for analysis.
[2] DP Barcode D210742, 3/15/95, M. Rodriguez.

TABLE C.3.	Residue Data from Processing Study with Sorghum Grown in Rotation with Propiconazole-treated Wheat.					
RAC	Processed Commodity	Total Rate [1] (lb ai/A)	Harvest Interval DAT [2]	Harvest Interval DAP [3]	Residues (ppm)	Processing Factor
Sorghum	Grain (from field)	0.110	177	110	<0.05, <0.05	NA
		0.330	177	110	<0.05, <0.05	
		0.550	177	110	<0.05, 0.06	
	Grain (from processor)	0.110	177	110	<0.05	NA
		0.330	177	110	<0.05	
		0.550	177	110	<0.05	
	Flour	0.110	177	110	<0.05	NA
		0.330	177	110	<0.05	
		0.550	177	110	<0.05	

[1] Rate applied to primary crop of winter wheat.
[2] DAT = days after treatment.
[3] DAP = days after planting.
NA = not applicable

D. CONCLUSION

The sorghum processing data are adequate and indicate that residues do not concentrate in flour from sorghum grain grown in rotation with propiconazole-treated wheat.

E. REFERENCES

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

DP Barcode: D279300
Subject: Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From: Y. Donovan
To: S. Lewis/J. Guerry
Dated: 8/18/05
MRID: None

F. DOCUMENT TRACKING

RDI: Yan Donovan
Petition Number(s): 5F4498 (superseded by PP#2F6371)
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, HED/RRB4 Yan Donovan	Date: 5/31/06
Approved by	Susan Hummel, Branch Senior Scientist, HED/RRB4 Susan Hummel	Date: 5/31/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 4/28/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

43640401 Ross, J.A. (1994) Propiconazole – Magnitude of Residues in Wheat and Raw Agricultural commodities and Processed Fractions of Rotational Grain Alfalfa and Alfalfa Following application of Tilt® 3.6 E to Wheat: Lab Project Number: ABR-92089. Unpublished study prepared by Ciba-Geigy Corporation. 885 p.

EXECUTIVE SUMMARY:

In a field trial study conducted during 1989 in NE, propiconazole (3.6 lb/gal EC) was applied to a primary crop of winter wheat in the spring as a single broadcast foliar application at flag leaf emergence at 0.11, 0.33, or 0.55 lb ai/A (1x, 3x and 5x rates). The wheat was grown to maturity and harvested following common agricultural practices, and a rotational crop alfalfa was planted 77 days after treatment (DAT). Alfalfa hay was harvested the following spring (380 DAT) and processed into meal and pellets using simulated commercial practices. Prior to analysis, hay meal and pellets were stored frozen up to 27 months, an interval supported by the available storage stability data.

Residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in alfalfa hay, meal and pellets were determined using a GC/ECD method (Method AG-454 B). This method is an updated version of the current tolerance enforcement method and was adequately validated in conjunction with the analysis of field trial samples. The validated method LOQ is 0.05 ppm, and an LOD was not reported.

Following an application of propiconazole (3.6 lb/gal EC) to a primary crop of winter wheat at 0.11 or 0.33 lb ai/A (1x or 3x), residues were <0.05 ppm in hay, meal and pellets from alfalfa planted at a 77-day PBI. For the application at 0.55 lb ai/A (5x), residues were <0.05 ppm in alfalfa hay and meal and 0.06 ppm in pellets, indicating the potential for possible concentration of residue at 1.2x in pellets.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the alfalfa processing data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study authors noted numerous minor deviations from GLP compliance at the test site, including the collection of weather data and descriptions of the field plot. However, these deviations do not impact the validity of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities [40 CFR §180.434].

Syngenta has previously proposed tolerances (PP# 5F4498) for inadvertent residues on sorghum and alfalfa planted in rotation with propiconazole-treated wheat. This petition has been superseded by PP#2F6371, in which tolerances are being requested on a wide variety of crops (DP Barcode D279300, Y. Donovan, 8/18/2005).

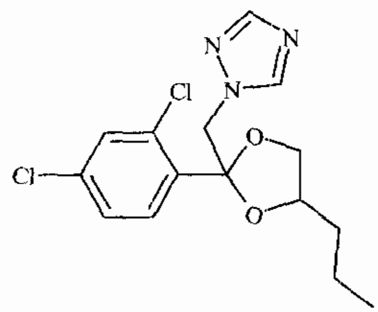
TABLE A.1.	**Nomenclature of Propiconazole**
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EP	3.6 lb/gal EC (*Tilt Fungicide*, EPA Reg. No. 100-617)
Regulated Metabolite	None
Common name	N/A
IUPAC name	N/A
CAS #	N/A

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.

Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No.:43698701
pH	4.9 @ 25°C (1% aqueous tdispersion)	MRID No.:43698701
Density	1.289 g/cm3 typical @ 20°C	MRID No.: 43698701
Water solubility (20°C)	0.10 g/L at 20°C	MRID No.: 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. n-hexane = 47 g/L	MRID No.: 42030201
Vapor pressure at 25°C	4.2×10^{-7} mm Hg @ 25°C	MRID No.: 41720301
Dissociation constant (pK_a)	1.09	MRID No.: 43698701
Octanol/water partition coefficient $Log(K_{OW})$ (25 °C)	3.72 @ pH 6.6	MRID No.: 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No.: 40583703

B. EXPERIMENTAL DESIGN

B.1. Application and Crop Information

Propiconazole (EC) was applied to a primary crop of winter wheat at 0.11, 0.33, or 0.55 lb ai/A (Table B.1.1). The wheat was grown to maturity and harvested following common agricultural practices, and a rotational crop of alfalfa was planted in each plot at 77 DAT.

TABLE B.1.1. Study Use Pattern on Primary Crop of Winter Wheat.

Location (County, State; Year) Trial ID	End-use Product	Application to Primary Wheat Crop					Tank Mix/ Adjuvants
		Method; Timing	Volume (gal/A)	Rate (lb ai/A)	PBI [1] (days)	Total Rate (lb ai/A)	
York, NE, 1989 MW-FR-602-89	3.6 lb/gal EC	Single broadcast foliar application at Feekes Growth Stage 8	20	0.110	77	0.110	none
				0.330		0.330	
				0.550		0.550	

[1] PBI = plant-back interval.

B.2. Sample Handling and Processing Procedures

Single bulk samples of control and treated alfalfa hay were harvested at normal crop maturity, 303 DAP Samples were shipped frozen via air express to the Food Protein R&D Center, Texas A&M University System, College Station, TX, where the hay was processed into meal and pellets using simulated commercial practices. After collection, samples were placed in frozen storage and shipped on dry ice to Ciba-Geigy (Greensboro, NC), where samples were stored at -20EC and prepared for analysis. Samples were later shipped frozen the analytical laboratory (EPL-BioAnalytical Services, Harristown, IL), where samples were stored frozen prior to analysis.

B.3. Analytical Methodology

Samples of alfalfa hay, meal and pellets were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-454B), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2.4-DCBA and expressed in parent equivalents.

For this method, residues are extracted and base hydrolyzed by refluxing for 1 hour with NH_4OH/MeOH (20:80, v/v) and filtered. Residues are concentrated and oxidized to 2,4-DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, sodium meta-bisulfite is added to deactivate the $KMnO_4$, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using diazomethane. Residues are then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and analyzed by GC/ECD, using external standards. The validated method LOQ is 0.05 ppm for residues in/on wheat forage, and an LOD was not reported.

In conjunction with the analysis of treated samples, the above method was validated using control samples of alfalfa hay, meal and pellets fortified with propiconazole at 0.05-0.50 ppm. Recoveries averaged 88 ± 18% control samples of hay were fortified with propiconazole at 0.05-0.50 ppm, 112% from meal was fortified at 0.10 ppm, and 84% from pellets were fortified at 0.05-0.10 ppm.

C. RESULTS AND DISCUSSION

The GC/ECD method (Method AG-454 B) used to determine propiconazole residues in/on alfalfa hay, meal and pellets was adequately validated in conjunction with the analysis of treated samples. Recoveries averaged 88 ± 18% control samples of hay were fortified with propiconazole at 0.05-0.50 ppm, 112% from meal was fortified at 0.10 ppm, and 84% from pellets were fortified at 0.05-0.10 ppm (Table C.1). Apparent residues of propiconazole were <LOQ in/on all control samples. The validated method LOQ for propiconazole is 0.05 ppm, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided.

Prior to analysis, alfalfa hay, meal and pellets were stored frozen for up to 27 months (Table C.2.). Adequate storage stability data are available indicating the weathered residues of propiconazole and its metabolites are stable for up to 38 months at -20° C in grass forage, straw and seed (DP Barcode D210742, 3/15/95, M. Rodriguez). These data will support the storage intervals and conditions for the alfalfa processing study.

Following an application of propiconazole (3.6 lb/gal EC) to a primary crop of winter wheat at 0.11 or 0.33 lb ai/A (1x or 3x), residues were <0.05 ppm in hay, meal and pellets from alfalfa planted at a 77-day PBI (Table C.3). For the application at 0.55 lb ai/A (5x), residues were <0.05 ppm in alfalfa hay and meal and 0.06 ppm in pellets.

TABLE C.1. Summary of Concurrent Recoveries of Propiconazole from Alfalfa Hay, Meal and Pellets Using GC/ECD Method AG-454 B.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ± std dev (%)
Hay	0.05-0.50	4	91, 76, 112, 74	88 ± 18
Meal	0.10	1	112	112
Pellets	0.05-0.10	2	88, 80	84

TABLE C.2. Summary of Storage Conditions.

Matrix (Extract)	Storage Temperature (°C)	Actual Storage Duration (Months) [1]	Interval of Demonstrated Storage Stability (days) [2]
Alfalfa hay/meal/pellets	-20	27	38

1 From harvest to extraction for analysis.
2 DP Barcode D210742, 3/15/95, M. Rodriguez.

TABLE C.3. Residue Data from Processing Study on Alfalfa Grown in Rotation with Propiconazole-treated Wheat.

RAC	Processed Commodity	Total Rate [1] (lb ai/A)	Harvest Interval DAT [2]	Harvest Interval DAP [3]	Residues (ppm)	Processing Factor
Alfalfa Hay	Hay (RAC)	0.110	380	303	<0.05	NA
		0.330	380	303	<0.05	
		0.550	380	303	<0.05	
	Meal	0.110	380	303	<0.05	NA
		0.330	380	303	<0.05	
		0.550	380	303	<0.05	
	Pellets	0.110	380	303	<0.05	NA
		0.330	380	303	<0.05	
		0.550	380	303	0.06	~1.2x

1 Rate applied to primary crop of winter wheat.
2 DAT = days after treatment.
3 DAP = days after planting.
NA = not applicable

D. CONCLUSION

The alfalfa processing data are adequate and indicate that there is a slight (1.2x) potential for concentration of residues in pellets produced from alfalfa hay grown in rotation with propiconazole-treated wheat.

E. REFERENCES

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

DP Barcode:	D279300
Subject:	Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From:	Y. Donovan
To:	S. Lewis/J. Guerry
Dated:	8/18/05
MRID:	None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 5F4498 (superseded by PP#2F6371)
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED Yan Donovan	Date: 07/06/06
Approved by	Susan Hummel, Chemist, RRB4/HED Susan Hummel	Date: 07/06/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 6/27/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

46159401 Purdy, J. (2000) Crop Residue Trials to Determine the Residues of CGA 279202, CGA 64250 and Their Significant Crop Metabolites After Application of an Emulsifiable Concentrate Formulation Containing Both Active Ingredients on Barley. Project Number: CER04407/98, 110300, 99NOV48/REP. Unpublished study prepared by Novartis Crop Protection Canada, Inc., Enviro-Test Laboratories and Ag-Quest Inc. 385 p.

EXECUTIVE SUMMARY:

In 12 field trials conducted in Canada during 1999, a multiple active ingredient EC formulation containing propiconazole at 1.04 lb ai/gal was applied to barley as two broadcast foliar applications at 59-72 g ai/ha/application for totals of 112-139 g ai/ha/season. These rates are equivalent to 0.053-0.064 lb ai/A/application and 0.11-0.12 lb ai/A/season. Applications were made to separate plots for the collection of either forage and hay or grain and straw. For the forage and hay plots, the applications were made at tillering (BBCH 21-29) and flag leaf emergence (BBCH 37-39), at a retreatment interval (RTI) of 6-18 days. For the grain and straw plots, the applications were made at flag leaf emergence (BBCH 37-39) and heading through early flowering (BBCH 58-61), at RTIs of 7-22 days. All applications were made using ground equipment in volumes of 100-200 L/ha, and did not include the use of any adjuvants. Single control and duplicate treated samples of forage were harvested 29-31 days after treatment (DAT), hay was cut at 43-46 DAT, and grain and straw were harvested 42-62 DAT. At two sites, additional samples of forage were collected at 21, 29 and 37 DAT, and samples of hay were collected at 37, 44 and 53 DAT to assess residue decline. Samples were stored frozen up to 5 months prior to analysis, an interval supported by available storage stability data.

Barley samples were analyzed both for residues of propiconazole, *per se*, and for the combined residues of propiconazole and its metabolites containing 2,4-dichlorobenzoic acid (DCBA), determined as DCBA. Residues of propiconazole were determined using a GC/MS method (REM 130.02), in which residues are extracted with aqueous methanol, partitioned into dichloromethane (DCM), and cleaned up using an alumina column. Residues are then analyzed by GC/MS using select ion monitoring (SIM) with external standards. The method limit of quantitation (LOQ) for propiconazole is 0.02 ppm, and the limit of detection LOD was not reported.

Total combined residues were determined using another GC/MS method (REM 3/86), which is similar to the current tolerance enforcement method. For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization. Residues of DCBA are then partitioned into DCM, methylated and analyzed by GC/MS-SIM, using external standards. Total residues are expressed in parent equivalents. The validated method LOQ is 0.04 ppm, and a LOD was not reported. Both methods were adequately validated prior to and in conjunction with the analysis of field trail samples.

The above methods were adequately validated for data collection.

Following the two applications at tillering and flag leaf emergence, residues of propiconazole, *per se*, were <0.02-0.27 ppm in/on forage at ~30 DAT and <0.02-0.51 ppm in/on hay cut at ~45 DAT. Following two applications at flag leaf emergence and heading, residues of parent were <0.02-0.05 ppm in/on grain and <0.02-0.99 ppm in/on straw harvested at maturity (42-62 DAT). Average propiconazole residues were 0.055 ppm for forage, 0.077 ppm for hay, 0.015 ppm for grain (<LOQ) and 0.232 ppm for straw. From the same tests, total combined residues were 0.11-3.00 ppm in/on forage, 0.08-2.40 ppm in/on hay, <0.04-0.33 ppm in/on grain, and 0.14-5.2 ppm in/on straw. Average combined residues were 0.75 ppm for forage, 0.89 ppm for hay, 0.16 ppm for grain and 1.68 ppm for straw. Data on parent residues and total combined residues in/on forage and hay over time indicate that residues in these commodities decreased at longer post-treatment intervals.

The number of trials and the geographic representation of the trials are adequate for Canada but Not adequate for U.S. The data support the use of propiconazole (EC) on barley as two broadcast foliar applications at up to 62.5 g ai/ha/application from tillering through heading, for a total of 125 g ai/ha/season. The data support a minimum RTI of 14 days and PHIs of 30 days for forage and 45 days for hay, grain and straw.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the barley field trial data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited minor deviations from GLP compliance, pertaining to the collection of weather data, soil data, and the entry and correction of data in reports. None of these deviations affect the overall acceptability of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities, including permanent tolerances of 0.1 and 1.5 ppm on barley grain and straw [40 CFR §180.434(a)].

Syngenta has submitted at petition (PP#2F6371) proposing new tolerances and the use of propiconazole on a variety of cereal grains, including barley. The current submission includes residue data from barley field trials conducted in Canada.

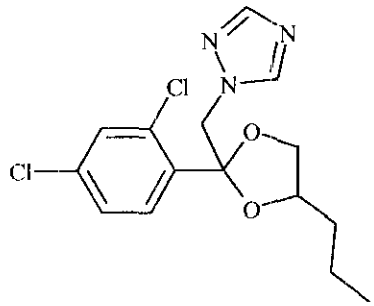
TABLE A.1. Nomenclature of Propiconazole	
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EPs	1.04 lb/gal EC (Stratego 250 EC; MAI containing both propiconazole and trifloxystrobin, each at 1.04 lb ai/gal)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.		
Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK_a)	1.09	MRID No. 43698701
Octanol/water partition coefficient $Log(K_{OW})$	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Barley was grown and maintained at each test site using typical agricultural practices for the various regions (Table B.1.1). Monthly rainfall and irrigation data were provided for each site, along with temperature data. No usual weather conditions were noted that would have an adverse effect on the field trial data. Information was provided on soil characteristics at each site, along with the maintenance chemicals and other pesticides used.

Four separate plots were established at each field site, two each for the collection of forage and hay or grain and straw (Table B.1.2). Propiconazole (1.04 lb/gal EC) was applied to all plots as two broadcast foliar applications at a target rate of 62.5 g ai/ha/application, for a total of 125 g ai/ha/season. Applications were made approximately at tillering (BBCH 21-29) and flag leaf emergence (BBCH 37-39) for the forage and hay plots, and at flag leaf emergence (BBCH 37-39) and heading (BBCH 58-61) for the grain and straw plots.

TABLE B.1.1. Trial Site Conditions.				
Trial Identification (City; Province; Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC[2] (meq/g)
Outlook, SK 1999	Clay Loam	2.84	6.6	18.6
Delisle, SK, 1999	Loam	3.83	5.8	19.6
Rosthern, SK 1999	Clay Loam	5.51	6.0	24.1
Leask, SK 1999	Loam	7.09	7.0	30.4
Lacombe, AB 1999	Loam	8.7	5.9	30.4
Lacombe, AB 1999	Sandy Loam	9.8	7.5	33.7
Monarch, AB 1999	Loam	6.3	7.5	38.3
Kipp, AB 1999	Clay Loam	5.4	7.6	34.6
Minto, MB 1999	Clay Loam	5.6	7.7	26.1
Minto, MB 1999	Clay Loam	7.7	7.4	28.9
Ailsa Craig, ON 1999	Clay Loam	4.7	6.3	25.5
Kemptville, ON 1999	Clay Loam	4.8	7.5	24.9

[1] These parameters are optional except in cases where their value affects the use pattern for the chemical.
[2] Cation exchange capacity.

TABLE B.1.2. Study Use Pattern on Barley.

Location (City, Province; Year) Trial ID	End-use Product [1]	Application Information [2]				
		Method; Timing	Volume (L/ha)	Single Rate [3] (g ai/ha)	RTI (days)	Total Rate [3] (g ai/ha)
Outlook, SK 1999 1	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 22-23 and 41-47	100	65.0-71.3	17	132.9, 139.3
		Two broadcast foliar applications at BBCH stages 41-47 and 60-61	100	65.5-72.2	7	133.4, 135.8
Delisle, SK, 1999 2	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 22-23 and 39-41	100	62.0-64.9	6	127.8, 126.9
		Two broadcast foliar applications at BBCH stages 39-41 and 60-61	100	65.8-68.0	7	133.9, 132.8
Rosthern, SK 1999 3	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 22-23 and 37-39	100	62.2-65.1	17	127.8, 126.8
		Two broadcast foliar applications at BBCH stages 37-39 and 60-61	100	64.8-66.1	20	130.3, 131.2
Leask, SK 1999 4	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 22-23 and 39-41	100	62.8-65.9	9	131.0, 127.9
		Two broadcast foliar applications at BBCH stages 39-41 and 60-61	100	63.7-66.5	22	129.6, 130.2
Lacombe, AB 1999 5	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 22-23 and 37-39	100	60.6-62.1	10	122.7, 122.5
		Two broadcast foliar applications at BBCH stages 37-39 and 60	100	61.7-62.4	21	124.1, 123.5
Lacombe, AB 1999 6	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 22-23 and 37-39	100	61.3-63.6	14	125.3, 124.6
		Two broadcast foliar applications at BBCH stages 37-39 and 60	100	62.7-63.6	8	126.5, 126.3
Monarch, AB 1999 7	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 22-23 and 37-39	100	61.9-63.8	11	126.9, 125.2
		Two broadcast foliar applications at BBCH stages 37-39 and 60	100	59.4-62.7	11	132.1, 121.4
Kipp, AL 1999 8	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 22-23 and 37-39	100	60.8-62.3	7	123.7, 123.1
		Two broadcast foliar applications at BBCH stages 37-39 and 60	100	60.8-62.3	20	124.1, 123.1
Minto, MB 1999 9	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 21-22 and 38-39	100	62.6-64.1	18	128.6, 127.5
		Two broadcast foliar applications at BBCH stages 38-39 and 60	100	63.0-64.3	9	127.7, 126.9
Minto, MB 1999 10	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 14-22 and 38-39	100	62.8-64.0	15	127.2, 126.4
		Two broadcast foliar applications at BBCH stages 38-39 and 60	100	62.7-63.6	13	126.3, 126.5
Ailsa Craig, ON 1999 11	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 22-23 and 37-39	200	59.0-63.6	10	126.1, 119.8
		Two broadcast foliar applications at BBCH stages 37-39 and 56-60	200	59.3-64.6	11	123.9, 123.0
Kemptville, ON 1999 12	1.04 lb/gal EC	Two broadcast foliar applications at BBCH stages 21-25 and 37-45	200	61.6-69.7	9	131.3, 134.3
		Two broadcast foliar applications at BBCH stages 37-39 and 58-60	200	62.3-67.3	14	131.1, 126.8

1 The end-use product was a multiple active ingredient formulation (EC) containing both propiconazole and trifloxystrobin, each at 1.04 lb ai/gal.

2 All applications were made using ground equipment, and no adjuvants were included in the spray mixture.

3 The single application rates of 59.0-72.2 g ai/ha are equivalent to 0.053-0.064 lb ai/A, and the total rates of 119.8-135.8 g ai/ha are equivalent to 0.11-0.12 lb ai/A.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones[1]	Barley		
	Submitted	Requested	
		Canada	U.S.
1	1	---	1 [1]
2	---	---	1 [1]
3	---	---	---
4	---	---	---
5	2	1	3
5A	--	---	NA
5B	1	1	NA
6	---	---	---
7	2	2	4
8	---	---	---
9	---	---	1
10	---	---	1
11	---	---	2
12	---	---	---
13	---	---	---
14	6	12	---
Total	12	16	12

[1] For the U.S., barley field trials should include one trial from Region 1 or 2.
NA = not applicable

B.2. Sample Handling and Preparation

Single control samples and duplicate treated samples of barley forage, hay, grain and straw (~0.5-3 kg/sample) were harvested from each test at 29-31 DAT for forage, 43-46 DAT for hay and 42-62 DAT for grain and straw. At two sites, additional samples of forage were collected at 21, 29 and 37 DAT, and samples of hay were collected at 37, 44 and 53 DAT to assess residue decline. Samples of forage, grain and straw were frozen shortly after harvest, and samples of hay were allowed to dry under ambient conditions to moisture contents of 10-20% prior to being placed in frozen storage at -10°C. The exact drying intervals for hay were not reported, but the study authors noted that hay from Sites 1 through 4 were dried for 52-57 days, which was longer than normal practices. Samples were stored at -10°C until shipment on dry ice to the analytical laboratory, Enviro-Test Laboratories (Edmonton, AB), where samples were stored at -20°C until analysis.

B.3. Analytical Methodology

Samples were analyzed both for residues of propiconazole, *per se*, and for the combined residues of propiconazole and its DCBA-containing metabolites, determined as DCBA. Residues of propiconazole were determined using a GC/MS method (REM 130.02), and total combined residues were determined using another GC/MS method (REM 3/86). Method REM 3/86 converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For Method REM 130.02, residues were extracted with methanol:water (80:20), salinized, and partitioned into DCM. Residues were then filtered through anhydrous sodium sulfate, concentrated to dryness, and redissolved in hexane. Residues were further purified using an alumina column washed with hexane:methyl t-butyl ether (80:20) and then eluted with methyl t-butyl ether. Residues of propiconazole were then determined by GC/MS-SIM using the m/z 239 and 173 ions with external standards. The method LOQ is 0.02 ppm, and the LOD was not reported.

For Method REM 3/86, barley samples were refluxed in methanol/ammonium hydroxide (80:20) for 30 minutes, concentrated and oxidized by refluxing with basic $KMnO_4$ for 20 minutes. Residues were then acidified, partitioned into DCM, dried through sodium sulfate and concentrated. Residues of DCBA were then methylated with diazomethane, and analyzed by GC/MS-SIM using the m/z 204, 175 and 144 ions with external standards. The method LOQ for each matrix is 0.04 ppm, and the LOD was not reported.

In conjunction with the analysis of field trial samples, the above GC/MS methods were validated using control samples fortified with propiconazole or DCBA at 0.02-5.0 ppm.

C. RESULTS AND DISCUSSION

In 12 field trials conducted in Canada during 1999, propiconazole (1.04 lb/gal EC) was applied to barley as two broadcast foliar applications at 59.0-72.2 g ai/ha/application for totals of 119.8-139.3 g ai/ha/season. Applications were made to separate plots for either the collection of forage and hay or grain and straw. For the forage and hay plots, the applications were made at tillering (BBCH 21-29) and flag leaf emergence (BBCH 37-39), at RTIs of 6-18 days. For the grain and straw plots, the applications were made at flag leaf emergence (BBCH 37-39) and heading through early flowering (BBCH 58-61), at RTIs of 7-22 days. All applications were made using ground equipment in volumes of 100-200 L/ha, and did not include the use of any adjuvants. Single control and duplicate treated samples of forage were harvested 29-31 DAT, hay was cut at 43-46 DAT, and grain and straw were harvested 42-62 DAT. At two sites, additional samples of forage were collected at 21, 29 and 37 DAT, and samples of hay were collected at 37, 44 and 53 DAT to assess residue decline.

The GC/MS methods used to determine either residues of propiconazole (REM 130.02) or total combined residues including DCBA-containing metabolites (REM 3/86) in/on hay, forage, grain and straw were adequately validated prior to and in conjunction with the analysis of field trial samples. For Method REM 130.02, method validation recoveries averaged 74-106% from the four matrices, with standard deviations of 3-6%, and concurrent method recoveries averaged 80-100%, with standard deviations of 11-20% (Table C.1). Apparent residues of propiconazole were <LOQ on all control samples. The validated method LOQ for propiconazole is 0.02 ppm, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided.

For Method REM 3/86, method validation recoveries for DCBA averaged 77-86% from the four matrices, with standard deviations of 7-22%, and concurrent method recoveries averaged 78-93%, with standard deviations of 11-18% (Table C.1). Apparent residues were <LOQ on all control samples. The validated method LOQ for DCBA is 0.04 ppm, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided.

Samples of barley matrices were stored frozen for up to 5 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating that the residues of propiconazole and its metabolites are stable at -20° C for up to 38 months in grass forage, straw and seed (DP Barcode D279300, Y. Donovan, 8/18/05). As these matrices are similar to barley matrices, these data will support the storage intervals and conditions for the barley field trials. Although extracts used for analysis of DCBA were stored for >30 days prior to analysis, data are also available from corn forage and soybeans indicating that residues are stable in extracts at 4°C for at least 3 months.

TABLE C.1. Summary of Method Validation and Concurrent Recoveries of Propiconazole and Total Propiconazole Residues (determined as DCBA) from Barley Matrices.

Matrix	Analyte	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Method Validation Recoveries					
Forage	Propiconazole	0.02-0.2	6	103, 99, 87, 94, 93, 102	96 ± 6
	DCBA	0.04-0.8	6	73, 84, 72, 81, 86, 68	77 ±7
Hay	Propiconazole	0.02-0.2	6	108, 117, 102, 103, 106, 102	106 ± 6
	DCBA	0.04-0.8	6	68, 79, 80, 86, 90, 87	82 ± 8
Grain	Propiconazole	0.02-0.2	6	82, 79, 91, 92, 85, 88	86 ±5
	DCBA	0.02-0.4	6	65, 86, 74, 80, 75, 81	77 ± 7
Straw	Propiconazole	0.02-0.2	6	73, 76, 71, 74, 71, 78	74 ± 3
	DCBA	0.04-0.8	6	63, 61, 109, 105, 102, 78	86 ± 22
Concurrent Method Recoveries					
Forage	Propiconazole	0.02-0.1	8	81, 74, 116, 98, 79, 76, 84, 85	87 ± 14
	DCBA	0.04-3.0	11	78, 79, 78, 94, 78, 85, 74, 75, 119, 111, 94	88 ± 15
Hay	Propiconazole	0.02-0.2	10	118, 111, 81, 70, 93, 78, 118, 74, 120, 92	96 ± 20
	DCBA	0.04-2.50	11	97, 100, 83, 95, 78, 86, 67, 77, 125, 93, 93	90 ± 15
Grain	Propiconazole	0.02-0.1	8	94, 95, 105, 107, 87, 85, 119, 104	100 ± 11
	DCBA	0.02-0.4	8	75, 73, 70, 71, 78, 70, 104, 79	78 ± 11
Straw	Propiconazole	0.02-0.2	8	100, 56, 76, 90, 93, 74, 73, 77	80 ± 14
	DCBA	0.04-5.0	9	119, 71, 75, 89, 90, 91, 78, 102, 123	93 ± 18

TABLE C.2. Summary of Storage Conditions for Barley Matrices.

Matrix	Storage Temperature (°C)	Maximum Storage Duration [1] (months)	Interval of Demonstrated Storage Stability (months) [2]
Forage	-20	5	38
Hay			
Grain			
Straw			

1 From harvest to extraction for analysis. Samples were analyzed for parent within 5-15 days of extraction and for total combined residues (DCBA) within 35-44 days of extraction.
2 DP Barcode D279300, Y. Donovan, 8/18/05.

Following two applications of propiconazole (EC) at tillering and flag leaf emergence at rates totaling 120-139 g ai/ha (0.11-0.12 lb ai/A), residues of propiconazole, *per se*, were <0.02-0.27 ppm in/on 24 samples of forage at ~30 DAT and <0.02-0.51 ppm in/on 24 samples of hay cut at ~45 DAT (Table C.3). Following two applications at flag leaf emergence and heading at rates totaling 121-139 g ai/ha, residues of propiconazole, *per se*, were <0.02-0.05 ppm in/on 24 samples of grain and <0.02-0.99 ppm in/on 24 samples of straw harvested at maturity (42-62 DAT). Average propiconazole residues were 0.055 ppm for forage, 0.077 ppm for hay, 0.015 ppm for grain (<LOQ) and 0.232 ppm for straw (Table C.4.1). Although samples of hay from Sites 1-4 were allowed to dry for longer intervals (~50 days) than normal, residues in hay samples from these sites were similar to residues from the remaining eight sites.

From the same tests, total combined residues were 0.11-3.00 ppm in/on forage, 0.08-2.40 ppm in/on hay, <0.04-0.33 ppm in/on grain, and 0.14-5.2 ppm in/on straw. Average combined residues were 0.75 ppm for forage, 0.89 ppm for hay, 0.16 ppm for grain and 1.68 ppm for straw.

In the two residue decline trails, average residues of propiconazole declined in forage from 0.12 ppm at 21 DAT to 0.05 ppm by 37 DAT, and average parent residues declined in hay from 0.08 ppm at 37 DAT to 0.03 ppm by 53 DAT (Table C.4.2; Figure C.1). Declines in total residues were also observed in both forage and hay at increasing post-treatment intervals (Figure C.2).

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data

TABLE C.3. Residue Data for Propiconazole and Total Combined Residues on Barley Forage, Hay, Grain and Straw.

Trial ID (City, Province: Year)	Zone	Variety	Total Rate (g ai/ha) [1]	Commodity	PHI (days)	Residues (ppm) [2]	
						Propiconazole	Total Combined
Outlook, SK 1999 1	7	Harrington	132.9, 139.3	Forage	30	0.25, 0.27	2.5, 3.0
				Hay	45	0.26, 0.51	2.4, 1.6
			133.4, 135.8	Grain	52	0.039, 0.048	0.33, 0.26
				Straw		0.86, 0.99	5.2, 5.0
Delisle, SK, 1999 2	7	Harrington	127.8, 126.8	Forage	29	0.028, 0.05	0.69, 0.83
				Hay	44	0.05, 0.071	1.2, 1.3
			130.3, 131.2	Grain	45	<0.02, <0.02	0.23, 0.16
				Straw		0.26, 0.18	1.9, 2.0
Rosthern, SK 1999 3	14	Harrington	127.8, 126.8	Forage	29	<0.02, <0.02	0.11, 0.11
				Hay	44	<0.02, <0.02	0.079, 0.096
			130.3, 131.2	Grain	49	0.029, 0.023	0.20, 0.19
				Straw		0.39, 0.30	1.8, 1.3
Leask, SK 1999 4	14	Harrington	131.0, 127.9	Forage	21	0.15, 0.18	1.5, 1.6
					29	0.039, 0.043	1.1, 0.85
					37	0.081, 0.085	1.3, 1.1
				Hay	37	0.13, 0.11	2.2, 2.1
					44	0.068, 0.028	0.99, 1.0
					53	0.067, 0.041	0.26, 0.16
			129.6, 130.2	Grain	49	<0.02, <0.02	0.24, 0.21
				Straw		0.59, 0.69	3.7, 3.8
Lacombe, AB 1999 5	14	Harrington	122.7, 122.5	Forage	31	0.035, 0.031	0.32, 0.32
				Hay	45	0.041, 0.035	0.59, 0.64
			124.1, 123.5	Grain	55	<0.02, <0.02	0.11, 0.11
				Straw		0.068, 0.061	1.0, 0.63
Lacombe, AB 1999 6	14	Harrington	125.3, 124.6	Forage	29	0.062, 0.050	0.82, 0.97
				Hay	46	0.055, 0.030	0.80, 0.84
			126.5, 126.3	Grain	62	<0.02, <0.02	0.076, 0.099
				Straw		0.046, 0.038	1.0, 0.68
Monarch, AB 1999 7	14	Stander	126.9, 125.2	Forage	29	0.11, 0.15	0.70, 0.98
				Hay	43	0.16, 0.21	1.5, 1.8
			132.1, 121.4	Grain	42	<0.02, <0.02	<0.04, 0.065
				Straw		0.17, 0.14	1.9, 1.7
Kipp, AL 1999 8	14	Stander	123.7, 123.1	Forage	30	<0.02, <0.02	0.16, 0.16
				Hay	43	0.031, 0.029	0.94, 0.79
			124.1, 123.1	Grain	46	<0.02, <0.02	0.074, 0.13
				Straw		<0.02,0.023	0.14, 0.19
Minto, MB 1999 9	14	Robust	128.6, 127.5	Forage	30	0.044, 0.026	0.55, 0.54
				Hay	45	0.052, 0.046	1.1, 1.2
			127.7, 126.9	Grain	43	<0.02, <0.02	0.14, 0.18
				Straw		0.11, 0.077	1.5, 1.4
Minto, MB 1999 10	14	Robust	127.2, 126.4	Forage	30	<0.02, <0.02	0.29, 0.23
				Hay	45	0.023, 0.036	0.65, 1.0
			126.3, 126.5	Grain	43	0.029, <0.02	0.21, 0.22
				Straw		0.20, 0.15	1.0, 1.0

TABLE C.3. Residue Data for Propiconazole and Total Combined Residues on Barley Forage, Hay, Grain and Straw.

Trial ID (City, Province; Year)	Zone	Variety	Total Rate (g ai/ha) [1]	Commodity	PHI (days)	Residues (ppm) [2] Propiconazole	Total Combined
Ailsa Craig, ON 1999 11	5	Chapais	126.1, 119.8	Forage	21	0.12, 0.032	1.9, 1.1
					31	0.049, <0.02	1.4, 1.0
					38	0.023, 0.029	0.60, 0.50
				Hay	38	0.038, 0.042	0.65, 0.32
					45	0.031, 0.040	0.19, 0.28
					52	0.021, <0.02	0.17, 0.14
			123.9, 123.0	Grain	55	<0.02, <0.02	0.084, 0.13
				Straw		0.053, 0.054	0.69, 1.1
Kemptville, ON 1999 12	5B	Chapais	131.3, 134.3	Forage	29	<0.02, <0.02	0.14, 0.15
				Hay	44	<0.02, <0.02	0.14, 0.20
			131.1, 126.8	Grain	42	<0.02, <0.02	0.15, 0.16
				Straw		0.056, 0.050	0.99, 0.81

1 *Total rates are equivalent to 0.11-0.12 lb ai/A of propiconazole.*
2 Residues of propiconazole, per se, were determined using GC/MS Method REM 130.02, and total combined residues were determined as methyl-DCBA and expressed in parent equivalents using GC/MS Method 3/86. For each matrix, the validated method LOQ is 0.02 ppm for propiconazole, and 0.04 ppm for combined residues. LODs were not reported.

TABLE C.4.1 Summary of Residue Data from Barley Field Trials with Propiconazole (EC)

Commodity	Total Applic. Rate (g ai/ha) [1]	PHI (days)	Residue Levels (ppm) [2] n	Min.	Max.	HAFT[3]	Median (STMdR)[4]	Mean (STMR)[4]	Std. Dev.
Propiconazole Residues									
Forage	119.8-139.3	29-31	24	<0.02	0.270	0.260	0.033	0.055	0.072
Hay		43-46	24	<0.02	0.510	0.385	0.038	0.077	0.112
Grain	121.4-135.8	42-62	24	<0.02	0.048	0.044	0.010	0.015	0.011
Straw			24	<0.02	0.990	0.925	0.125	0.232	0.276
Total Combined Residues									
Forage	119.8-139.3	29-31	24	0.11	3.00	2.75	0.62	0.75	0.72
Hay		43-46	24	0.08	2.40	2.00	0.89	0.89	0.58
Grain	121.4-135.8	42-62	24	<0.04	0.33	0.30	0.16	0.16	0.07
Straw			24	0.14	5.20	5.10	1.20	1.68	1.38

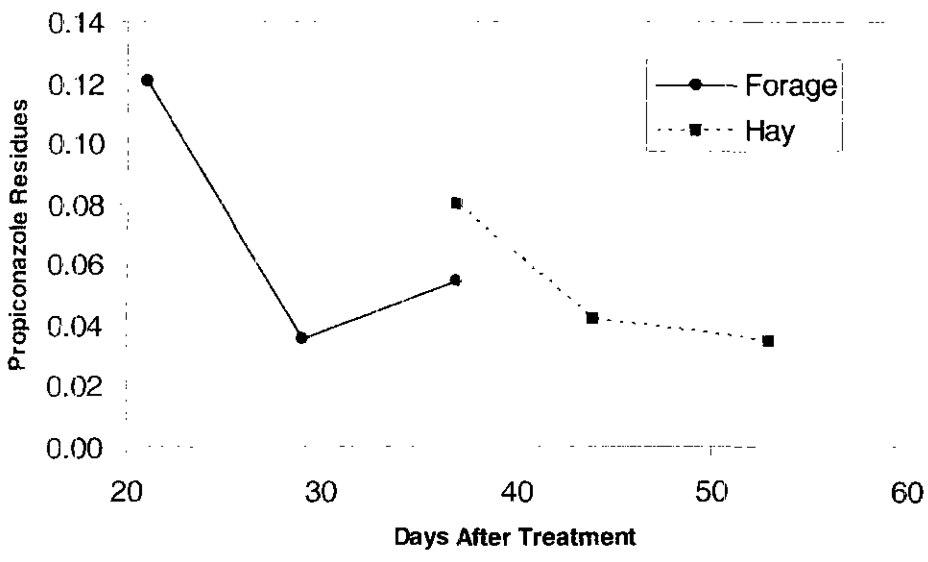
1 Total rates are equivalent to 0.11-0.12 lb ai/A of propiconazole.
2 The validated method LOQs are 0.02 ppm for propiconazole and 0.04 ppm for combined total residues. For calculation of the median, mean and standard deviation, ½LOQ (0.01 or 0.02 ppm) was used for grain samples with residues <LOQ.
3 HAFT = Highest Average Field Trial.
4 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

TABLE C.4.2 Summary of Residue Decline Data from Barley Field Trials with Propiconazole (EC).

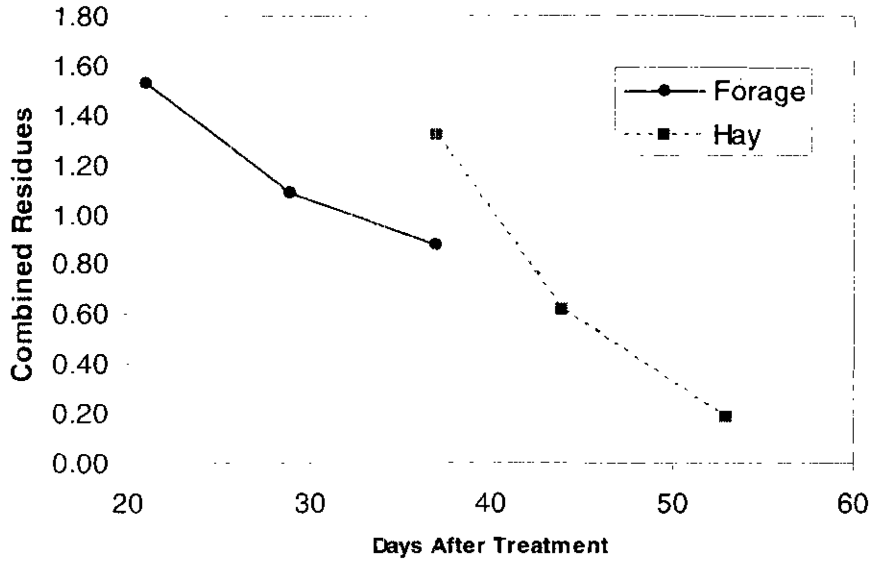
Commodity	Total Applic. Rate (g ai/ha)	PHI (days)	Residue Levels (ppm) [1] n	Min.	Max.	HAFT[2]	Median (STMdR)[3]	Mean (STMR)[3]	Std. Dev.
Propiconazole Residues									
Forage	119.8-131.0	21	4	0.03	0.18	0.17	0.14	0.12	0.06
		29	4	<0.02	0.05	0.04	0.04	0.04	0.02
		37	4	0.02	0.09	0.08	0.06	0.05	0.03
Hay	119.8-131.0	37	4	0.04	0.13	0.12	0.08	0.08	0.05
		44	4	0.03	0.07	0.05	0.04	0.04	0.02
		53	4	<0.02	0.07	0.05	0.03	0.03	0.03
Total Combined Residues									
Forage	119.8-131.0	21	4	1.10	1.90	1.55	1.55	1.53	0.33
		29	4	0.85	1.40	1.20	1.05	1.09	0.23
		37	4	0.50	1.30	1.20	0.85	0.88	0.39
Hay	119.8-131.0	37	4	0.32	2.20	2.15	1.38	1.32	0.97
		44	4	0.19	1.00	1.00	0.64	0.62	0.44
		53	4	0.14	0.26	0.21	0.17	0.18	0.05

1 The validated method LOQs are 0.02 ppm for propiconazole and 0.04 ppm for combined total residues. For calculation of the median, mean and standard deviation, ½LOQ (0.01 or 0.02 ppm) was used for grain samples with residues <LOQ.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

Figures C.1. Decline of Parent Residues in Forage and Hay.



Figures C.1. Decline of Total Combined Residues in Forage and Hay.



D. CONCLUSION

The barley field trials are adequate and support the use of propiconazole (EC) on barley as two broadcast foliar applications at up to 62.5 g ai/ha/application at up to heading, for a total of 125 g ai/ha/season. The data support a minimum RTI of 14 days and PHIs of 30 days for forage and 45 days for hay, grain and straw.

E. REFERENCES

DP Barcode:	D279300
Subject:	Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From:	Y. Donovan
To:	S. Lewis/J. Guerry
Dated:	8/18/05
MRID:	None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4, HED
Petition Number(s): 2F6371
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED	Date: 07/3/06
	Yan Donovan	
Approved by	Susan Hummel, Senior Scientist, RRB4/HED	Date: 07/3/06
	Susan Hummel	

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Road, Building 100, Suite B, Durham, NC 27713; submitted 6/30/2006). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

46576302 Beedle, E. and Harbin, A. (2005) STRATEGO 250EC – Magnitude of the Residue in/on Soybean Aspirated Grain Fractions and Soybean Processed Commodities. Lab Project Number: FL19SY03, RCTFY005. Unpublished study prepared by Bayer CropScience, Texas A&M University, and Morse Laboratories. 310 p.

EXECUTIVE SUMMARY:

In a field trial conducted during 2003 in MS, a multiple active ingredient EC formulation, containing propiconazole at 1.04 lb/gal, was applied to soybeans as three broadcast foliar applications during pod development (BBCH75-77) at 0.398-0.420 lb ai/A/application, at retreatment intervals (RTIs) of 8-9 days, for a total of 1.225 lb ai/A (3.6x maximum rate). Single bulk samples of control and treated seeds were harvested at commercial maturity, 19 days after the last treatment (DAT). Following harvest, three samples of aspirated grain fractions (AGF) were generated, and seeds were then processed using simulated commercial procedures into hulls, meal, and refined oil. Samples of seed were stored frozen for up to 3 months prior to analysis, and samples of AGF and processed commodities were stored frozen for ≤1 month; these intervals are supported by the available storage stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on soybean seed, AGF and processed fractions were determined using an adequate GC/MSD method, which is a modification to Method AG-626. For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization with $KMnO_4$. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated and concentrated. Residues are redissolved in hexane, cleaned up using an alumina column, and determined by GC/MSD using external standards. Residues are expressed in parent equivalents. The method was adequately validated, the validated limit of quantitation (LOQ) was 0.5 ppm for all matrices, and the calculated limits of detection (LOD) were 0.07 ppm for seeds, 0.4 ppm for hulls, 0.15 ppm for meal and 0.14 ppm for refined oil. An LOD for AGF was not reported.

Following three applications of propiconazole (EC) to soybeans during pod development at rates totaling 1.23 lb ai/A, average propiconazole residues were 1.26 ppm in/on seeds (RAC) harvested at 19 DAT. Average residues in/on processed commodities were <0.5 ppm in/on hulls,

F

meal and refined oil, and 39.7 ppm in/on AGF. Based on the average combined residues in seeds (RAC) and each processed fractions, the calculated processing factors are 0.2x for hulls, meal, and for refined oil, and 32x for AGF.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the soybean processing study data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated GLP, quality assurance, and data confidentiality statements were provided. No deviations from regulatory requirements were noted that would impact the study results or their interpretation.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. A multiple active ingredient EC formulation containing both trifloxystrobin and propiconazole, each at 1.04 lb ai/gal, is registered to Bayer CropScience under the trade name Stratego®. This formulation is being proposed by Bayer for control of Soybean Rust in soybeans. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities, including time-limited tolerances of 2.0, 10 and 25 on soybean seeds, forage and hay, respectively [40 CFR §180.434(b)]

The current submission includes residue data from a single processing study in which Stratego Fungicide was applied at an exaggerated rate during pod and seed development (R4-R6). As residues of trifloxystrobin were discussed in an earlier review, this review deals only with residues of propiconazole.

TABLE A.1. Nomenclature of Propiconazole

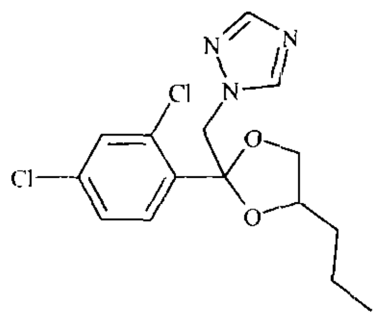
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products EPs	1.04 lb/gal EC (Stratego Fungicide, EPA Reg. No. 264-779: MAI which also contains 1.04 lb/gal of trifloxystrobin)

TABLE A.2. **Physicochemical Properties of Technical Grade Propiconazole.**		
Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK_a)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K_{OW})	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

In a single trial, Stratego Fungicide was applied to soybeans as three broadcast foliar applications during pod and seed development at rates equivalent to 0.40-0.42 lb ai/A of propiconazole, for a total of 1.23 lb ai/A/season (Table B.1.1), which was reported to be a 5x use rate. The application timing was generally around growth stage R5.

Table B.1.1. **Study Use Pattern on Soybean.**							
Location (County, State; Year) *Trial ID*	End-use Product	Application					Tank Mix/ Adjuvants
		Method; Timing	Volume (GPA)	Single Rate (lb ai/A)	RTI [1] (days)	Total Rate (lb ai/A)	
Leland, MS 2003 FL077-03P	1.04 lb/gal EC	Broadcast foliar applications from 50% to 70% pods at final length (BBCH 75-77 or approximately R5)	12-13	0.407, 0.420, 0.398	8, 9	1.225	Non-ionic surfactant at 0.125% v/v

[1] RTI = Retreatment Interval.

B.2. Sample Handling and Processing Procedures

Single bulk samples (≥1000 lb) of control and treated soybeans were harvested at normal crop maturity, 19 DAT. Samples were frozen within 1 hour of collection and shipped the following day by ACDS freezer truck to the processing facility, Food Protein Research and Development Center (Texas A&M University, Bryan, TX). Triplicate subsamples of soybean seeds were collected at the processor, and AGF samples were initially generated and collected using procedures that simulate the movement of seed during transport and storage. Cleaned seed were then processed into hulls, meal and refined oil using simulated commercial procedures. After processing, triplicate subsamples of each commodity were collected, frozen, and shipped by freezer truck to Bayer Research Park (BRP, Stilwell, KS). At BRP, samples were homogenized and stored at <-15°C until shipment on dry ice by overnight courier to the analytical laboratory, Morse Laboratories (Sacramento, CA), where samples were stored at -20°C until analysis.

B.3. Analytical Methodology

Samples of soybean seeds, hulls, meal, refined oil and AGF were analyzed for the combined residues of propiconazole and its 2,4-DCBA containing metabolites using a modification of Novartis Method AG-626, which is an updated version of the current tolerance enforcement method. The principle modification to Method AG-626 was that GC/MSD was used for analysis rather than GC/ECD.

For this method, total propiconazole residues were extracted by refluxing with methanol/ammonium hydroxide (4:1), concentrated and oxidized with $KMnO_4$ to convert propiconazole and its metabolites to 2,4-DCBA. Residues were acidified, partitioned into hexane/ethyl ether (9:1) and evaporated to dryness. Residues of 2,4-DCBA were then methylated with diazomethane and purified using an alumina A SPE cartridge. The methylated residues were then determined using GC/MSD using external standards and by scanning for the m/z 173, 175, and 204 ions. The validated LOQ is 0.5 ppm for all matrices, and the calculated LODs were 0.07 ppm for seeds, 0.4 ppm for hulls, 0.15 ppm for meal and 0.14 ppm for refined oil. An LOD for AGF was not reported.

The above GC/MSD method was validated in conjunction with the analysis of the treated samples using control samples of seed, hulls, meal, refined oil and AGF at 0.50-70 ppm.

C. RESULTS AND DISCUSSION

The GC/MSD method used to determine residues of propiconazole in/on soybean seeds and processed fraction was adequate for data collection. Average method validation recoveries for propiconazole were 69 ± 2% and 76 ± 10% from seed fortified at 0.5 and 5.0 ppm, respectively (Table C.1). Average recoveries were 75 ± 11 % from hulls, 81 ± 5% from meal, 63 ± 4% from refined oil and 98 ± 5% from AGF. The validated LOQ was 0.5 ppm for all matrices, and the calculated LODs were 0.07 ppm for seed, 0.4 ppm for hulls, 0.15 ppm for meal and 0.14 ppm for refined oil. An LOD was not reported for AGF. Apparent residues were <LOD in/on all control samples of seeds and processed fractions, and were 0.07 and 0.08 ppm in two control samples of AGF. Adequate example calculations and sample chromatograms were provided.

Samples of soybean seeds were stored frozen for up to 3 months prior to analysis, and samples of hulls, meal, refined oil and AGF were stored frozen for ≤1 month (Table C.2). Storage stability data are available indicating that propiconazole is stable at -20°C for at least 36 months in corn meal, wheat grain, corn oil, and peanut nutmeats and hulls. Also, processed samples were stored <1 month, therefore storage stability data is not necessary on those commodities. These data will support the current soybean processing study.

Following three applications of propiconazole (EC) to soybeans during pod development (BBCH75-77) at rates totaling 1.23 lb ai/A (3.6x maximum use rate), average combined residues of propiconazole was 1.26 ppm in/on seeds (RAC) at maturity, Average combined residues in/on soybean processed commodities were <0.5 ppm in/on hulls, meal and refined oil and 39.7 ppm in/on aspirated grain fractions. Based on the average combined residues in seeds (RAC) and each processed fraction, the calculated processing factors are 0.2x for hulls, meal, and for refined oil, and 32x for AGF.

TABLE C.1. Summary of Method Validation Recoveries of Propiconazole from Soybean Seed Matrices.

Analyte	Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Propiconazole	Seed	0.50	3	68, 68, 72	69 ± 2
		5.0	3	77, 75, 76	76 ± 10
	Hulls	0.50	3	69, 68, 88	75 ± 11
	Meal	0.50	3	81, 85, 76	81 ± 5
	Refined Oil	0.50	3	68, 60, 62	63 ± 4
	AGF	0.50	1	86	NA
		70	3	99, 102, 92	98 ± 5

NA = Not Applicable.

TABLE C.2. Summary of Storage Conditions.

Matrix (Extract)	Storage Temperature (°C)	Actual Storage Duration (months) [1]	Interval of Demonstrated Storage Stability (months) [2]
Seed	-1 to -25	3	36
Hulls	-10 to -25	≤1	
Meal			
Refined Oil			
Aspirated Grain Fractions			

1 Interval from harvest to extraction for analysis. Extracts were stored for 4 days prior to analysis.
2 DP Barcode D279300, Y. Donovan, 8/18/05.

TABLE C.3. Residue Data from Soybean Processing Study with Propiconazole

RAC	Processed Commodity	Total Rate (lb ai/A)	PHI (days)	Combined Residues (ppm) [1]	Processing Factor
Soybean Seed	Seed	1.225	19	1.23, 1.32, 1.23 [1.26]	NA
	Hulls			<0.5, <0.5, <0.5 [<0.5]	0.2x
	Meal			<0.5, <0.5, <0.5 [<0.5]	0.2x
	Refined Oil			<0.5, <0.5, <0.5 [<0.5]	0.2x
	Aspirated Grain Fractions (AGF)			39.4, 39.6, 40.1 [39.7]	32x

1 The validated LOQ is 0.5 ppm. In cases where residues are <LOQ, ½LOQ (0.25 ppm) was used to calculate the processing factor.
2 Average combined residues are listed in [ ] and were used to calculate the processing factors
NA = not applicable

D. CONCLUSION

The soybean processing study is adequate. The processing factors for combined propiconazole residues in soybean commodities are 0.2x for hulls, meal, and for refined oil, and 32x for AGF.

E. REFERENCES

DP Barcode:	D279300
Subject:	Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From:	Y. Donovan
To:	S. Lewis/J. Guerry
Dated:	8/18/05
MRID:	None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): PP#2F6371
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED Yan Donovan	Date: 07/03/06
Approved by	Susan Hummel, Senior Scientist, RRB4/HED Susan Hummel	Date:07/03/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B; Durham, NC 27713; submitted 6/30/2006). The DER has been reviewed by the HED and revised to reflect current OPP policies.

STUDY REPORT:

46576301 Beedle, E.; Harbin, A. (2005) Stratego 250 EC - Magnitude of the Residue in/on Soybeans. Project Number: FL19SY02, RCTFY004, FL079/03H. Unpublished study prepared by Bayer Corp., Morse Laboratories, Inc. and Bayer Research Farm. 519 p.

EXECUTIVE SUMMARY:

A total of 20 soybean field trials were conducted during 2003 in EPA Regions 2, 4, and 5. Each field trial included two treated plots, one for the harvest of forage and hay and the other for the harvest of seed. In the forage and hay plot, a multiple active ingredient EC formulation containing propiconazole at 1.04 lb ai/gal was applied as three broadcast foliar applications beginning at early to mid-flowering (BBCH 60-65 or R1-R2) at 0.075-0.095 lb ai/A/application, at retreatment intervals (RTIs) of 8-11 days, for totals of 0.24-0.25 lb ai/A. In two of these trials, the initial application was inadvertently made at ~0.164 lb ai/A (~2x), for total rates of 0.33 and 0.35 lb ai/A (1.3x target rate). In the tests for harvest of seed, propiconazole (1.04 lb/gal EC) was applied as three broadcast foliar applications during pod development (BBCH 65-79, or R2-R6) at 0.075-0.085 lb ai/A/application, at RTIs of 8-11 days, for totals of 0.24-0.26 lb ai/A. All applications were made using ground equipment and included the use of a non-ionic surfactant at 0.125% v/v. At each site, soybean forage and hay were harvested at 0 days after the last application (DAT) and seeds were harvested at maturity, 19-24 DAT. At two field sites, forage and hay samples were also harvested at 3, ~5, ~7, and 10 DAT, and seeds were harvested at 18, 21, ~25, ~30, and ~32 DAT to examine residue decline. A single control and duplicate treated samples of each commodity were collected from each test at each interval. Samples were stored frozen from collection to analysis for up to 18 months, an interval supported by available storage stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on soybean forage, hay and seeds were determined using an adequate GC/MSD method, which is a modification to Method AG-626. For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization with $KMnO_4$. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and cleaned up using an alumina column. Residues are then determined by GC/MSD using external standards, with residues being expressed in parent equivalents. The validated limit of quantitation (LOQ) was

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0.5 ppm for forage and hay and 0.1 ppm for seeds, and the calculated limits of detection (LOD) were 0.111 ppm for forage, 0.108 ppm for hay, 0.042 ppm for seeds.

Although recoveries from forage and hay were low, averaging 65-68% at all fortification levels, the recoveries were very consistent with low standard deviations (≤7%). Recoveries of propiconazole averaged 82% (±6-15%) from seed. Therefore, the method is deemed adequate for data collection. Although the raw data (instead of corrected data) were used to report residue values, the data collection method detects parent plus all metabolites containing DCBA, and yet the Agency's tolerance expression for propiconazole will be established at parent only, there fore, tolerances will not under represent the real residue levels.

Combined propiconazole residues ranged from 1.70-12.0 ppm in/on forage and 2.63-27 ppm in/on hay at 0 DAT, and averaged 4.9 ppm in/on forage and 12.7 ppm in/on hay. For mature seeds harvested at 19-24 DAT, combined residues ranged from <0.1-0.27 ppm and averaged 0.09 ppm. The highest average field trial (HAFT) residues were 8.43 ppm for forage, 26.4 ppm for hay, and 0.21 ppm for seeds. Data from the two residue decline trails indicate that combined residues declined slowly in forage and hay from 0 to 10 DAT, but remained relatively steady in seeds from 18 to 33 DAT.

<u>STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS</u>:

Under the conditions and parameters used in the study, the soybean field trial data are classified as scientifically acceptable. Although two of the twenty tests on forage and hay were conducted at a slightly exaggerated rate (~1.3x target rate), the increased application rate in these tests did not have an adverse effect on the adequacy of the residue data as only the first of three applications was made at the exaggerated rate and neither of these field trials produced the highest residues in forage, hay or seed. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Chemistry Summary Document D238458.

<u>COMPLIANCE</u>:

Signed and dated GLP, quality assurance, and data confidentiality statements were provided. No deviations from regulatory requirements were noted that would impact the study results or their interpretation

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. A multiple active ingredient EC formulation containing both trifloxystrobin and propiconazole, each at 1.04 lb ai/gal, is registered to Bayer CropScience under the trade name Stratego®. This formulation is being proposed by Bayer for control of Soybean Rust in soybeans. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities, including time-limited tolerances of 2.0, 10 and 25 on soybean seeds, forage and hay, respectively [40 CFR §180.434(b)].

The current submission includes field trail residue data supporting the use of propiconazole (1.04 lb/gal EC) on soybeans. As residues of trifloxystrobin were discussed in an earlier review, this review deals only with residues of propiconazole.

TABLE A.1. Nomenclature of Propiconazole

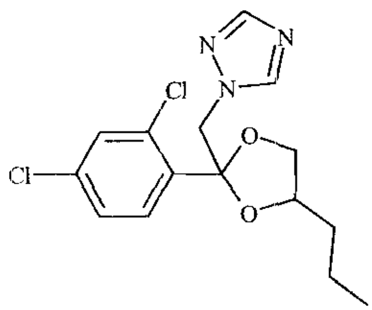
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EPs	1.04 lb/gal EC (Stratego Fungicide, EPA Reg. No. 264-779: MAI which also contains 1.04 lb/gal of trifloxystrobin)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.

Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK_a)	1.09	MRID No. 43698701
Octanol/water partition coefficient $Log(K_{OW})$	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Soybeans were grown and maintained at each test site using typical agricultural practices for the respective geographical regions (Table B.1.1). Detailed temperature data were reported for all sites, and the study authors noted that temperature and precipitation during the field trials were comparable to historical averages for the regions. Rainfall was supplemented with irrigation at 7 of the 20 sites. Detailed information was also provided on maintenance chemicals and other pesticides used at each site.

Each test site included a control plot and two treated plots, one for the harvest of forage and hay and the other for the harvest of mature seed (Table B.1.2). Treated plots received three broadcast foliar applications of propiconazole (1.04 lb/gal EC) at a target rate of 0.082 lb ai/A/application, for a total of 0.244 lb ai/A/season. The authors noted that in two tests the initial application to the forage and hay plot was inadvertently made at a 2x rate (~0.164 lb ai/A). All applications were made using ground equipment and included the use of a non-ionic surfactant at 0.125% v/v. The initial application was made at early to mid-flowering to the forage and hay plots and from first visible pods to all pods at final length to the plots for harvest of seed. Retreatment intervals were 8 to 11 days for all subsequent applications.

TABLE B.1.1. Trial Site Conditions for Soybeans.

Trial Identification (City, State, Year)	Soil characteristics			
	Type	%OM	pH	CEC
Tifton, GA 2003	Sand	1.86	4.8	3.01
Molino, FL 2003	Sandy Loam	2.2	6.3	7.6
Proctor, AR 2003	Silty Clay Loam	1.7	6.5	NR
Newport, AR 2003	Sandy Loam	0.9	5.0	3.2
Leland, MS 2003	Loam	0.6	6.4	NR
Seymour, IL 2003	Silt Loam	3.1	6.5	21
Springfield, NE 2003	Silt Loam	2.7	6.3	NR
Stilwell, KS 2003	Clay Loam	2.0	7.0	15
Oxford, IN 2003	Clay Loam	4.7	5.9	18
Bagley, IA 2003	Loam	4.0	6.0	NR
Carlyle, IL 2003	Silt Loam	1.5	6.7	NR
Saginaw, MI 2003	Clay Loam	2.1	7.7	NR
Gardner, ND 2003	Clay Loam	3.4	7.8	33.4
New Holland, OH 2003	Loam	2.9	6.4	NR
Campbell, MN 2003	Silt Loam	5.0	7.4	NR
Geneva, MN 2003	Loam	4.0	6.5	NR
Sheridan, IN 2003	Loam	2.6	5.9	NR
Northwood, ND 2003	Loam	4.1	6.6	NR
Richland, IA 2003	Silty Clay Loam	3.8	6.9	NR
Arkansaw, WI 2003	Sandy Loam	1.8	6.5	6

NR = Not reported.

TABLE B.1.2. Study Use Pattern on Soybean.

Location (City, State), Year	Application Information							
	End-use Product	Method [1]; Timing [2]	Volume (GPA)	Single Rate (lb ai/A) [3]	No. of Appl.	RTI (days)	Total Rate (lb ai/A)	Tank Mix Adjuvants
Tifton, GA 2003	1.04 lb/gal EC	Broadcast foliar: early flowering to flower decline	15-19	0.082	3	9, 10	0.246	NIS [4]
		Broadcast foliar: pods at final length to 50% pods ripe	15	0.082	3	10, 10	0.246	NIS
Molino, FL 2003	1.04 lb/gal EC	Broadcast foliar: 60% flowers open to 40% pods final size	21-23	0.077-0.084	3	10	0.243	NIS
		Broadcast foliar: all pods at final length	21-22	0.075-0.082	3	8, 10	0.236	NIS
Proctor, AR 2003	1.04 lb/gal EC	Broadcast foliar: 50% flowers open to 10% pods at final size	15-16	0.082	3	9	0.246	NIS
		Broadcast foliar: 40% pods at final size to 10% leaves discolored or fallen	15-16	0.081-0.082	3	9	0.245	NIS
Newport, AR 2003	1.04 lb/gal EC	Broadcast foliar: 40% flowers open to 50% pods final length	20-21	0.082-0.084	3	9, 11	0.248	NIS
		Broadcast foliar: all pods at final length	20	0.082-0.083	3	10	0.247	NIS

TABLE B.1.2. Study Use Pattern on Soybean.

Location (City, State), Year	Application Information							
	End-use Product	Method [1]; Timing [2]	Volume (GPA)	Single Rate (lb ai/A) [3]	No. of Appl.	RTI (days)	Total Rate (lb ai/A)	Tank Mix Adjuvants
Leland, MS 2003	1.04 lb/gal EC	Broadcast foliar: 20% flowers open to end of flowering	13	0.081-0.084	3	8	0.246	NIS
		Broadcast foliar: 50% pods at final length to 70% pods at final length	13-14	0.078-0.082	3	8, 9	0.240	NIS
Seymour, IL 2003	1.04 lb/gal EC	Broadcast foliar: 50% flowers open to 20% pods at final size	16	0.083	3	9, 10	0.249	NIS
		Broadcast foliar: 70% pods at final length to 50% pods ripe	15-16	0.082-0.083	3	8, 10	0.247	NIS
Springfield, NE 2003	1.04 lb/gal EC	Broadcast foliar: 20% flowers open to 50% flowers open	15-16	0.163 [5], 0.082, 0.082	3	8, 9	0.327	NIS
		Broadcast foliar: NR	15-16	0.082	3	10	0.246	NIS
Stilwell, KS 2003	1.04 lb/gal EC	Broadcast foliar: 50% flowers open to all pods at final length	15-18	0.167 [5], 0.083, 0.095	3	10	0.345	NIS
		Broadcast foliar: 70% pods at final length to 50% pods ripe	15-16	0.078-0.085	3	9	0.246	NIS
Oxford, IN 2003	1.04 lb/gal EC	Broadcast foliar: 10% flowers open to end of flowering	17-20	0.084-0.085	3	8, 10	0.253	NIS
		Broadcast foliar: all pods at final length	18-21	0.081-0.083	3	8, 10	0.246	NIS
Bagley, IA 2003	1.04 lb/gal EC	Broadcast foliar: 20% flowers open to end of flowering	22-27	0.079-0.082	3	9	0.241	NIS
		Broadcast foliar: end of flowering to 70% pods at final length	24-25	0.080-0.084	3	9, 10	0.245	NIS
Carlyle, IL 2003	1.04 lb/gal EC	Broadcast foliar: 40% flowers open to end of flowering	15-16	0.079-0.083	3	8	0.244	NIS
		Broadcast foliar: 70% pods at final length to all pods at final length	16-20	0.080-0.084	3	9, 10	0.246	NIS
Saginaw, MI 2003	1.04 lb/gal EC	Broadcast foliar: 10% flowers open to end of flowering	20-21	0.081-0.082	3	10	0.244	NIS
		Broadcast foliar: all pods at final length to 10% pods ripe	20-21	0.082	3	9, 10	0.246	NIS
Gardner, ND 2003	1.04 lb/gal EC	Broadcast foliar: 30% flowers open to 10% pods at final length	27-33	0.082-0.083	3	8, 9	0.247	NIS
		Broadcast foliar: 50% pods at final length to all pods at final length	31-32	0.081-0.083	3	9, 11	0.246	NIS
New Holland, OH 2003	1.04 lb/gal EC	Broadcast foliar: 50% flowers open to end of flowering	15-16	0.081-0.083	3	8, 11	0.247	NIS
		Broadcast foliar: 20% pods at final length to all pods at final length	16-17	0.079-0.083	3	9, 10	0.243	NIS

TABLE B.1.2. Study Use Pattern on Soybean.

Location (City, State), Year	Application Information							
	End-use Product	Method [1]; Timing [2]	Volume (GPA)	Single Rate (lb ai/A) [3]	No. of Appl.	RTI (days)	Total Rate (lb ai/A)	Tank Mix Adjuvants
Campbell, MN 2003	1.04 lb/gal EC	Broadcast foliar: 20% flowers open to first pods at final length	30	0.081-0.082	3	9	0.245	NIS
		Broadcast foliar: 70% pods at final length to 30% leaves discolored or fallen	30	0.081-0.082	3	9	0.245	NIS
Geneva, MN 2003	1.04 lb/gal EC	Broadcast foliar: 50% flowers open to end of flowering	16-17	0.081-0.082	3	9	0.245	NIS
		Broadcast foliar: all pods at final length to 50% leaves discolored or fallen	16	0.081-0.084	3	9	0.247	NIS
Sheridan, IN 2003	1.04 lb/gal EC	Broadcast foliar: 50% flowers open to first pods at final length	17	0.081-0.082	3	9, 10	0.244	NIS
		Broadcast foliar: 30% pods at final length to 10% pods ripe	16-18	0.081-0.084	3	9, 10	0.247	NIS
Northwood, ND 2003	1.04 lb/gal EC	Broadcast foliar: 20% flowers open to end of flowering	30	0.079-0.084	3	9, 10	0.245	NIS
		Broadcast foliar: all pods at final length to 60% leaves discolored or fallen	29-30	0.081-0.084	3	9, 10	0.248	NIS
Richland, IA 2003	1.04 lb/gal EC	Broadcast foliar: 20% flowers open to end of flowering	15-19	0.081-0.084	3	9, 10	0.247	NIS
		Broadcast foliar: all pods at final length to 10% leaves discolored or fallen	16-23	0.080-0.082	3	9, 10	0.243	NIS
Arkansaw, WI 2003	1.04 lb/gal EC	Broadcast foliar: 50% flowers open to end of flowering	30-31	0.083-0.086	3	8, 9	0.254	NIS
		Broadcast foliar: 70% pods at final length to 10% pods ripe	31	0.085	3	9, 10	0.255	NIS

1. All applications were made using ground equipment.
2. Applications were generally made at BBCH 60-65 (R1-R2) to the forage and hay plots and at BBCH 65-79 (R2-R6) to the seed plots.
3. The target application rate was 0.082 lb ai/A/application, for a total of 0.244 lb ai/A/season.
4. All applications included the use of a non-ionic surfactant (NIS; INDUCE®, Helena Chemical Co.) at 0.125% v/v.
5. In these tests, the first application to the plots used for collection of forage and hay were accidentally treated at 0.163-0.167 lb ai/A (2x protocol rate).

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Region [1]	Soybean		
	Submitted	Requested	
		Canada	US
1	--	NA	--
2	2	NA	2
3	--	NA	--
4	3	NA	3
5	15	NA	15
6	--	NA	--
7	--	NA	--
8	--	NA	--
9	--	NA	--
10	--	NA	--
11	--	NA	--
12	--	NA	--
Total	20	NA	20

1 Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the proposed use is for the US only.
NA = not applicable

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of soybean forage and hay were collected at 0 DAT, and control and duplicate treated samples of seed were collected at maturity, 19-24 DAT. In two of the field trials used to examine residue decline, forage and hay were also harvested at 3, 5/6, 7/8, and 10 DAT, and seed was harvested at 18, 21, 24/26, 27 and 32/33 DAT. Samples were frozen within 4 hours of collection and remained frozen until shipment by freezer truck to Bayer Research Park (BRP), Stilwell, KS, where samples were homogenized and stored at <-15 °C. For analysis, samples were shipped frozen to Morse Laboratories, Sacramento, CA, and stored at <-10°C until analysis.

B.3. Analytical Methodology

Samples of soybean forage, hay and seeds were analyzed for the combined residues of propiconazole and its 2,4-DCBA containing metabolites using a modification of Novartis Method AG-626, which is an updated version of the current tolerance enforcement method. The principle modification to Method AG-626 was that GC/MSD was used for analysis rather than GC/ECD.

For this method, total residues were extracted and hydrolyzed by refluxing in methanol/ammonium hydroxide (4:1) and were then oxidized with $KMnO_4$ to convert propiconazole and its metabolites to 2,4-DCBA. Residues were acidified, partitioned into hexane/ethyl ether (9:1) and evaporated to dryness. Residues of 2,4-DCBA were then methylated with diazomethane and purified using an alumina A SPE cartridge. The methylated residues were then determined using GC/MSD using external standards and by scanning for the m/z 173, 175, and 204 ions. The validated method LOQs are 0.5 ppm for forage and hay and 0.1 ppm for seeds, and the calculated LODs are 0.111 ppm for forage, 0.108 ppm for hay and 0.042 ppm for seed.

The above GC/MSD method was validated prior to and in conjunction with the analysis of the field trial samples using control samples fortified with propiconazole at 0.5-20 ppm for forage, 0.5-50 ppm for hay, and 0.1 and 0.5 ppm for seed.

C. RESULTS AND DISCUSSION

The number and geographic representation of the soybean field trials are adequate. A total of 20 soybean field trials were conducted during 2003 in EPA Regions 2, 4, and 5. Each field trial included two treated plots, one for the harvest of forage and hay and the other for the harvest of seeds. In the forage and hay plots, propiconazole (1.04 lb/gal EC) was applied as three broadcast foliar applications beginning at early to mid-flowering (BBCH 60-65 or Stages R1-R2) at 0.075-0.095 lb ai/A/application, at RTIs of 8-11 days, for a total of 0.241-0.254 lb ai/A. In two of these tests, the initial application was inadvertently made at ~0.164 lb ai/A (~2x), for total rates of 0.327 and 0.345 lb ai/A (1.3x target rate). In the plots for harvest of seed, propiconazole (1.04 lb/gal EC) was applied as three broadcast foliar applications beginning during pod and seed development (BBCH 65-79 or Stages R2-R6) at 0.075-0.085 lb ai/A/application, at RTIs of 8-11 days, for a total of 0.236-0.255 lb ai/A. All applications were made using ground equipment and included the use of a non-ionic surfactant at 0.125% v/v.

In all tests, soybean forage and hay were harvested at 0 DAT and seeds were harvested at maturity, 19-24 DAT. At two field sites, forage and hay samples were also harvested at 3, ~5, ~7, and 10 DAT, and seeds were harvested at 18, 21, ~25, ~30, and ~32 DAT to examine residue decline. A single control and duplicate treated samples of each commodity were collected from each test at each interval.

The GC/MSD method used to determine total combined propiconazole residues in/on soybean commodities was adequate for data collection. Although recoveries from forage and hay were low, averaging 65-68% at all fortification levels, the recoveries were very consistent with low standard deviations (≤7%). Recoveries of propiconazole averaged 65-67% (±3-4%) from forage, 67-68% (±4-7%) from hay, and 82% (±6-15%) from seed (Table C.1). The validated LOQs are 0.5 ppm for forage and hay and 0.1 ppm for seeds, and the calculated LODs are 0.111 ppm for forage, 0.108 ppm for hay and 0.042 ppm for seed. Apparent residues of propiconazole were <LOQ in/on all control samples of forage, hay and seed. Adequate example calculations and sample chromatograms were provided.

Samples of soybean forage, hay and seeds were stored frozen for up to 18 months prior to analysis (Table C.2). Storage stability data are available indicating that propiconazole is stable at

-20°C for at least 36 months in wheat grain, celery, peanut nutmeats and hay, and grass forage, fodder and seeds. These data will adequately support the storage intervals and conditions for soybean forage, hay and seeds.

TABLE C.1. Summary of Method Recoveries of Propiconazole from Soybean Forage, Hay and Seeds.

Analyte	Matrix	Spike level (mg/kg) [1]	Sample size (n)	Recoveries (%)	Mean Recovery ∀SD
Propiconazole	Forage	0.5	3	68, 62, 67	66 ± 3
		2.0	10	62, 60, 69, 65, 66, 63, 65, 64, 65, 68	65 ± 3
		20	11	64, 65, 60, 68, 66, 62, 68, 67, 70, 70, 74	67 ± 4
	Hay	0.5	6	66, 81, 66, 64, 68, 64	68 ± 7
		5.0	11	66, 72, 73, 64, 67, 63, 69, 60, 68, 69, 67	67 ± 4
		50	11	63, 69, 74, 68, 66, 67, 79, 61, 68, 65, 72	68 ± 5
	Seed	0.10	12	70, 70, 70, 81, 79, 72, 72, 75, 91, 78, 111, 113	82 ± 15
		0.50	15	77, 78, 71, 73, 80, 81, 80, 92, 82, 86, 86, 82, 86, 77, 92	82 ± 6

1 Spiking levels were reported in total parent equivalents.

TABLE C.2. Summary of Freezer Storage Conditions for Soybean Forage, Hay and Seed

Matrices	Storage Temp. (°C)	Actual Storage Duration [1] (months)	Limit of Demonstrated Storage Stability (months) [2]
Soybean forage, hay and seeds	-25 to -10	18	36

1 Interval from harvest to extraction for analysis. Extracts were stored for 0-12 days prior to analysis.
2 DP Barcode D279300, Y. Donovan, 8/18/05.

Combined propiconazole residues at 0 DAT ranged from 1.70-12.0 ppm in/on 40 samples of forage and 2.63-27 ppm in/on 40 samples of hay (Table C.3), and average residues were 4.9 ppm in/on forage and 12.7 ppm in/on hay (Table C.4). For seed samples harvested 19-24 DAT, combined residues ranged from <0.1-0.27 ppm in/on 40 samples and averaged 0.09 ppm. HAFT residues were 8.43 ppm for forage, 26.4 ppm for hay, and 0.21 ppm for seeds.

Data from the two residue decline trails (Table C.3, Figure C.1) indicate that combined residues declined slowly from 0 to 10 DAT in forage and hay, but remained relatively steady in seeds from 18 to 33 DAT.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

TABLE C.3. Residue Data from Soybean Field Trials with Propiconazole (1.04 lb/gal EC).

Trial ID (City, State, Year)	EPA Region	Variety	Total Rate (lb ai/A)	Commodity	PHI [1] (days)	Combined Residues (ppm) [2]
Tifton, GA 2003 FL079-03H	2	Hartz Seed H6686RR	0.246	Forage	0	2.81, 9.89
				Hay	0	13.6, 16.4
			0.246	Seed	20	<0.10, <0.10
Molino, FL 2003 FL080-03H	2	NK S73-Z5	0.243	Forage	0	1.90, 1.70
				Hay	0	12.4, 8.45
			0.236	Seed	24	<0.10, <0.10
Proctor, AR 2003 FL081-03H	4	Hornbeck 5588RR	0.246	Forage	0	5.69, 9.55
				Hay	0	7.05, 9.01
			0.245	Seed	21	0.135, 0.115
Newport, AR 2003 FL082-03H	4	Delta King 5661RR	0.248	Forage	0	4.75, 4.76
				Hay	0	11.8, 2.63
			0.247	Seed	20	0.100, 0.105
Leland, MS 2003 FL083-03D	5	S56-D7	0.246	Forage	0	3.45, 4.23
					3	4.98, 3.85
					5	2.99, 4.43
					7	3.47, 3.72
					10	2.21, 1.81
			0.246	Hay	0	10.3, 10.5
					3	6.95, 10.3
					5	6.44, 8.94
					7	6.23, 7.37
					10	7.03, 7.78
			0.240	Seed	18	0.211, <0.10
					21	<0.10, <0.10
					26	<0.10, <0.10
					27	<0.10, <0.10
					32	<0.10, <0.10

TABLE C.3. Residue Data from Soybean Field Trials with Propiconazole (1.04 lb/gal EC).

Trial ID (City, State, Year)	EPA Region	Variety	Total Rate (lb ai/A)	Commodity	PHI [1] (days)	Combined Residues (ppm) [2]
Seymour, IL 2003 FL084-03D	5	FS HT322 STS	0.249	Forage	0	3.03, 3.97
					3	2.98, 2.77
					5	2.39, 2.73
					7	2.37, 2.50
					10	2.41, 2.34
			0.249	Hay	0	8.39, 9.67
					3	8.73, 8.37
					6	6.16, 6.44
					8	5.65, 5.87
					10	5.61, 5.26
			0.247	Seed	18	0.120, 0.129
					21	0.129, 0.111
					24	0.104, 0.120
					27	0.131, 0.123
					33	0.136, 0.131
Springfield, NE 2003 FL085-03H	5	NK S29 C9	0.327 [3]	Forage	0	2.82, 1.94
				Hay	0	6.47, 6.46
			0.246	Seed	21	<0.10, <0.10
Stilwell, KS 2003 FL086-03H	5	Patriot Roundup Ready	0.345 [3]	Forage	0	6.89, 9.97
				Hay	0	16.1, 14.0
			0.246	Seed	22	0.268, 0.161
Oxford, IN 2003 FL087-03H	5	Becks 323RR	0.253	Forage	0	3.72, 3.83
				Hay	0	16.4, 18.8
			0.246	Seed	20	0.121, 0.104
Bagley, IA 2003 FL088-03H	5	92B94	0.241	Forage	0	4.52, 6.24
				Hay	0	15.7, 19.4
			0.245	Seed	20	0.177, 0.194
Carlyle, IL 2003 FL089-03H	5	BT-402	0.244	Forage	0	4.62, 4.86
				Hay	0	15.8, 17.3
			0.246	Seed	19	0.108, 0.112
Saginaw, MI 2003 FL090-03H	5	GL2301RR	0.244	Forage	0	4.30, 12.0
				Hay	0	19.1, 25.3
			0.246	Seed	20	<0.10, <0.10
Gardner, ND 2003 FL091-03H	5	Mycogen 44150	0.247	Forage	0	6.54, 6.74
				Hay	0	25.8, 27.0
			0.246	Seed	20	0.160, 0.135
New Holland, OH 2003 FL092-03H	5	SC 9373	0.247	Forage	0	3.83, 4.07
				Hay	0	11.3, 14.5
			0.243	Seed	19	0.115, 0.100
Campbell, MN 2003 FL093-03H	5	Dekalb 06-51	0.245	Forage	0	3.61, 3.32
				Hay	0	9.77, 10.3
			0.245	Seed	20	<0.10, <0.10

TABLE C.3. Residue Data from Soybean Field Trials with Propiconazole (1.04 lb/gal EC).

Trial ID (City, State, Year)	EPA Region	Variety	Total Rate (lb ai/A)	Commodity	PHI [1] (days)	Combined Residues (ppm) [2]
Geneva, MN 2003 FL094-03H	5	Pioneer 91M50	0.245	Forage	0	6.19, 7.48
				Hay	0	13.6, 14.7
			0.247	Seed	20	<0.10, <0.10
Sheridan, IN 2003 FL095-03H	5	Dekalb 3151	0.244	Forage	0	4.43, 5.31
				Hay	0	5.73, 12.7
			0.247	Seed	21	<0.10, 0.116
Northwood, ND 2003 FL096-03H	5	Rough Rider	0.245	Forage	0	3.13, 3.64
				Hay	0	7.83, 7.22
			0.248	Seed	21	<0.10, <0.10
Richland, IA 2003 FL097-03H	5	Pioneer 93B86	0.247	Forage	0	3.15, 2.76
				Hay	0	5.31, 6.90
			0.243	Seed	19	<0.10, <0.10
Arkansaw, WI 2003 FL098-03H	5	Brunner BR-1500RR	0.254	Forage	0	5.36, 4.80
				Hay	0	15.4, 10.5
			0.255	Seed	20	<0.10, <0.10

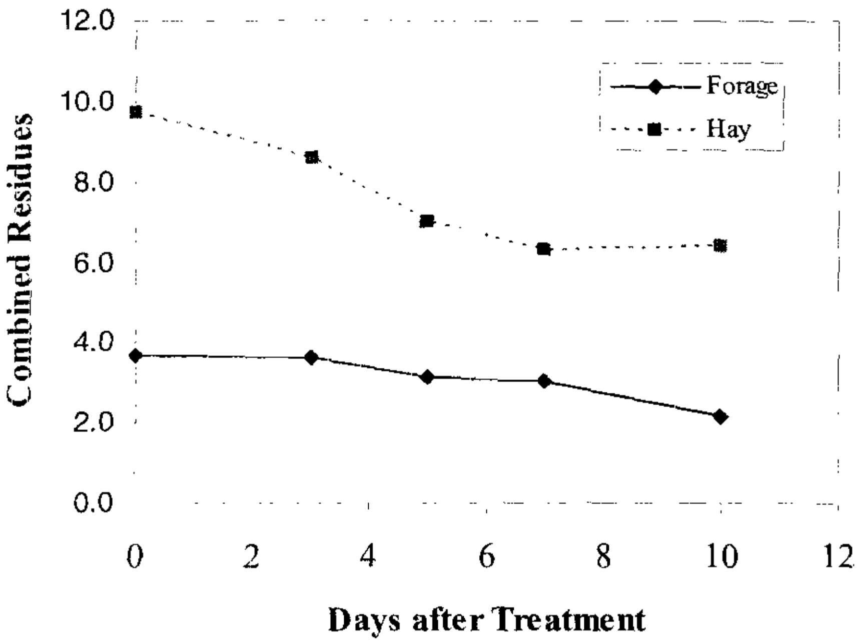
1 The target PHI was 0 days for forage and hay and 21 days for mature seed.
2 Combined residues are expressed in parent equivalents. The LOQs are 0.5 ppm for forage and hay and 0.1 ppm for seed.
3 In two tests on forage and hay, the initial application was made at a 2x rate (~0.164 lb ai/A), but the final two applications were made at ~1x rate.

TABLE C.4. Summary of Residue Data for Soybean Field Trials using a 1.04 lb/gal EC Formulation of Propiconazole.

Matrix	Total Rate (lb ai/A)	PHI (days)	Combined Residues (ppm) [1]						
			n	Min.	Max.	HAFT [2]	Median (STMdR) [3]	Mean (STMR) [3]	Std. Dev.
Forage	0.241-0.254 [4]	0	40	1.70	12.0	8.43	4.37	4.90	2.32
Hay		0	40	2.63	27.0	26.4	12.1	12.74	5.66
Seed	0.236-0.255	19-24	40	<0.10	0.268	0.215	0.050	0.090	0.052

1 Total propiconazole residues were determined as methylated DCBA and expressed in parent equivalents. The validated LOQ is 0.1 ppm for seeds and 0.5 ppm for forage and hay. Residues <LOQ in/on seeds were estimated to be 2LOQ (0.05 ppm), for calculation of mean, median and standard deviation.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue. STMR = Supervised Trial Mean Residue.
4 For forage and hay, the total application rate at two test sites was 0.327-0.345 lb ai/A (1.3x-1.4x).

Figure C.1 Decline in Average Combined Residues in Forage and Hay



D. CONCLUSION

The soybean field trial data are adequate and support the use of up to 3 broadcast foliar applications of propiconazole (1.04 lb/gal EC) to soybeans from early flowering through later pod development (R6) at up to 0.082 lb ai/A/application, for a total of 0.244 lb ai/A/season. The data also support a minimum RTI of 10 days and PHIs of 0 days for forage and hay and 21 days for seed.

E. REFERENCES

DP Barcode:	D279300
Subject:	**Propiconazole** (122101): Reregistration Eligibility Decision (RED) Document-Product Chemistry Considerations
From:	Yan Donovan
To:	Susan Lewis/Patrick Dobak
Dated:	6/1/05
MRID(s):	None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number: PP#2F6371
DP Barcode: D238458
PC Code: 122101

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED	Date: 06/30/06
	Yan Donovan	
Approved by	Susan Hummel, Senior Scientist, RRB4/HED	Date: 06/30/06
	Susan Hummel	

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B. Durham, NC 27713; submitted 6/12/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

45275801 Lin, K. (2000) Propiconazole-Magnitude of the Residue in or on Grain Sorghum: Final Report: Lab Project Number: 145-98: MW-FR-503-98: 0S-FR-103-98. Unpublished study prepared by Novartis Crop Protection, Inc. 222 p.

EXECUTIVE SUMMARY:

Propiconazole (3.6 lb/gal EC) was applied to sorghum in 12 field trials conducted throughout the U.S. during 1998. The number of trials and the geographic representation of the trials are adequate. At each field site, separate plots were established for the collection of forage or grain and stover. For the forage plots, propiconazole was applied as two broadcast foliar applications beginning around flower initiation at 0.11 lb ai/A/application, at a retreatment interval (RTI) of 5 days, for a total of 0.22 lb ai/A/season. In the grain/stover plots, propiconazole was applied as four broadcast foliar applications at 0.11 lb ai/A/application, beginning at flowering or early grain development, for a total of 0.44 lb ai/A/season. Two test sites also included separate grain/stover plots treated at exaggerated rates of 0.33 or 0.55 lb ai/A/application, for a total of 1.32 or 2.20 lb ai/A/season (reported as 3x and 5x rates). The RTIs for the grain/stover plots ranged from 3-11 days, but were 4-5 days at most test sites. All applications were made using ground equipment at volumes of 5-21 gal/A, and included the addition of either an organo-silicone or non-ionic surfactant at 0.06-0.25% of the spray volume.

Single control and duplicate treated samples were collected from each plot, with forage samples being harvested at 0 and 29-31 days after the final treatment (DAT) and grain and stover samples being harvested 18-22 DAT. Repeated samples were also collected at two sites to examine residue decline, with forage being sampled at 0, 9, 16, 23, 30 and 37/38 DAT, and grain and stover being sampled at 0, 7, 14, 21 and 28 DAT. Samples were stored frozen for up to 17.1 months prior to extraction for analysis. Adequate storage stability data are available to support the storage intervals and conditions for the current sorghum field trials.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on sorghum forage, stover and grain were determined using an adequate GC/ECD method (Method AG-626, modified). For this method, residues are extracted and converted to

2,4-DCBA by base hydrolysis and oxidization with $KMnO_4$. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and partitioned into hexane. Methylated DBCA is determined by GC/ECD using external standards, and residues are expressed in parent equivalents. The validated method limit of quantitation (LOQ) is 0.05 ppm, and the limit of detection (LOD) was not reported. The method was adequately validated in conjunction with the analysis of field trial samples.

Following two applications totaling 0.22 lb ai/A, combined residues in/on forage were 1.80-11.6 ppm in/on 14 samples at 0 DAT and 1.5-8.2 ppm in/on 24 samples at 29-31 DAT, and average residues in/on forage were 6.3 ppm at 0 DAT and 4.4 ppm at 29-31 DAT. Following four applications totaling 0.44 lb ai/A, residues were 2.8-11.7 in/on 24 samples of stover and 0.52-2.30 ppm in/on 24 samples of grain harvested at 18-22 DAT, and average residues were 5.8 ppm in/on stover and 1.14 ppm in/on grain. In the exaggerated rate test at 1.32 lb ai/A (3x rate), residues were 12.6 and 15.0 ppm in/on stover and 4.7 and 4.8 ppm in/on grain at 18 DAT. In the two exaggerated rate tests at 2.20 lb ai/A (5x rate), residues were 7.4-30.6 ppm in/on stover and 2.1-7.1 ppm in/on grain at 18-20 DAT.

Data from the two residue decline field trials showed a slight downward trend in residue levels in all three commodities over time, but the decline was erratic in forage and stover and there was a substantial degree of variability in residue levels at each interval.

These data will support up to four broadcast foliar applications of propiconazole (EC) to sorghum at 0.11 lb ai/A/application, beginning around flower initiation, at minimum RTIs of 5 days, for a total of 0.44 lb ai/A/season. The available data support PHIs of 30 days for forage and 21 days for grain and stover, but will allow for only two applications, totaling 0.22 lb ai/A, prior to the harvest of forage.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the sorghum field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited minor deviations from GLP compliance, pertaining to the collection of weather data, tank mix storage stability data, maintenance chemicals, irrigation application, and weight documentation. None of these deviations affect the overall acceptability of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-DCBA (expressed as parent) in/on a variety of plant and animal commodities, including time-limited tolerances of 0.2 and 1.5 ppm on sorghum grain and stover [40 CFR §180.434(b)].

Syngenta has previously proposed tolerances (PP# 5F4498) for inadvertent residues on sorghum planted in rotation with propiconazole-treated wheat. This petition has been superseded by PP#2F6371, in which tolerances are being requested on sorghum commodities resulting from the direct use of propiconazole on sorghum (DP Barcode D279300, Y. Donovan, 8/18/2005). The current submission includes residue data on sorghum forage, grain and stover.

TABLE A.1. Nomenclature of Propiconazole

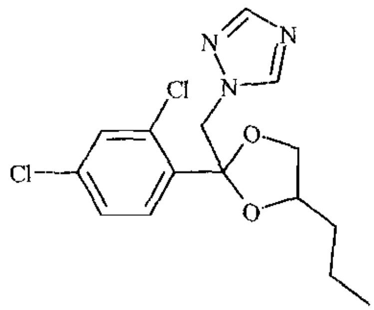
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EP	3.6 lb/gal EC (Tilt Fungicide, EPA Reg. No. 100-617)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.

Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK_a)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K_{OW})	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Sorghum was grown and maintained at each test site using typical agricultural practices for the respective geographical regions (Table B.1.1). With the exception of the field trial in Burleston, TX, average temperature data were provided along with monthly rainfall and irrigation data. No usual weather conditions were noted that would have an adverse effect on the field trial data. Information was also provided on maintenance chemicals and other pesticides used at each site. Soil types were provided for each site, but no other soil data were provided. As the application to sorghum was foliar, additional information on soil characteristics are not required.

At least two field plots were established at each test site, one for the harvest of forage and the other for the harvest of mature grain and stover (Table B.1.2). Only two applications were made at the target 1x rate before the harvest of forage, and four applications were made before the harvest of grain and stover. Two field sites also included additional plots for applications at exaggerated use rates (3x and 5x) in order to provided grain for processing.

TABLE B.1.1. Trial Site Conditions.

Trial Identification (County Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC[2] (meq/g)
Yankton, SD 1998	Clay Loam	NR	NR	NR
Jackson, AR 1998	Sandy Loam	NR	NR	NR
Caddo, OK 1998	Loamy sand	NR	NR	NR
Adair, MO 1998	Silty Clay Loam	NR	NR	NR
Sampson, NC 1998	Loamy sand	NR	NR	NR
York, NE 1998	Silty Clay Loam	NR	NR	NR
Hall, NE 1998	Silt Loam	NR	NR	NR
Hidalgo, TX 1998	Sandy Clay Loam	NR	NR	NR
Sedgwick, KS 1998	Clay Loam	NR	NR	NR
Kiowa, KS 1998	Loam	NR	NR	NR
Weld, CO 1998	Sandy Clay Loam	NR	NR	NR
Burleston, TX 1998	Silt Loam	NR	NR	NR

[1] These parameters are optional except in cases where their value affects the use pattern for the chemical.
[2] Cation exchange capacity.
NR = Not Reported.

TABLE B.1.2. Study Use Pattern on Sorghum.

Location (County, State; Year) Trial ID	End-use Product	Application Information [1]					
		Method; Timing	Volume (GPA)	Rate (lb ai/A)	RTI (days)	Total Rate (lb ai/A)	Adjuvants [2]
Yankton, SD 1998 503	3.6 lb/gal EC	Two broadcast foliar applications at floral initiation and mid flowering	19	0.11	5	0.22	Organosilicon 0.1%
		Four broadcast foliar applications from dough to ripe grain	20-21	0.11	5, 7, 3	0.44	
Jackson, AR 1998 103	3.6 lb/gal EC	Two broadcast foliar applications at floral initiation and late flowering	5	0.11	5	0.22	Kinetic 0.1%
		Four broadcast foliar applications from soft dough to mature stages	5	0.11	5, 7, 3	0.44	
Caddo, OK 1998 730	3.6 lb/gal EC	Two broadcast foliar applications at floral initiation and half bloom	14	0.11	5	0.22	Freeway 0.06%
		Four broadcast foliar applications from soft to hard dough stages	14-15	0.11	5, 4, 5	0.44	
Adair, MO 1998 202	3.6 lb/gal EC	Two broadcast foliar applications at 60% blooming and 10% still flowering	17	0.11	5	0.22	R-11 0.25%
		Four broadcast foliar applications from late milk to seed color change stages	17-18	0.11	5, 5, 5	0.44	
Sampson, NC 1998 610	3.6 lb/gal EC	Two broadcast foliar applications at floral initiation and flowering	10	0.11	5	0.22	Excel 2000 0.5%
		Four broadcast foliar applications from milk to hard dough stages	10	0.11	5, 5, 5	0.44	
York, NE 1998 613	3.6 lb/gal EC	Two broadcast foliar applications at floral initiation and full flowering	5	0.11	5	0.22	Slygard 0.1%
		Four broadcast foliar applications from milk to hard dough	5	0.11	5, 5, 5	0.44	
Hall, NE 1998 614	3.6 lb/gal EC	Two broadcast foliar applications at floral initiation and full head	20	0.11	5	0.22	Slygard 0.1%
		Four broadcast foliar applications from milk to hard dough stages	20	0.11	5, 5, 5	0.44	
Hidalgo, TX 1998 309	3.6 lb/gal EC	Two broadcast foliar applications at early flowering and flowering stages	17-18	0.11	5	0.22	Silwet L-77 0.25%
		Four broadcast foliar applications from soft to hard dough stages	16-19	0.11	4, 5, 5	0.44	
Sedgwick, KS 1998 310	3.6 lb/gal EC	Two broadcast foliar applications at flowering and late flowering	19	0.11	5	0.22	Silwet L-77 0.1%
		Four broadcast foliar applications from post flower to GS8	12-21	0.11	8, 8, 3	0.44	
Kiowa, KS 1998 311	3.6 lb/gal EC	Two broadcast foliar applications at flowering and late bloom stages	17-18	0.11	5	0.22	Silwet L-77 0.1%
		Four broadcast foliar applications from GS8 to GS9	12-13	0.11	11, 3, 8	0.44	
				0.55		2.20	
Weld, CO 1998 312	3.6 lb/gal EC	Two broadcast foliar applications at flower initiation	15	0.11	5	0.22	Silwet L-77 0.1%
		Four broadcast foliar applications from bloom to soft dough stages	16	0.11	5, 5, 5	0.44	
Burleston, TX 1998 202	3.6 lb/gal EC	Two broadcast foliar applications at flowering and pollination	13	0.11	5	0.22	Kinetic 0.25%
		Four broadcast foliar applications from soft to hard dough stages	13	0.11	5, 5, 5	0.44	
				0.33		1.32	
				0.55		2.20	

1 All applications were made using ground equipment.
2 The adjuvants used were organo-silicone surfactants, with the exceptions of R-11 and Excel which are non-ionic type surfactants. Concentrations are reported as percent of spray volume.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones[1]	Sorghum		
	Submitted	Requested	
		Canada	U.S.
1	--	---	--
2	1	---	1
3	--	---	--
4	1	---	1
5	4	---	4
6	2	---	2
7	1	---	1
8	3	---	3
9	--	---	--
10	--	---	--
11	--	---	--
12	--	---	--
Total	12	NA	12

[1] Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the use is for only in the U.S.
NA = Not applicable

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of sorghum forage, stover and grain (weight unspecified) were harvested from each test site. Forage samples were collected at 0 and 29-31 DAT from each test site, although the 0 DAT samples of forage were only analyzed from seven sites. Grain and stover samples were harvested at 18-22 DAT from each test site. To examine residue decline, repeated samples were collected at two test sites. In these tests, forage samples were collected at 0, 9, 16, 23, 30 and 37/38 DAT, and grain and stover samples were collected at 0, 7, 14, 21 and 18 DAT. After collection, samples were placed in frozen storage (temperature unspecified) at the field sites and later shipped by freezer truck to the analytical laboratory, Novartis Crop Protection (Greensboro, NC), where samples were stored up to 17.1 month at -20°C until preparation for analysis.

B.3. Analytical Methodology

Sorghum samples were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-626, modified), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, residues were extracted and base hydrolyzed by refluxing for 1 hour with NH_4OH/MeOH (20:80, v/v) and filtered. Residues were concentrated and oxidized to 2,4-DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract was diluted with water, sodium meta-bisulfite was added to deactivate the $KMnO_4$, and the extract was acidified by the addition of 6N HCl. Residues of DCBA were partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using methyl iodide in tertabutyl ammonium hydroxide. Residues were then diluted with hexane, concentrated, and partitioned against water. Methylated residues remaining in the hexane were then analyzed by GC/ECD using external standards. The validated method LOQ is 0.05 ppm the LOD was not reported

Summary tables of the residue data were corrected by the registrant for procedural recoveries of <100%; however, spreadsheets including the uncorrected residue values were available in the raw data and were used by the reviewer to report residue values.

In conjunction with the analysis of field trial samples, the above method was validated using control samples of sorghum forage, stover and grain each fortified with propiconazole at 0.05-50 ppm.

C. RESULTS AND DISCUSSION

Propiconazole (3.6 lb/gal EC) was applied to sorghum in 12 field trials conducted throughout the U.S. during 1998. . The number of trials and the geographic representation of the trials are adequate. At each field site, separate plots were established for the collection of forage or grain and stover. For the forage plots, propiconazole was applied as two broadcast foliar applications beginning around flower initiation at 0.11 lb ai/A/application, with a RTI of 5 days, for a total of 0.22 lb ai/A/season. In the grain/stover plots, propiconazole was applied as four broadcast foliar applications at 0.11 lb ai/A/application, beginning at flowering or early grain development, for a total of 0.44 lb ai/A/season. Two test sites also included separate grain/stover plots treated at exaggerated rates of 0.33 or 0.55 lb ai/A/application, for a total of 1.32 or 2.20 lb ai/A/season (3x and 5x rates). The RTIs for the grain/stover plots ranged from 3-11 days, but were 4-5 days at most test sites. All applications were made using ground equipment at volumes of 5-21 gal/A, and included the addition of either an organo-silicone or non-ionic surfactant at 0.06-0.25% of the spray volume.

Single control and duplicate treated samples were collected from each plot, with forage samples being harvested at 0 and 29-31 DAT and grain and stover samples being harvested at 18-22 DAT. Repeated samples were also collected at two sites to examine residue decline, with forage being sampled at 0, 9, 16, 23, 30 and 37/38 DAT, and grain and stover being sampled at 0, 7, 14, 21 and 28 DAT.

The GC/ECD method (Method AG-626, modified) used to determine propiconazole residues in/on sorghum stover, forage and grain was adequately validated in conjunction with the analysis of the field trial samples. The recovery of propiconazole averaged 92 ± 17% from forage, 98 ± 15 % from stover and 100 ± 16% from grain (Table C.1). Apparent residues of propiconazole were at or above the LOQ (0.05 ppm) in 6 out of 27 control samples of forage (0.05-0.12 ppm), 5 out of 20 control samples of stover (0.07-0.15 ppm), and 6 out of 20 control samples of grain (0.06-0.12 ppm). No explanation was provided as to why control residues were above the LOQ in these samples. However, the apparent residues in control samples were considerably lower

(<6%) than the actual residues in the associated treated samples. Therefore, the low levels detected in selected control samples did not have an adverse impact on the field trial data. The validated method LOQ for propiconazole is 0.05 ppm, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided. Although the study author reported residue values corrected for concurrent recoveries of <100%, uncorrected residues values are used and reported in this review.

Sorghum forage, stover and grain samples were stored frozen for 17.1 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating that weather residues of propiconazole are stable at -20°C for up to 38 months in grass forage, seeds and straw (DP Barcode D279300, Y. Donovan, 8/18/05). As these matrices are similar to sorghum grain, forage and stover, these storage stability data will support the storage intervals and conditions for the current sorghum field trials.

Following two applications of propiconazole (EC) totaling 0.22 lb ai/A, combined residues were 1.80-11.6 ppm in/on 14 samples of forage harvested at 0 DAT and 1.5-8.2 ppm in/on 24 samples of forage harvested at 29-31 DAT (Table C.3). Average residues in/on forage were 6.3 ppm at 0 DAT and 4.4 ppm at 29-31 DAT (Table C.4.1). Following four applications totaling 0.44 lb ai/A, residues were 2.8-11.7 in/on 24 samples of stover and 0.52-2.30 ppm in/on 24 samples of grain harvested at 18-22 DAT. Average residues were 5.8 ppm in/on stover and 1.14 ppm in/on grain at maturity. In the single exaggerated rate test at 1.32 lb ai/A (3x rate), residues were 12.6 and 15.0 ppm in/on stover and 4.7 and 4.8 ppm in/on grain at 18 DAT. In the two exaggerated rate tests at 2.20 lb ai/A (5x rate), residues were 7.4-30.6 ppm in/on stover and 2.1-7.1 ppm in/on grain at 18-20 DAT.

Data from the two residue decline field trials showed a slight downward trend in residue levels in all three commodities over time (Table C.4.2; Figure C.1). However, particularly for forage and stover, the decline was erratic and there was a substantial degree of variability in residue levels at each interval.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data

TABLE C.1. Summary of Method Recoveries of Propiconazole from Sorghum.

Analyte	Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Propiconazole	Forage	0.05-50	27	112, 110, 78, 84, 66, 91, 78, 119, 79, 101, 108, 106, 92, 97, 90, 100, 114, 108, 71, 86, 96, 80, 114, 103, 95, 66, 75,	92 ± 17
	Stover	0.05-50	20	110, 80, 79, 115, 96, 67,81, 98, 103, 109, 104, 102, 113, 93, 86, 97, 125, 110, 99, 78, 114	98 ± 15
	Grain	0.05-50	20	123, 83, 72, 114, 68, 95 104, 76, 97, 101, 92, 108, 120, 109, 105, 93, 130, 98, 93, 109	100 ± 16

TABLE C.2 Summary of Storage Conditions.			
Matrix	Storage Temperature (°C)	Actual Storage Duration[1] *(months)*	Interval of Demonstrated Storage Stability (months)[2]
Forage	-20	9.9-17.1	38
Stover		9.1-15.9	
Grain		10.7-15.0	

1 Interval from harvest to extraction for analysis. Extracts were stored for 1-16 days prior to analysis, with the exception of two samples in which the extract was stored for 23 or 35 days.

2 DP Barcode D279300, Y. Donovan, 8/18/05.

TABLE C.3. Residue Data from Sorghum Field Trials with Propiconazole (3.6 lb/gal EC).						
Trial ID *(County, State; Year)*	Zone	Variety	Total Rate (lb ai/A)	Commodity	PHI (days)	Total Propiconazole Residues (ppm)[1]
Yankton, SD 1998 503	5	Novartis 251	0.22	Forage	0	5.4, 6.8 [2]
					30	3.7, 2.6 [2]
			0.44	Stover	22	11.0, 5.1 [2]
				Grain		1.0, 1.0 [2]
Jackson, AR 1998 103	4	Cherokee	0.22	Forage	30	5.8, 3.0
			0.44	Stover	21	2.8, 8.8
				Grain		0.96, 0.80
Caddo, OK 1998 730	8	Triumph TR 455	0.22	Forage	0	5.2,5.3
					30	7.4, 4.2
			0.44	Stover	20	6.2, 6.1 [2]
				Grain		0.52, 0.66
Adair, MO 1998 202	5	Pioneer 8505	0.22	Forage	0	6.2, 4.7
					30	2.8, 3.8
			0.44	Stover	22	4.7, 5.7
				Grain		0.75, 1.4 [2]
Sampson, NC 1998 610	2	DK 54	0.22	Forage	0	4.8, 1.8 [2]
					30	5.2, 4.8
			0.44	Stover	21	4.2, 8.3 [2]
				Grain		1.8, 2.3 [2]
York, NE 1998 613	5	DK 35	0.22	Forage	30	3.8, 3.4
			0.44	Stover	21	6.6, 11.7
				Grain		0.79, 0.76
Hall, NE 1998 614	7	DK 35	0.22	Forage	0	8.8, 5.4
					29	8.0, 8.2
			0.44	Stover	21	4.5, 4.6
				Grain		1.0, 0.86

TABLE C.3. Residue Data from Sorghum Field Trials with Propiconazole (3.6 lb/gal EC).

Trial ID (County, State; Year)	Zone	Variety	Total Rate (lb ai/A)	Commodity	PHI (days)	Total Propiconazole Residues (ppm)[1]
Hidalgo, TX 1998 309	6	Pioneer 8313	0.22	Forage	0	9.8, 11.6 [2]
					9	6.2, 6.1
					16	3.8, 6.5
					23	6.3, 4.1
					30	5.5, 3.8 [2]
					37	8.3, 6.4
			0.44	Stover	0	12.3, 10.3
					7	20.5, 20.9
					14	11.1, 11.9
					21	6.0, 6.1
					28	14.2, 12.7
				Grain	0	2.3, 2.0
					7	2.6, 1.8
					14	2.7, 3.1
					21	2.0, 2.1
					28	1.9, 2.1
Sedgwick, KS 1998 310	5	Pioneer 8699	0.22	Forage	0	4.1, 8.2
					9	4.9, 4.1
					16	3.4, 5.1
					23	6.5, 3.4
					30	6.8, 6.0
					38	6.6, 3.8
			0.44	Stover	0	7.3, 8.5 [2]
					7	3.5, 3.5
					14	5.4, 3.8
					21	4.7, 6.5
					28	4.3, 4.4
				Grain	0	4.9, 4.2
					7	3.3, 2.1 [2]
					14	2.0, 1.3
					21	1.6, 1.5
					28	2.4, 1.8
Kiowa, KS 1998 311	8	Pioneer 87657	0.22	Forage	31	2.6, 2.2
			0.44	Stover	20	2.8, 5.6
				Grain		0.56, 0.58
			2.20	Stover	20	7.4, 13.1
				Grain		2.4, 2.1
Weld, CO 1998 312	8	Triumph TR 430	0.22	Forage	30	5.5, 2.7
			0.44	Stover	21	4.7, 5.4
				Grain		0.89, 0.83
Burleston, TX 1998 202	6	NK73-J6	0.22	Forage	31	2.2, 1.5 [2]
			0.44	Stover	18	3.2, 4.2 [2]
				Grain		1.3, 1.3 [2]
			1.32	Stover	18	15.0, 12.6
				Grain		4.7, 4.8
			2.20	Stover	18	30.6, 15.4
				Grain		7.0, 7.1

1 Total propiconazole residues were determined as DCBA and expressed in parent equivalents. Reported values were obtained from the raw data and are <u>not</u> corrected procedural recoveries. The LOQ for propiconazole residues in/on sorghum commodities is 0.05 ppm. The LOD was not reported.

2 Control samples in these tests had apparent residues of propiconazole above the LOQ, at 0.05-0.15 ppm.

TABLE C.4.1 Summary of Residue Data from Sorghum Field Trials with Propiconazole.

Commodity	Total Applic. Rate (lb ai/A)	EP	PHI (days)	Residue Levels (ppm)[1]						
				n	Min.	Max.	HAFT[2]	Median (STMdR)[3]	Mean (STMR)[3]	Std. Dev.
Forage	0.22	3.6 lb/gal EC	0	14	1.8	11.6	10.7	5.4	6.29	2.54
			30-31	24	1.5	8.2	8.1	3.8	4.40	1.92
Stover	0.44		18-22	24	2.8	11.7	9.2	5.5	5.81	2.25
Grain				24	0.52	2.3	2.1	0.98	1.14	0.51

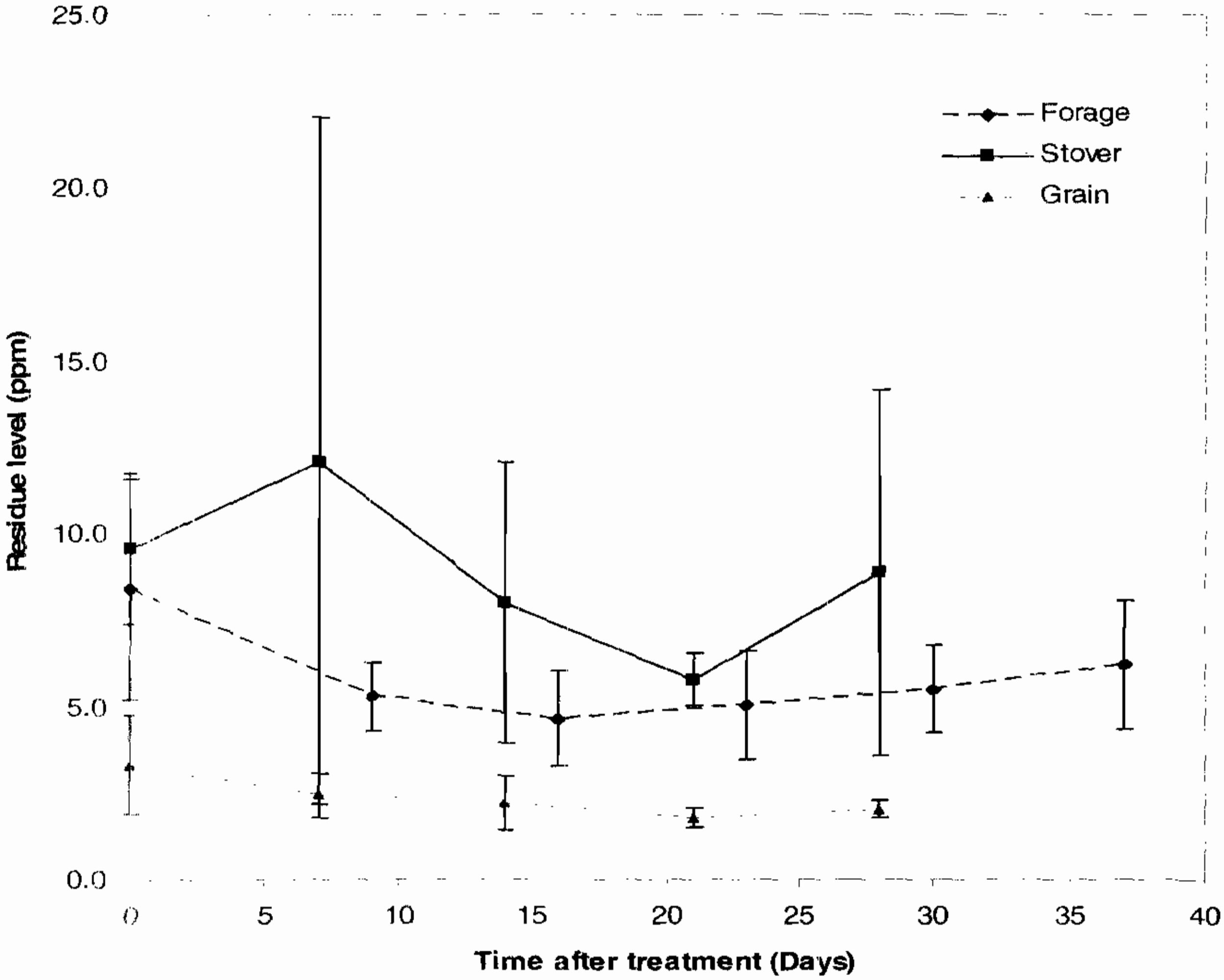
1 Total propiconazole residues were determined as DCBA (expressed in parent equivalents) and are not corrected for procedural recoveries. The LOQ for propiconazole residues is 0.05 ppm.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

TABLE C.4.2 Summary of Residue Decline Data from Sorghum Field Trials with Propiconazole.

Commodity	Total Applic. Rate (lb ai/A)	EP	PHI (days)	Residue Levels (ppm)[1]						
				n	Min.	Max.	HAFT[2]	Median (STMdR)[3]	Mean (STMR)[3]	Std. Dev.
Forage	0.22	3.6 lb/gal EC	0	4	4.1	11.6	10.7	9.0	8.43	3.20
			9	4	4.1	6.2	6.2	5.5	5.33	1.01
			16	4	3.4	6.5	5.2	4.5	4.70	1.40
			23	4	3.4	6.5	5.2	5.2	5.08	1.56
			30	4	3.8	6.8	6.4	5.8	5.53	1.27
			37/38	4	3.8	8.3	7.4	6.5	6.28	1.86
Stover	0.44	3.6 lb/gal EC	0	4	7.3	12.3	11.3	9.4	9.60	2.18
			7	4	3.5	20.9	20.7	12.0	12.10	9.93
			14	4	3.8	11.9	11.5	8.3	8.05	4.05
			21	4	4.7	6.5	6.1	6.1	5.83	0.78
			28	4	4.3	14.2	13.5	8.6	8.90	5.29
Grain	0.44	3.6 lb/gal EC	0	4	2	4.9	4.6	3.3	3.35	1.42
			7	4	1.8	3.3	2.7	2.4	2.45	0.66
			14	4	1.3	3.1	2.9	2.4	2.28	0.79
			21	4	1.5	2.1	2.1	1.8	1.80	0.29
			28	4	1.8	2.4	2.1	2.0	2.05	0.26

1 Total propiconazole residues were determined as DCBA and expressed in parent equivalents, and are not corrected for procedural recoveries. The LOQ for propiconazole residues is 0.05 ppm.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

Figure C.1. Average Residues in or on Sorghum Commodities Over Time.



D. CONCLUSION

The sorghum field trial data are adequate and will support the use of propiconazole (EC) on sorghum as up four broadcast foliar applications beginning around flower initiation at 0.11 lb ai/A/application, at minimum RTIs of 5 days, for a total of 0.44 lb ai/A/season. The available data support PHIs of 30 days for forage and 21 days for grain and stover. Use directions must specify that only two applications, totaling 0.22 lb ai/A, are allowed prior to the harvest of forage.

E. REFERENCES

DP Barcode: D279300
Subject: Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From: Y. Donovan
To: S. Lewis/J. Guerry
Dated: 8/18/05
MRID: None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 5F4498 (superseded by 2F6371)
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED Yan Donovan	Date: 7/31/06
Approved by	Susan Hummel, Senior Scientist, RRB4/HED Susan Hummel	Date: 7/31/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B; Durham, NC 27713; submitted 06/12/2006). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

45275801 Lin, K. (2000) Propiconazole-Magnitude of the Residue in or on Grain Sorghum: Final Report: Lab Project Number: 145-98: MW-FR-503-98: 0S-FR-103-98. Unpublished study prepared by Novartis Crop Protection, Inc. 222 p.

EXECUTIVE SUMMARY:

In two field trials conducted in KS and TX in 1998, propiconazole (3.6 lb/gal EC) was applied to two plots of sorghum at each site as four broadcast foliar applications during grain development at 0.11 or 0.55 lb ai/A/application, for totals of 0.44 or 2.2 lb ai/A/season (1x and 5x rates). All applications were made using ground equipment in volumes of 12-13 gal/A, and included the use of a surfactant at 0.1-0.25% of the spray volume. Single control and treated bulk samples of grain were harvested from each test at normal crop maturity, 18 or 20 days after the final treatment (DAT). The grain was cleaned to generate aspirated grain fractions (AGF) and then processed using simulated commercial procedures into flour. Prior to analysis, the grain and processed fractions were stored frozen for up to 15 months, an interval supported by the available stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on sorghum grain, AGF and flour were determined using an adequate GC/ECD method (Method AG-626, modified). For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization with $KMnO_4$. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and partitioned into hexane. Methylated DBCA is determined by GC/ECD using external standards, and residues are expressed in parent equivalents. The validated method limit of quantitation (LOQ) is 0.05 ppm, and the limit of detection (LOD) was not reported.

Total propiconazole residues in/on bulk samples of grain harvested at 18-20 DAT were 0.43 or 1.2 ppm following applications at the 1x rate and 2.2 and 6.9 ppm following applications at the 5x rate. For the 1x rate, residues in AGF were 3.39 and 6.5 ppm and residues in flour were 0.06 and 0.48 ppm. For the 5x rates, residues in AGF were 9.2 and 21.3 ppm and residues in flour were 0.22 and 2.6 ppm. The processing factors for AGF range from 3.1x-7.9x and averaged 5.1x, and the processing factors for flour range from 0.1x-0.4x and averaged at 0.3x.

I

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the sorghum processing study is classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited minor deviations from GLP compliance, pertaining to the collection of weather data, tank mix storage stability data, maintenance chemicals, irrigation application, and weight documentation. None of these deviations affect the overall acceptability of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-DCBA (expressed as parent) in/on a variety of plant and animal commodities, including time-limited tolerances of 0.2 and 1.5 ppm on sorghum grain and stover [40 CFR §180.434(b)].

Syngenta has previously proposed tolerances (PP# 5F4498) for inadvertent residues on sorghum planted in rotation with propiconazole-treated wheat. This petition has been superseded by PP#2F6371, in which tolerances are being requested on sorghum commodities resulting from the direct use of propiconazole on sorghum (DP Barcode D279300, Y. Donovan, 8/18/2005). The current submission includes residue data on sorghum processed products.

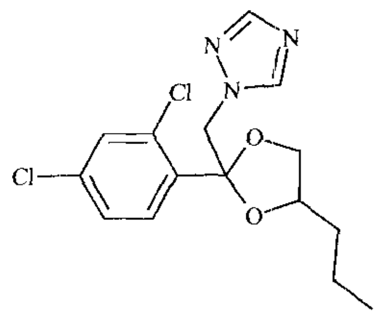
TABLE A.1. Nomenclature of Propiconazole	
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EP	3.6 lb/gal EC (Tilt Fungicide, EPA Reg. No. 100-617)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.

Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (*temperature not specified*)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK_a)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K_{OW})	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Application and Crop Information

At two field sites in KS and TX during 1998, propiconazole (EC) was applied to two separate plots of sorghum at each site during grain development as four broadcast foliar applications at either 0.11 or 0.55 lb ai/A/application. These rates were reported to be 1x and 5x the proposed use rate (Table B.1.1).

TABLE B.1.1. Study Use Pattern

Location (County; Year) Trial ID	End-use Product	Application Information [1]					Tank Mix/ Adjuvants
		Method; Timing	Volume (GPA) [1]	Single Rate (lb ai/A)	RTI [2] (days)	Total Rate (lb ai/A)	
Kiowa, KS 1998 MW-FR-311-98	3.6 lb/gal EC	Four broadcast foliar applications from GS 8 to GS 9 stage	12-13	0.11	11, 3, 8	0.44	Silwet 0.1%
				0.55		2.20	
Burleston, TX 1998 0S-FR-202-98	3.6 lb/gal EC	Four broadcast foliar applications from soft to hard dough stages	13	0.11	5, 5, 5	0.44	Kinetic 0.25%
				0.55		2.20	

1 All applications were made using ground equipment.
2 Gallons per acre
3 RTI = Retreatment Interval.

B.2. Sample Handling and Processing Procedures

Single bulk samples (weight unspecifed) of control and treated (1x and 5x) grain were harvested from each site at normal crop maturity, 18 or 20 DAT. Samples from the TX site were shipped under ambient conditions on the day of harvest directly to the processing facility, Food and Protein Research and Development Center (FPRDC), Texas A&M University, Bryan, TX. These samples were received by FPRDC on the same day as harvest and placed in storage at ≤-12°C. Samples from the KS site were frozen immediately after harvest and then shipped on dry ice by overnight courier to FPRDC, where samples were stored at ≤-12°C. Samples from both field sites were stored frozen for ~3 months prior to processing.

A subsample of grain from each test was collected at the processing facility, and samples of AGF were then generated and collected using procedures that simulate the movement of grain during transport and storage. Cleaned grain was then processed into flour using simulated commercial procedures. Samples were frozen after processing and shipped on dry ice by overnight courier to Novartis Crop Protection (Greensboro, NC), where samples were prepared (homogenized) and stored at -20EC until analysis.

B.3. Analytical Methodology

Samples of sorghum grain, AGF and flour were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-626, modified), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, residues were extracted and base hydrolyzed by refluxing for 1 hour with NH_4OH/MeOH (20:80, v/v) and filtered. Residues were concentrated and oxidized to 2,4-DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract was diluted with water, sodium meta-bisulfite was added to deactivate the $KMnO_4$, and the extract was acidified by the addition of 6N HCl. Residues of DCBA were partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using methyl iodide in tertabutyl ammonium hydroxide. Residues were then diluted with hexane, concentrated, and partitioned against water. Methylated residues remaining in the hexane were then analyzed by GC/ECD using external standards. The validated method LOQ is 0.05 ppm and the LOD was not reported.

Summary tables of the residue data were corrected by the registrant for procedural recoveries of <100%; however, spreadsheets including the uncorrected residue values were available in the raw data and were used by the reviewer to report residue values.

In conjunction with the analysis of treated samples, the above method was validated using control samples of grain, AGF and flour fortified with propiconazole at 0.05-10 ppm.

C. RESULTS AND DISCUSSION

The GC/ECD method (Method AG-626, modified) used to determine propiconazole residues in/on sorghum grain and processed products was adequately validated in conjunction with the analysis of field trial samples. Average recoveries were 79% from grain and AGF and 97% from flour. Apparent residues were <LOQ in/on all control samples of grain and flour and the control sample of AGF from the test in KS, but apparent residues were detected at 0.189 ppm in the

control sample of AGF from the test in TX. As the apparent residues in this control sample were <3% of the residues measured in the two treated samples from the same test (6.5 and 21.3 ppm), the residues in this control sample will not have an adverse impact on the processing data. The validated method LOQ for propiconazole is 0.05 ppm, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided. Although the study author reported residue values corrected for concurrent recoveries of <100%, uncorrected residues values are used and reported in this review.

Samples were stored at -20°C for up to 15 months prior to analysis of grain and 12.2 months prior to analysis of AGF and flour. Adequate storage stability data are available indicating that residues of propiconazole and its metabolites are stable at -20° C for up to 36 months on a wide variety of plant commodities, including wheat grain and corn meal, (DP Barcode D279300, Y. Donovan, 8/18/05). As these matrices are similar in nature to the matrices in the current processing study, these data will support the storage intervals and conditions for the sorghum grain processing study.

Total uncorrected propiconazole residues in/on bulk samples of grain harvested at 18-20 DAT were 0.43 or 1.2 ppm following applications at the 1x rate and 2.2 and 6.9 ppm following applications at the 5x rate (Table C.3). For the 1x rates, residues in AGF were 3.39 and 6.5 ppm and residues in flour were 0.06 and 0.48 ppm. For the 5x rates, residues in AGF were 9.2 and 21.3 ppm and residues in flour were 0.22 and 2.6 ppm. As residues were >LOQ in all fractions, processing factors could be calculated for each test. The processing factors were 3.1x-7.9x for AGF and 0.1x-0.4x for flour. Average processing factors were 5.1x for AGF and 0.3x for flour.

TABLE C.1. Summary of Concurrent Recoveries of Propiconazole from Sorghum and its Processed Products

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Grain	0.05, 1.0	2	70, 88	79
AGF	0.05	2	82, 76	79
Flour	1.0, 10	2	88, 106	97

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration [1] (days)	Interval of Demonstrated Storage Stability (months) [2]
Grain	-20	10.4-15.0	36
AGF		7.8-12.2	
Flour		7.8-12.2	

[1] Interval from harvest to extraction for analysis. Extracts were stored for 3-14 days prior to analysis.
[2] DP Barcode D279300, Y. Donovan, 8/18/05.

TABLE C.3. Residue Data from Sorghum Processing Study with Propiconazole (EC).

Location	RAC	Processed Commodity	Total Rate (lb ai/A) [1]	PHI (days)	Total Combined Residues (ppm) [2]	Processing Factor [3]
Kiowa, KS 1998 (MW-FR-311-98)	Grain	NA	0.44	20	0.43	NA
		AGF			3.39	7.9x
		Flour			0.06	0.1x
	Grain	NA	2.20		2.20	NA
		AGF			9.18	4.2x
		Flour			0.22	0.1x
Burleston, TX 1998 (0S-FR-202-98)	Grain	NA	0.44	18	1.2	NA
		AGF			6.5 [4]	5.4x
		Flour			0.48	0.4x
	Grain	NA	2.20		6.9	NA
		AGF			21.3 [4]	3.1x
		Flour			2.6	0.4x

1 The application rates were reported to be at 1x and 5x the use rate for sorghum.
2 Total propiconazole residues were determined as DCBA and expressed in parent equivalents. Reported values were obtained from the raw data and are not corrected procedural recoveries. The LOQ for propiconazole residues is 0.05 ppm in/on sorghum grain, AGF and flour. Th LOD was not reported.
3 Processing factors were calculated by the reviewer using uncorrected residues.
4 The associated control sample had apparent residues of 0.189 ppm.
NA = not applicable.

D. CONCLUSION

The sorghum grain processing tests are adequate, and the results from all four tests were similar. The average processing factors for combined propiconazole residues were 5.1x in AGF and 0.3x in flour.

E. REFERENCES

DP Barcode: D279300
Subject: Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From: Y. Donovan
To: S. Lewis/J. Guerry
Dated: 8/18/05
MRID: None

F. DOCUMENT TRACKING

RDI: Yan Donovan
Petition Number(s): 5F4498 (superseded by 2F6371)
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED	Date: 07/3/06
	Yan Donovan	
Approved by	Susan Hummel, Senior Scientist, RRB4/HED	Date: 07/3/06
	Susan Hummel	

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 6/12/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

45542401 Vincent, T. (1998) Propiconazole--Magnitude of the Residue in or on Strawberries: Final Report: Lab Project Number: ABR-98066: 48-96: 110S44. Unpublished study prepared by Novartis Crop Protection, Inc. 113 p.

EXECUTIVE SUMMARY:

In 8 field trials conducted throughout the U.S. in 1996, propiconazole (3.6 lb/gal) was applied to strawberries as four broadcast foliar applications during fruit development at 0.11 lb ai/A/application at retreatment intervals (RTIs) of 6-8 days, for a total of 0.44 lb ai/A/season. All applications were made using ground equipment at volumes of 50-100 gal/A, and no adjuvants were used. Single control and duplicate treated samples of strawberries were harvested from each site on the same day as the final application (0 DAT) and at 3 or 8 DAT at two sites. Samples were stored frozen from collection to analysis for up to 18 months, an interval supported by available storage stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on strawberries were determined using an adequate GC/ECD method (Method AG-45B). For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization with $KMnO_4$. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and cleaned-up using an acidic alumina cartridge. Methylated DBCA is determined by GC/ECD using external standards, and residues are expressed in parent equivalents. The validated method limit of quantitation (LOQ) is 0.05 ppm, and the limit of detection (LOD) was not reported. The concurrent recovery of propiconazole averaged 77 ± 8% from control samples fortified at 0.05 or 0.50 ppm. Although the raw data (instead of corrected data) were used to report residue values, the data collection method detects parent plus all metabolites containing DCBA, and yet the Agency's tolerance expression for propiconazole will be established at parent only, there fore, tolerances will not under represent the real residue levels.

Following the last of four foliar applications totaling 0.44 lb ai/A, total <u>uncorrected</u> propiconazole residues were 0.07-0.69 ppm in/on 16 samples of strawberries harvested on the day of the final application (0 DAT). Average residues were 0.35 ppm and the highest average field trial (HAFT) residues were 0.60 ppm. Data from both residue decline tests indicated that residues declined on strawberries at longer post-treatment intervals.

The number of trials and the geographic representation of the trials are adequate. These data will support the use of propiconazole (EC) on strawberries as up four broadcast foliar applications at 0.11 lb ai/A/application, at a minimum RTI of 7 days, for a total of 0.44 lb ai/A/season, with a 0-day PHI.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in these studies, the strawberry field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited minor deviations from GLP compliance, pertaining to the collection of weather data, tank mix storage stability data and maintenance chemicals. None of these deviations affect the overall acceptability of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities [40 CFR §180.434(a)].

Syngenta has submitted at petition (PP#2F6371) proposing a tolerance and the use of propiconazole on strawberry. The current submission includes residue data supporting the use on strawberry of propiconazole, formulated as a 3.6 lb/gal EC.

TABLE A.1. Nomenclature of Propiconazole

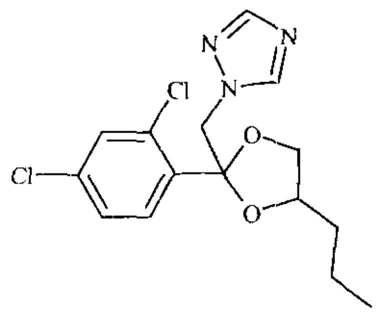
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EPs	3.6 lb/gal EC (Tilt 3.6E Fungicide, EPA Reg. No. 100-617)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.		
Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK_a)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K_{OW})	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Strawberries were grown and maintained at each test site using typical agricultural practices for the respective geographical regions (Table B.1.1). Monthly rainfall and irrigation data were provided for each site, along with temperature data. No usual weather conditions were noted that would have an adverse effect on the field trial data. Information was also provided on maintenance chemicals and other pesticides used at each site, along with data on soil characteristics. At each test site, propiconazole (EC) was applied as four broadcast foliar applications using ground equipment (Table B.1.2). No adjuvants were included in the spray mixtures.

TABLE B.1.1. Trial Site Conditions.				
Trial Identification (County, State; Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC[2] (meq/g)
Fresno, CA 1996	Sandy loam	0.7	5.7	7.25
Hillsborough, FL 1996	Sand	2.3	6.8	5.99
Wayne, NC 1996	Loamy sand	0.6	5.0	1.79
Monterey, CA 1996	Sandy loam	2.2	7.0	7.63
San Bernardino, CA 1996	Sandy loam	1.8	5.2	7.35
Washington, OR 1996	Silt loam	2.9	5.2	14.67
Ottawa, MI 1996	Loamy sand	2.7	6.3	7.11
Wayne, NY 1996	Loamy Sand	2.5	6.4	4.83

[1] These parameters are optional except in cases where their value affects the use pattern for the chemical.
[2] Cation exchange capacity.

TABLE B.1.2. Study Use Pattern on Strawberry.						
Location (County, State; Year) Trial ID	End-use Product	Application Information [1]				
		Method; Timing	Volume (GPA)	Rate (lb ai/A)	RTI (days)	Total Rate (lb ai/A)
Fresno, CA 1996 02-FR-014-96	3.6 lb/gal EC	Four broadcast foliar applications during fruit development	50	0.11	7, 7, 7	0.44
Hillsborough, FL 1996 07-FR-001-96	3.6 lb/gal EC	Four broadcast foliar applications during fruit development	85	0.11	7, 7, 8	0.44
Wayne, NC 1996 0S-FR-601-96	3.6 lb/gal EC	Four broadcast foliar applications during fruit development	50	0.11	7, 7, 7	0.44
Monterey, CA 1996 0W-FR-502-96	3.6 lb/gal EC	Four broadcast foliar applications during fruit development	100	0.11	7, 7, 7	0.44
San Bernardino, CA 1996 0W-FR-503-96	3.6 lb/gal EC	Four broadcast foliar applications during fruit development	75	0.11	6, 8, 6	0.44
Washington, OR 1996 0W-FR-610-96	3.6 lb/gal EC	Four broadcast foliar applications during fruit development	80	0.11	7, 7, 7	0.44
Ottawa, MI 1996 NE-FR-710-96	3.6 lb/gal EC	Four broadcast foliar applications during fruit development	51-52	0.11	7, 7, 8	0.44
Wayne, NY 1996 NE-FR-817-96	3.6 lb/gal EC	Four broadcast foliar applications during fruit development	50	0.11	7, 7, 7	0.44

[1] All applications were made using ground equipment, and no adjuvants were used.

TABLE B.1.3. Trial Numbers and Geographical Locations.			
NAFTA Growing Zones[1]	Strawberry		
	Submitted	Requested	
		Canada	U.S.
1	1	---	1
2	1	---	1
3	1	---	1
4	---	---	---
5	1	---	1
6	---	---	---
7	---	---	---
8	---	---	---
9	---	---	---
10	3	---	3
11	---	---	---
12	1	---	1
Total	8	NA	8

[1] Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the use is for only in the U.S.
NA = Not applicable

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of strawberries (2-3 lb/sample) were harvested from each site at 0 DAT, and additional treated samples were harvested at 3 or 8 DAT from two sites to examine residue decline. Samples were frozen shortly after harvest and shipped by freezer truck to Novartis Crop Protection (Greensboro, NC), where samples were prepared for analysis and stored at -20 °C. Samples were later shipped frozen on dry ice by overnight courier to the analytical laboratory, EPL-Bio Analytical Services (Harristown, IL), where samples were stored frozen until analysis.

B.3. Analytical Methodology

Samples were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-454B), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, residues are extracted and base hydrolyzed by refluxing for 1 hour with NH_4OH/MeOH (20:80, v/v) and filtered. Residues are concentrated and oxidized to 2,4-DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, sodium meta-bisulfite is added to deactivate the $KMnO_4$, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using diazomethane. Residues are then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and the methylated DCBA is analyzed by GC/ECD using external standards. Residues are expressed in propiconazole equivalents. The validated method LOQ is 0.05 ppm for residues, the LOD was not reported.

Summary tables of the residue data were corrected by the registrant for procedural recoveries of <100%; however, spreadsheets including the uncorrected residue values were available in the raw data and were used by the reviewer to report residue values. Although the raw data (instead of corrected data) were used to report residue values, the data collection method detects parent plus all metabolites containing DCBA, and yet the tolerance expression will be parent only, there fore, tolerances will not under represent the real residue levels.

In conjunction with the analysis of field trial samples, the above method was validated using control samples of strawberries fortified with propiconazole at 0.05 and 0.50 ppm.

C. RESULTS AND DISCUSSION

In 8 field trials conducted during 1996 in Regions 1, 2, 3, 5, 10 (3 tests) and 12, propiconazole (EC) was applied to strawberries during fruit development as four broadcast foliar applications at 0.11 lb ai/A/application, at RTIs of 6-8 days, for a total of 0.44 lb ai/A/season. All applications were made using ground equipment at volumes of 50-100 gal/A, and no adjuvants were included in the spray mixtures. Single control and duplicate treated samples of strawberries were harvested from each site at 0 DAT, and samples were also collected at 3 or 8 DAT from two test sites to examine residue decline.

The GC/ECD method (Method AG-454B) used to determine propiconazole residues in/on strawberries was validated in conjunction with the analysis of field trial samples. The recovery of propiconazole averaged 77 ± 8% from control samples fortified at 0.05 or 0.50 ppm (Table C.1). Apparent residues of propiconazole were <LOQ in/on 8 control samples and just above the LOQ (0.060 ppm) in/on 2 control samples. The validated method LOQ for propiconazole is 0.05 ppm, and the LOD is 0.02 ppm. Adequate sample calculations and example chromatograms were provided.

Strawberry samples were stored frozen for up to 18 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating the fortified residues of propiconazole and its metabolites are stable for up to 36 months at -20°C in peaches (DP Barcode D279300, Y. Donovan, 8/18/05). These data will support the storage intervals and conditions for the current field trials.

Following the last of four foliar applications totaling 0.44 lb ai/A, total uncorrected propiconazole residues were 0.07-0.69 ppm in/on 16 samples of strawberries harvested at 0 DAT (Table C.3). Average residues were 0.35 ppm and HAFT residues were 0.60 ppm (Table C.4). In the two residue decline tests, average residues declined from 0.16 ppm at 0 DAT to 0.12 ppm at 3 DAT in one test and from 0.19 ppm at 0 DAT to 0.11 ppm at 8 DAT in the other test.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data

TABLE C.1. Summary of Method Recoveries of Propiconazole from Strawberry.

Analyte	Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Propiconazole	Strawberry	0.05	4	67, 76, 93, 83	77 ± 8
		0.50	6	74, 83, 80, 71, 69, 71	

TABLE C.2 Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1] (months)	Interval of Demonstrated Storage Stability (months)[2]
Strawberry	-20	12-18	36

1 From harvest to extraction for analysis. Extracts were stored for 1-3 days prior to analysis.
2 DP Barcode D279300, Y. Donovan, 8/18/05.

TABLE C.3. Residue Data on Strawberry from Field Trials with Propiconazole (EC).

Trial ID (County, State; Year)	Zone	Variety	End-use Product	Total Rate (lb ai/A)	Commodity	PHI (days)	Total Propiconazole Residues (ppm)[1]
Fresno, CA 1996 02-FR-014-96	10	Camarosa	3.6 lb/gal EC	0.44	Fruit	0	0.16, 0.15
						3	0.10, 0.13
Hillsborough, FL 1996 07-FR-001-96	3	Oso Grande	3.6 lb/gal EC	0.44	Fruit	0	0.41, 0.60
Wayne, NC 1996 0S-FR-601-96	2	Chandler	3.6 lb/gal EC	0.44	Fruit	0	0.38, 0.69
Monterey, CA 1996 0W-FR-502-96	10	776	3.6 lb/gal EC	0.44	Fruit	0	0.58, 0.61
San Bernardino, CA 1996 0W-FR-503-96	10	Chandler	3.6 lb/gal EC	0.44	Fruit	0	0.26, 0.24
Washington, OR 1996 0W-FR-610-96	12	Totem	3.6 lb/gal EC	0.44	Fruit	0	0.07, 0.22
Ottawa, MI 1996 NE-FR-710-96	5	Kent	3.6 lb/gal EC	0.44	Fruit	0	0.19, 0.19
						8	0.11, 0.11
Wayne, NY 1996 NE-FR-817-96	1	Tribute	3.6 lb/gal EC	0.44	Fruit	0	0.38, 0.39

1 Total propiconazole residues were determined as DCBA and expressed in parent equivalents. Reported values were obtained from the raw data and are not corrected procedural recoveries. The LOQ for propiconazole residues is 0.05 ppm in/on strawberry, and the LOD is 0.02 ppm.

TABLE C.4. Summary of Residue Data from Strawberry Field Trials with Propiconazole (EC).

Commodity	Total Applic. Rate (lb ai/A)	End-use Product	PHI (days)	Residue Levels (ppm)[1]						
				n	Min.	Max.	HAFT[2]	Median (STMdR)[3]	Mean (STMR)[4]	Std. Dev.
Strawberry	0.44	3.6 lb/gal EC	0	16	0.07	0.69	0.60	0.32	0.35	0.19

1 The LOQ is 0.05 ppm. Residue data are not corrected for procedural recoveries.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

D. CONCLUSION

The strawberry field trial data are adequate and will support the use of propiconazole (EC) on strawberries as up four broadcast foliar applications at 0.11 lb ai/A/application, at a minimum RTI of 7 days, for a total of 0.44 lb ai/A/season, with a 0-day PHI.

E. REFERENCES

DP Barcode: D279300
Subject: Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From: Y. Donovan
To: S. Lewis/J. Guerry
Dated: 8/18/05
MRID: None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 2F6371
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED Yan Donovan	Date: 07/03/06
Approved by	Susan Hummel, Senior Scientist, RRB4/HED Susan Hummel	Date:07/03/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 6/1/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

45778901 Thompson, D. (2002) Propiconazole: Magnitude of the Residue on Cranberry: Lab Project Number: 07359: 07359.99-CIR06: 07359.99-OR30. Unpublished study prepared by Syngenta Crop Protection, Inc. and Oregon State University. 117 p.

44338101 Thompson, D. (1997) Propiconazole: Magnitude of Residue on Cranberry: Lab Project Number: 06320: 06320.95-ABC08: 06320.95-WI14. Unpublished study prepared by Interregional Research Project No. 4. 343 p.

EXECUTIVE SUMMARY:

A total for three cranberry field trials were conducted, including two in WI during 1995 and one in OR during 1999. In each test, propiconazole (3.6 lb/gal EC) was applied to established fields of cranberries as four broadcast foliar applications at 0.156-0.170 lb ai/A/application, for a total of 0.66-0.68 lb ai/A/season. The first two applications were made at bud break and at ~14 days after bud break, and the final two applications were made during fruit development. Retreatment intervals (RTIs) were 13-14 days between the first and second applications, 45-56 days between the second and third applications, and 11-14 days or 78 days between the third and fourth applications. No adjuvants were included in the spray mixes, and all application were made using ground equipment in 18-80 gal/A. One to four control samples and duplicate treated samples of cranberries were harvested from each site at 43 or 44 days after the final application (DAT). Samples were stored frozen from collection to analysis for up to 78 days. This interval is supported by the concurrent storage study indicating that propiconazole is stable at -20°C in cranberries for up to 92 days.

The combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on cranberries were determined using either a GC/NPD method (Method AG-454B, modified) for the 1995 tests or a GC/ECD method (Method AAG-626) for the 1999 test. These methods are updated versions of the current tolerance enforcement method. For both methods, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and cleaned-up using an acidic alumina cartridge. Methylated DBCA was determined by GC/NPD

K

(1995 tests) or GC/ECD (1999 test), using external standards, and residues are expressed in parent equivalents. The validated method limit of quantitation (LOQ) is 0.05 ppm, and a limit of detection (LOD) was not reported. Control samples of cranberries were fortified with propiconazole at 0.05, 0.50, and 1.0 ppm and recoveries at each level averaged 74-96%, with standard deviations range from 2-25 %.

Following four applications of propiconazole (EC) totaling 0.66-0.68 lb ai/A, residues were 0.18-0.59 ppm in/on 6 cranberry samples harvested 43-44 DAT, and averaged 0.32 ppm. A residue decline trial was not conducted.

These field trial data support the use of propiconazole (EC) on cranberries grown in WI and the Pacific Northwest. The available data support up to four applications at 0.169 lb ai/A/application, for a total of 0.68 lb ai/A/season, with minimum RTIs of 14 days and a PHI of 45 days.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in these studies, the cranberry field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited a number of minor deviations from GLP requirements relating to records on maintenance chemicals, SOPs, collection of field trial environmental data, and correction of raw data. However, none of deviations were serious enough to adversely affect the conclusions of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities, including a Section 18 for cranberry at 1.0 ppm [40 CFR §180.434(b)], which is set to expired on 12/31/07.

IR-4 has submitted a petition (PP# 7E4860) proposing the use of propiconazole (3.6 lb/gal EC; EPA Reg. No. 100-702; Orbit™ Fungicide) for the control of cotton ball disease on cranberries grown in WI and the Pacific Northwest.

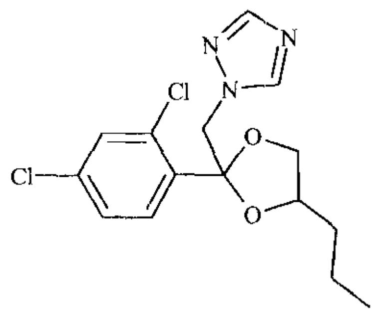
TABLE A.1. Nomenclature of Propiconazole	
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EP	3.6 lb/gal EC (Orbit™ Fungicide, EPA Reg. No. 100-702) 3.6 lb/gal EC Tilt® Fungicide, EPA Reg No. 100-617)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.

Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK$_a$)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K$_{OW}$)	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Cranberries were grown and maintained at each test site using typical agricultural practices for the geographical region (Table B.1.1). Monthly rainfall and irrigation data were provided for each site, along with detailed temperature data and soil data. Although the study authors noted that the spring was usually wet and cool for the OR trial, no usual weather conditions were otherwise noted that would have an adverse effect on the field trial data. Information was also provided on maintenance chemicals and other pesticides used at each site. Applications of propiconazole (EC) were made to established stands of cranberries (Table B.1.2).

TABLE B.1.1. Trial Site Conditions.

Trial Identification (City, State; Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC [2] (meq/g)
Warrens, WI, 1995	Sand	2.9	6.9	NR
Wisconsin Rapids, WI, 1995	Sand	2.7	5.7	NR
Bandon, OR, 1999	Sand	50.0	5.6	NR

[1] These parameters are optional except in cases where their value affects the use pattern for the chemical.
[2] Cation exchange capacity.
NR = Not Reported

TABLE B.1.2. Study Use Pattern on Cranberry.								
Location (City, State; Year) Trial ID	End-use Product	Application Information						Tank Mix/ Adjuvants
		Method; Timing	Volume (gal/A)	Rate (lb ai/A)	RTI [1] (days)	Total Rate (lb ai/A)		
Warrens, WI, 1995 WI14	3.6 lb/gal EC	broadcast foliar at bud break	18-21	0.169	--	0.656		None
		broadcast foliar at 14 days after bud break		0.169	14			
		broadcast foliar at early fruit set		0.162	56			
		broadcast foliar at mid-fruit development		0.156	14			
Wisconsin Rapids WI, 1995 WI15	3.6 lb/gal EC	broadcast foliar at bud break	23-26	0.169	--	0.676		None
		broadcast foliar at 14 days after bud break		0.169	14			
		broadcast foliar at green fruit stage		0.169	56			
		broadcast foliar at pink fruit stage		0.169	11			
Bandon, OR, 1999 07359.99-OR30	3.6 lb/gal EC	broadcast foliar at bud break	74-80	0.170	--	0.680		None
		broadcast foliar at hook stage (immediately prior to flowering)		0.170	13			
		Broadcast foliar at early bloom		0.170	45			
		broadcast foliar at fruiting		0.170	78			

[1] RTI = Retreatment Interval.

TABLE B.1.3. Trial Numbers and Geographical Locations.			
NAFTA Growing Zones[1]	Cranberry		
	Submitted[2]	Requested	
		Canada	U.S.
1	---	---	2
2	---	---	---
3	---	---	---
4	---	---	---
5	2	---	2
6	---	---	---
7	---	---	---
8	---	---	---
9	---	---	---
10	---	---	---
11	---	---	---
12	1	---	1
Total	3	NA	5

1 Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the proposed use is for the US only.
2 The petitioner is requesting use on cranberries only in Wisconsin and the Pacific N.W.
NA = Not applicable

B.2. Sample Handling and Preparation

One to four control and duplicate treated samples of cranberries (2 lb/sample) were harvested from each test site at commercial maturity, 43 or 44 DAT. All samples were placed into freezers within 6.25 hours of collection and stored frozen until shipment by freezer truck or overnight on dry ice to Syngenta (Greensboro, NC), where samples were stored at <-20°C. Samples from the

1999 test were analyzed at Syngenta, but samples from the 1995 tests were shipped on dry ice by overnight courier to ABC Laboratories (Columbia, MO) for analysis. Samples were stored frozen at the analytical laboratories prior to preparation and extraction for analysis.

B.3. Analytical Methodology

Cranberry samples were analyzed for residues of propiconazole and its DCBA-containing metabolites using either a GC/NPD method (Method AG-454B, modified) for the 1995 tests or a GC/ECD method (Method AG-626) for the 1999 test. Both these methods are updated versions of the current tolerance enforcement method for propiconazole residues in plant commodities. The methods convert all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents. The principle modification to Method AG-454B in this study was that a NP detector was used for analysis rather than an EC detector, and the principle difference for AG-626 is that iodomethane is used for methylation rather than diazomethane.

For both methods, residues are extracted and base hydrolyzed by refluxing for 1 hour with NH_4OH/MeOH (20:80, v/v) and filtered. Residues are concentrated and oxidized to 2,4-DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, the $KMnO_4$ is deactivated by the addition of sodium meta-bisulfite, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v) and evaporated to dryness. Residues are methylated using diazomethane in Method AG-454B and using iodomethane in Method AG-626. Residues are then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and analyzed by either GC/NPD (AG-454B) or by GC/ECD (AG-626), using external standards. The validated method LOQ is 0.05 ppm, and an LOD was not reported.

In conjunction with the analysis of field trial samples, the above methods were validated using control samples of cranberries fortified with propiconazole at 0.05, 0.5 and 1.0 ppm.

C. RESULTS AND DISCUSSION

In 2 field trials conducted in WI during 1995 and one field trial conducted in OR during 1999, propiconazole (EC) was applied to cranberries as four broadcast foliar applications at 0.156-0.170 lb ai/A/application, for a total of 0.66-0.68 lb ai/A/season. The first two applications were made at bud break and at 14 days after bud break, and the final two applications were made during fruit development. Minimum RTIs were 11-14 days between applications. Adjuvants were not included in the spray mixes, and all application were made using ground equipment in 18-80 gal/A. One to four control samples and duplicate treated samples of cranberries were harvested from each site at 43 and 44 DAT.

The GC/NPD (Method AG-454B, modified) and GC/ECD (Method AG-626) methods used to determine total combined propiconazole residues in/on cranberries were adequately validated in conjunction with the analysis of field samples. Control samples of cranberries were fortified with propiconazole at 0.05-1.0 ppm and recoveries at each level averaged 74-96%, with standard deviations of 2-25 % (Table C.1). Apparent residues of propiconazole were <LOQ in/on all 7 control samples. The validated method LOQ for propiconazole in cranberries is 0.05 ppm, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided.

Cranberry samples were stored frozen for 37-78 days prior to extraction for analysis (Table C.2.1). To demonstrate the stability of residues in/on cranberry, a freezer storage stability study was conducted in conjunction with analysis of samples from the WI field trials. Control samples of chopped cranberry were fortified with propiconazole at 1.0 ppm. Three fortified samples were analyzed immediately (Day 0) and the remaining fortified samples were placed in storage at -20°C. Three stored samples were analyzed after 92 days along with a control and two freshly fortified samples. The average corrected recovery of propiconazole was 101% following 92 days of storage (Table C.2.2). These data will support the frozen storage intervals in the current cranberry field trials.

Following applications of propiconazole totaling 0.66-0.68 lb ai/A/season, total propiconazole residues, determined as DCBA, were 0.18-0.59 ppm in/on 6 cranberry samples harvested 43-44 days following the fourth application (Table C.3). Average propiconazole residues were 0.32 ppm (Table C.4). A residue decline trial was not conducted.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

TABLE C.1. Summary of Method Recoveries of Propiconazole from Cranberry.

Analyte	Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
GC/NPD (Method AG-454B, modified)					
Propiconazole	Cranberry	0.05	3	74, 84, 64	74 ±10
		0.50	3	74, 76, 77	76 ± 2
		1.00	5	76, 79, 79, 86, 83	81 ± 4
GC/ECD (Method AG-626)					
Propiconazole	Cranberry	0.05	3	71, 96, 120	96 ± 25
		1.00	4	95, 93, 90, 86	91 ± 4

TABLE C.2.1 Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1] (days)	Interval of Demonstrated Storage Stability (days)
Cranberry RAC	-20	37-78	92

[1] From harvest to extraction for analysis.

TABLE C.2.2 Stability of Propiconazole in Frozen Cranberries.

Analyte	Spike Level (ppm)	Storage interval (days)	Freshly Fortified Recovery (%)	Stored Sample Residues (%)	Average Corrected Stored Recovery (%) [1]
Propiconazole	1.0	0	NA	76, 79, 79 [78] [2]	100
		92	86, 83 [85]	82, 88, 89 [86]	101

1 Average recovery of stored samples corrected using average recovery from fresh fortifications.
2 Average recoveries are listed in brackets.
NA = not applicable.

TABLE C.3. Residue Data from Cranberry Field Trials with Propiconazole (3.6 lb/gal EC).

Trial ID (City, State; Year)	Zone	Variety	Total Rate	PHI (days)	Total Propiconazole Residues (ppm)[1]
Warrens, WI, 1995 WI14	5	McFarlane	0.656	43	0.59, 0.46
Wisconsin Rapids, WI, 1995 WI15	5	Ben Lear	0.676	44	0.18, 0.22
Bandon, OR, 1999 99-OR30	12	Stevens	0.680	44	0.23, 0.23

1 Total propiconazole residues determined as DCBA and expressed in parent equivalents. The LOQ for propiconazole residues in/on cranberries is 0.05 ppm. The LOD was not reported.

TABLE C.4. Summary of Residue Data from Cranberry Field Trials with Propiconazole (3.6 lb/gal EC).

Commodity	Total Applic. Rate (lb a.i./A)	PHI (days)	Residue Levels (ppm)[1]						
			n	Min.	Max.	HAFT[2]	Median (STMdR)[3]	Mean (STMR)[3]	Std. Dev.
Cranberry	0.66-0.68	43-44	6	0.18	0.59	0.53	0.23	0.32	0.17

1 The LOQ is 0.05 ppm; and the LOD was not reported.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

D. CONCLUSION

The cranberry field trial data are adequate and support the use of propiconazole (EC) on cranberries grown in WI and the Pacific N.W. The available data support up to four applications at 0.169 lb ai/A/application, for a total of 0.68 lb ai/A/season, with minimum RTIs of 14 days and a PHI of 45 days.

E. REFERENCES

None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 7E4860
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED Yan Donovan	Date: 06/30/06
Approved by	Susan Hummel, Senior Scientist, RRB4/HED Susan Hummel	Date: 06/30/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 6/29/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

46473001 Lin, K. (2005) Propiconazole, Cyproconazole and Chlorothalonil - Magnitude of the Residues in Soybean Seed. Project Number: N4/FR/005/03, NJ/FR/006/03, S3/FR/002/03. Unpublished study prepared by Syngenta Crop Protection, Inc., Agvise Inc. and Morse Laboratories, Inc. 275 p.

EXECUTIVE SUMMARY:

In four soybean field trials conducted in IL, IN and MS during 2003, propiconazole (3.6 lb/gal EC) was applied to soybeans as late-season broadcast foliar applications during pod and seed development. Each field site compared three different application regimes for propiconazole: (1) three applications at 0.11-0.12 lb ai/A from BBCH Stages 71 to 89, for totals of 0.32-0.35 lb ai/A/season; (2) two applications at 0.10-0.12 lb ai/A at BBCH stages 77 to 89, for totals of 0.23-0.24 lb ai/A/season; and (3) two applications at 0.17-0.19 lb ai/A, at BBCH stages 77 to 89 for totals of 0.33-0.36 lb ai/A/season. The BBCH growth stages of 71-89 are equivalent to Stages R4-R8. All applications were made using ground equipment in volumes of 16-21 gal/A at retreatment intervals (RTIs) of 13-18 days, and did not include the use of any adjuvants. Single control and duplicate treated samples of soybean seed were harvested from each test at 30 days after treatment (DAT). Soybean seed samples were stored frozen for up to 8.5 months prior to extraction for analysis, an interval supported by available storage stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on soybean seeds were determined using an adequate GC/ECD method (Method AG-626). For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization with $KMnO_4$. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated with iodomethane, and partitioned into hexane. Methylated DBCA is determined by GC/ECD, using external standards, and residues are expressed in parent equivalents. The validated method LOQ is 0.05 ppm, and an LOD was not reported.

Following three late-season foliar applications totaling 0.32-0.35 lb ai/A, combined propiconazole residues were 0.56-1.40 ppm in/on 8 samples of soybean seeds harvested at 30

M

DAT and residues averaged 0.86 ppm. Following the two late-season applications at rates totaling 0.23-0.25 or 0.32-0.35 lb ai/A, total residues in/on soybean seeds were 0.10-0.67 ppm for 8 samples from the low rate tests and 0.17-0.94 ppm for 8 samples from the high rate tests. Average residues in/on seed from the two application tests were 0.27 ppm for the low rate and 0.39 ppm for the high rate. No residue decline trials were conducted.

At all four trial sites, residues levels in soybean seeds were highest following the three applications at ~0.11 lb ai/A and lowest following two applications at ~0.11 lb ai/A, with the two applications at ~0.17 lb ai/A having intermediate residue levels.

The soybean field trials are adequate for purposes of comparing the three different late-season application regimes. At all four trial sites, residues levels in soybean seeds were highest following the three applications at ~0.11 lb ai/A and lowest following two applications at ~0.11 lb ai/A, with the two applications at ~0.17 lb ai/A having intermediate residue levels.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the soybean field trial data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited minor deviations from GLP compliance, pertaining to the collection of weather data, tank mix storage stability data, and the application of maintenance chemicals. None of these deviations affect the overall acceptability of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities, including time-limited tolerances of 2.0, 10 and 25 on soybean seeds, forage and hay, respectively [40 CFR §180.434(b)].

Syngenta has submitted at petition (PP#2F6371) proposing tolerances and the use of propiconazole on soybeans. The current submission includes residue data from four field trials reflecting late-season applications of several fungicides for the control of soybean rust. Two to three foliar applications were made to soybeans at Growth Stages R4-R8 (BBCH stages 71-89). The treatments included the use of propiconazole or cyproconazole or propiconazole in combination with chlorothalonil. Only the treatments relating to the use of propiconazole are discussed in this review.

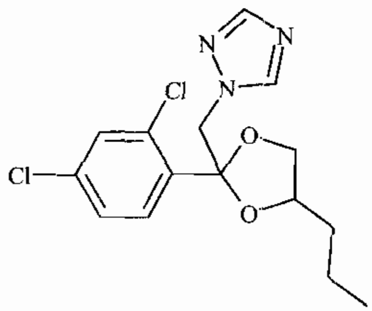
TABLE A.1. Nomenclature of Propiconazole	
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EPs	3.6 lb/gal EC (Tilt 3.6E Fungicide, EPA Reg. No. 100-617)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.		
Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK$_a$)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K$_{OW}$)	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (*8max, nm*)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Soybeans were grown and maintained at four test sites in Regions 4 and 5 using typical agricultural practices for these regions (Table B.1.1). Monthly rainfall and irrigation data were provided for each site, along with temperature data. No usual weather conditions were noted that would have an adverse effect on the field trial data. Information was provided on soil characteristics at each site, along with the maintenance chemicals and other pesticides used.

Each field site included the following three treatment regimes using late-season foliar applications of propiconazole (3.6 lb/gal EC) during pod and seed development: (1) three broadcast foliar applications at a target rate of 0.115 lb ai/A, for a total of 0.34 lb ai/A/season; (2) two broadcast foliar applications at a target rate of 0.115 lb ai/A, for a total of 0.23 lb ai/A/season; and (3) two broadcast foliar applications at a target rate of 0.172 lb ai/A, for a total of 0.34 lb ai/A/season (Table B.1.2). The first treatment also included applications of chlorothalonil, and a fifth treatment used two applications of cyproconazole. However, only the data relating to propiconazole are presented in this review.

TABLE B.1.1. Trial Site Conditions.				
Trial Identification (County, State; Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC[2] (meq/g)
Champaign, IL 2003	Silty Clay Loam	5.3	8.1	49.5
Attica, IN 2003	Silt Loam	2.9	5.0	11.3
Leland, MS 2003	Clay	1.84	6.6	31.6
Leland, MS 2003	Silt Loam	0.97	5.5	7.3

[1] These parameters are optional except in cases where their value affects the use pattern for the chemical.
[2] Cation exchange capacity.

TABLE B.1.2. Study Use Pattern on Soybean.

Location (County, State; Year) Trial ID	End-use Product	Application Information [1]				
		Method; Timing [2]	Volume (GPA)	Single Rate (lb ai/A)	RTI (days)	Total Rate (lb ai/A)
Champaign, IL 2003 N4-FR-007-03	3.6 lb/gal EC	Three broadcast foliar applications at BBCH growth stages 73, 79 and 89	16-17	0.11-0.12	15, 18	0.34
		Two broadcast foliar applications at BBCH growth stages 79 and 89	17	0.11-0.12	13	0.23
		Two broadcast foliar applications at BBCH growth stages 79 and 89	16-17	0.17	13	0.34
Attica, IN 2003 NJ-FR-008-03	3.6 lb/gal EC	Three broadcast foliar applications at BBCH growth stages 73, 79 and 89	16	0.11-0.12	14, 13	0.33
		Two broadcast foliar applications at BBCH growth stages 79 and 89	16-18	0.10-0.12	13	0.23
		Two broadcast foliar applications at BBCH growth stages 79 and 89	16-18	0.17-0.18	13	0.35
Leland, MS 2003 S3-FR-002-03	3.6 lb/gal EC	Three broadcast foliar applications at BBCH growth stages 71, 77 and 85	17-18	0.11	14, 13	0.32
		Two broadcast foliar applications at BBCH growth stages 77 and 85	18-21	0.11-0.12	13	0.24
		Two broadcast foliar applications at BBCH growth stages 77 and 85	19-20	0.18	13	0.36
Leland, MS 2003 SE-FR-003-03	3.6 lb/gal EC	Three broadcast foliar applications at BBCH growth stages 71, 77 and 85	19-20	0.12	14, 13	0.35
		Two broadcast foliar applications at BBCH growth stages 77 and 85	18-19	0.11-0.12	13	0.23
		Two broadcast foliar applications at BBCH growth stages 77 and 85	19-20	0.17-0.19	13	0.36

1 All applications were made using ground equipment, and no adjuvants were included in the spray mix.
2 BBCH Growth stages 73, 79 and 89 are equivalent to Growth stages R4, R6 and R8, respectively.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones[1]	Soybean		
	Submitted	Requested	
		Canada	U.S.
1	---	---	---
2	---	---	2
3	---	---	---
4	2	---	3
5	2	---	15
6	---	---	---
7	---	---	---
8	---	---	---
9	---	---	---
10	---	---	---
11	---	---	---
12	---	---	---
Total	4	NA	20

1 Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the use is for only in the U.S.
NA = Not applicable

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of mature soybean seeds (>3 lb/sample) were collected from each test at 30 DAT. Samples were frozen shortly after harvest and held in frozen storage (-15°C) at the field sites for 20-34 days until shipment by freezer truck to the analytical laboratory, Syngenta (Greensboro, NC), where samples were prepared (homogenized) and stored at -15EC until analysis.

B.3. Analytical Methodology

Samples were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-626), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, total propiconazole residues were extracted by refluxing for 1 hour in NH_4OH/methanol (20:80, v/v), and filtered. Residues were concentrated and oxidized to DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract was diluted with water, the $KMnO_4$ was deactivated by the addition of sodium meta-bisulfite, and the extract was acidified by the addition of 6N HCl. Residues of DCBA were partitioned into hexane:diethyl ether (90:10, v/v), evaporated to dryness, redissolved in acetone, and methylated using methyl iodide in the presence of tetrabutyl ammonium hydroxide. Methylated residues were then diluted with hexane, concentrated to remove the acetone, and partitioned against water. Residues in the remaining hexane fraction were then analyzed by GC/ECD using external standards. The validated method LOQ is 0.05 ppm for soybean seeds, and a LOD was not reported.

In conjunction with the analysis of field trial samples, the above method was validated using control samples fortified with propiconazole at 0.05-1.0 ppm.

C. RESULTS AND DISCUSSION

In four soybean field trials conducted in IL, IN and MS (2 trails) during 2003, propiconazole (3.6 lb/gal) was applied to soybeans as two or three late-season broadcast foliar applications during pod and seed development. Each field site compared three different application regimes for propiconazole: (1) three applications at 0.11-0.12 lb ai/A from BBCH Stages 71 to 89 at RTIs of 13-18 days, for totals of 0.32-0.35 lb ai/A/season; (2) two applications at 0.10-0.12 lb ai/A at BBCH stages 77 to 89, at a RTI of 13 days, for totals of 0.23-0.24 lb ai/A/season; and (3) two applications at 0.17-0.19 lb ai/A, at BBCH stages 77 to 89, at a RTI of 13 days for totals of 0.33-0.36 lb ai/A/season. All applications were made using ground equipment in volumes of 16-21 gal/A, and did not include the use of any adjuvants. Single control and duplicate treated samples of soybean seed were harvested from each test at 30 DAT.

The GC/ECD method (Method AG-626) used to determine total propiconazole residues in/on soybean seeds was adequately validated in conjunction with the analysis of field trial samples. The recovery of propiconazole averaged 98 ±17% from soybean seeds fortified at 0.05-1.0 ppm (Table C.1). Apparent residues of propiconazole were 0.052-0.068 ppm in/on the four control samples of soybean seed. No explanation was given as to why residues were detected in the control samples; however, the apparent residues in the control samples will not have an adverse impact on the field trial data, as residue levels in control samples were considerably lower than residues found in treated seeds. The validated method LOQ for propiconazole is 0.05 ppm, and a LOD was not reported. Adequate sample calculations and example chromatograms were provided.

Soybean seed samples were stored frozen for up to 8.5 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating the residues of propiconazole and its metabolites are stable at -20° C for up to 36 months in peanuts (DP Barcode D279300, Y. Donovan, 8/18/05), which is similar in composition to soybean seeds. Although seed extracts from one test were stored for up to 53 days prior to analysis, data are also available indicating that residues are stable in soybean extracts for at least 3 months at 4°C. These data will support the storage intervals and conditions for the soybean field trials.

Following three foliar applications of propiconazole (EC) from growth stage 71 to 89 at rates totaling 0.32-0.35 lb ai/A, total combined residues were 0.56-1.40 ppm in/on 8 samples of soybean seeds harvested at 30 DAT and averaged 0.86 ppm (Tables C.3 and C.4). Following the two applications from stages 77-89 at rates totaling 0.23-0.25 or 0.32-0.35 lb ai/A, total residues in/on soybean seeds were 0.10-0.67 ppm for 8 samples from the low rate and 0.17-0.94 ppm for 8 samples from the high rate. Average residues in/on seed from the two application tests were 0.27 ppm for the low rate and 0.39 ppm for the high rate. No residue decline trials were conducted.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

TABLE C.1. Summary of Concurrent Recoveries of Propiconazole from Soybean Seed.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Seed	0.05-1.0	5	85-126 [1]	98 ± 17

[1] Actual recoveries were not reported. Only the range, mean and standard deviation were reported.

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration [1] (months)	Interval of Demonstrated Storage Stability (months) [2]
Seed	-20	6.1-8.5	36

[1] From harvest to extraction for analysis. Samples from three test sites were analyzed within 1-6 days of extraction, but extracts from the fourth site were stored for 53 days prior to analysis.

[2] DP Barcode D279300, Y. Donovan, 8/18/05.

TABLE C.3. Residue Data on Soybean Seeds Following Two or Three Late Season Applications of Propiconazole (EC).

Trial ID (County, State; Year)	Zone	Variety	No. of Applications	Total Rate (lb ai/A) [1]	PHI (days)	Commodity	Total Propiconazole Residues (ppm) [2]
Champaign, IL 2003 N4-FR-007-03	5	Golden Harvest 3503 RR	3	0.34	30	Seed	0.75, 0.78
			2	0.23			0.15, 0.14
			2	0.34			0.19, 0.21
Attica, IN 2003 NJ-FR-008-03	5	Beck's 306	3	0.33	30	Seed	0.64, 0.68
			2	0.23			0.12, 0.10
			2	0.35			0.17, 0.23
Leland, MS 2003 S3-FR-002-03	4	NK X248R	3	0.32	30	Seed	1.4, 1.4
			2	0.24			0.59, 0.67
			2	0.36			0.86, 0.94
Leland, MS 2003 SE-FR-003-03	4	NK X249R	3	0.35	30	Seed	0.64, 0.56
			2	0.23			0.17, 0.18
			2	0.36			0.23, 0.26

1 Total propiconazole residues were determined as DCBA and expressed in parent equivalents. The method LOQ is 0.05 ppm, and a LOD was not reported. Apparent residues were detected in all control samples at 0.052-0.068 ppm.

TABLE C.4. Summary of Residue Data on Soybean Seeds from Field Trials with Propiconazole (EC)

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm) [1]						
			n	Min.	Max.	HAFT [2]	Median (STMdR) [3]	Mean (STMR) [3]	Std. Dev.
Seed	0.32-0.35 [4]	30	8	0.56	1.40	1.40	0.72	0.86	0.34
	0.23-0.25 [5]		8	0.10	0.67	0.63	0.16	0.27	0.23
	0.34-0.36 [5]		8	0.17	0.94	0.90	0.23	0.39	0.32

1 Total propiconazole residues were determined as methyl-DCBA and expressed in parent equivalents. The method LOQ is 0.05 ppm.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.
4 Rate reflects three applications at ~0.11 lb ai/A/application.
5 Rates reflect two applications at ~0.11 or ~0.17 lb ai/A/application.

D. CONCLUSION

The soybean field trials are adequate for purposes of comparing the three different late-season application regimes. At all four trial sites, residues levels in soybean seeds were highest following the three applications at ~0.11 lb ai/A and lowest following two applications at ~0.11 lb ai/A, with the two applications at ~0.17 lb ai/A having intermediate residue levels.

E. REFERENCES

DP Barcode:	D279300
Subject:	Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From:	Y. Donovan
To:	S. Lewis/J. Guerry
Dated:	8/18/05
MRID:	None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 2F6371
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED Yan Donovan	Date: 06/15/06
Approved by	Susan Hummel, Branch Senior Scientist, RRB4/HED Susan Hummel	Date: 06/15/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 5/26/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

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

EXECUTIVE SUMMARY:

In a two field trials conducted during 1998 in AR and LA, propiconazole (3.6 lb/gal EC) was applied to rice as single broadcast foliar application at heading at 0.28 or 1.40 lb ai/A (0.8x and 4.1x rates) at each site. Rice was grown and harvested at commercial maturity, 35 days after the last treatment (PHI = 35days). Following harvest, whole rice grain was processed using simulated commercial procedures into polished rice, hulls and bran. Prior to analysis, rice and processed fractions were stored frozen up to 11.1 months, an interval supported by the available storage stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on rice grain and processed fractions were determined using an adequate GC/ECD method (Method AG-626). For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization with $KMnO_4$. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and cleaned-up using an acidic alumina cartridge. Methylated DBCA is determined by GC/ECD, using external standards, and residues are expressed in parent equivalents. The validated method LOQ is 0.05 ppm, and a LOD was not reported.

Following application of propiconazole (3.6 lb/gal EC) to rice at 0.28 or 1.40 lb ai/A (0.8x and 4.1x), combined propiconazole residues in/on rice grain at 35 DAT were 0.82 and 0.86 ppm in the two 0.8x tests and 2.4 and 3.7 ppm in the two 4.1x tests. Combined residues were reduced in polished rice by 0.06x-0.19x, and concentrated in rice hulls by 3.0x-4.1x and in bran by 1.7x-3.9x. For all four tests, the average processing factors were 0.12x for polished rice, 3.8x for hulls, and 2.9x for bran.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the rice processing studies are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document D 238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited minor deviations from GLP compliance, pertaining to the collection of weather data, tank mix storage stability data and maintenance chemicals and irrigation application. None of these deviations affect the overall acceptability of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broard spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities, including tolerances of 0.1 and 3.0 ppm on rice grain and straw [40 CFR §180.434(a)].

Under PP#2F6371, Syngenta is requesting revised tolerances on rice commodities in conjunction with a proposal to modify the current use directions on rice to include an application later in the season. The current submission includes processing data on rice grain.

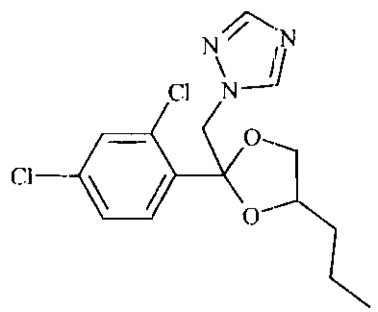
TABLE A.1. Nomenclature of Propiconazole	
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EP	3.6 lb/gal EC (Tilt Fungicide, EPA Reg. No. 100-617)
Regulated Metabolite	None
Common name	N/A
IUPAC name	N/A
CAS #	N/A

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.

Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No.:43698701
pH	4.9 @ 25°C (1% aqueous tdispersion)	MRID No.:43698701
Density	1.289 g/cm3 typical @ 20°C	MRID No.: 43698701
Water solubility (20°C)	0.10 g/L at 20°C	MRID No.: 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. n-hexane = 47 g/L	MRID No.: 42030201
Vapor pressure at 25°C	4.2 x 10^{-7} mm Hg @ 25°C	MRID No.: 41720301
Dissociation constant (pK_a)	1.09	MRID No.: 43698701
Octanol/water partition coefficient Log(K_{OW}) (25 °C)	3.72 @ pH 6.6	MRID No.: 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No.: 40583703

B. EXPERIMENTAL DESIGN

B.1. Application and Crop Information

Propiconazole (EC) was applied to rice at two field sites as single broadcast foliar application at 0.28 or 1.40 lb ai/A (Table B.1.1). These rates are equivalent to 0.8x and 4.1x the proposed maximum seasonal use rate on rice.

TABLE B.1.1. Study Use Pattern on Rice.

Location (County, State; Year) Trial ID	End-use Product	Application to Primary Wheat Crop				Tank Mix/ Adjuvants
		Method; Timing	Volume (gal/A)	Rate (lb ai/A)	Total Rate (lb ai/A)	
Jackson, AR 1998 105	3.6 EC	One broadcast foliar application at 30% headed	20	0.28	0.28	None
				1.40	1.40	
St. Landry Parish, LA 1998 901	3.6 EC	One broadcast foliar application at 60% heading	21	0.28	0.28	None
				1.40	1.40	

B.2. Sample Handling and Processing Procedures

Single bulk samples of control and treated rice grain were harvested at normal crop maturity, 35 DAT. After collection, the grain samples were frozen and immediately shipped frozen via overnight courier to the Food Protein R&D Center, Bryan, TX for processing. Grain was processed by dehulling, abrading and polishing using simulated commercial practices. The rice was processed into hulls, brown rice, bran and polished white rice. Unprocessed samples of rice were collected at the processor before processing and samples of each processed fraction were collected immediately after processing. Samples were then shipped frozen to the Human Safety Department at Novartis Crop Protection (Greensboro, NC), and stored at -20°C until analysis.

B.3. Analytical Methodology

Rice grain and processed fractions were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-626), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, residues are extracted and base hydrolyzed by refluxing for 1 hour with NH_4OH/MeOH (20:80, v/v) and filtered. Residues are concentrated and oxidized to 2,4-DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, sodium meta-bisulfite is added to deactivate the $KMnO_4$, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using methyl iodide in the presence of tetrabutyl ammonium hydroxide. Residues are partitioned into hexane and then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v). The methylated DCBA is then analyzed by GC/ECD, using external standards. Residues are expressed in propiconazole equivalents. The validated method LOQ is 0.05 ppm for residues in/on rice commodities; the LOD was not reported.

In conjunction with the analysis of the rice processing study samples, the above method was validated using control samples fortified with propiconazole at 0.05 and 1.0 ppm for grain, hulls, and polished rice and at 1.0-10 ppm for bran.

C. RESULTS AND DISCUSSION

The GC/ECD method (Method AG-626) used to determine propiconazole residues in/on rice grain and rice processed commodities was adequately validated in conjunction with the analysis of treated samples. Recoveries averaged 71-102% from grain and processed products fortified at 0.05-10 ppm. Apparent residues of propiconazole were <LOQ in/on all control samples. The validated method LOQ is 0.05 ppm for combined propiconazole residues in/on rice grain and processed fractions; the LOD was not reported. Adequate sample calculations and example chromatograms were provided.

Rice grain and processing samples were stored frozen for 11.1 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating 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. (DP Barcode D240856, T. Morton, 02/23/05) These data will support the storage intervals and conditions for the current processing study.

Combined propiconazole residues were readily quantifiable in/on rice grain harvested 35 days following an application of propiconazole (EC) at either 0.28 or 1.40 lb ai/A. Residues in/on rice grain were 0.82 and 0.86 ppm in the two tests treated at 0.28 lb ai/A, and 2.4 and 3.7 ppm in the two test treated at 1.40 lb ai/A (Table C.3). Combined residues were reduced in polished rice by 0.06x-0.19x, and concentrated in rice hulls by 3.0x-4.1x and in bran by 1.7x-3.9x. For all four tests, the average processing factors were 0.12x for polished rice, 3.8x for hulls, and 2.9x for bran.

TABLE C.1. Summary of Concurrent Recoveries of Propiconazole from Rice Grain and Processed Rice Commodities Using GC/ECD Method AG-626.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Grain (from processor)	0.5, 1.0	2	88, 77	83
Polished Rice	0.05, 1.0	2	88, 84	86
Rice Hulls	0.05, 1.0	2	110, 93	102
Rice Bran	1.0-10.0	3	57, 74, 81	71 ± 12

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration (Months) [1]	Interval of Demonstrated Storage Stability (days) [2]
Rice grain and processed products	-20	11.1	25

[1] From harvest to extraction for analysis.
[2] DP Barcode D210742, 3/15/95, M. Rodriguez.

TABLE C.3. Residue Data from Processing Studies with Rice.

Location	Total Rate (lb ai/A)	Processed Commodity	Harvest Interval DAT [2]	Residues (ppm)	Processing Factor
Jackson, AR 1998 105	0.28	Grain (from processor)	35	0.86	NA
		Polished Rice		0.14	0.16
		Rice Hulls		3.5	4.1
		Rice Bran		3.0	3.5
	1.40	Grain (from processor)	35	2.4	NA
		Polished Rice		0.45	0.19
		Rice Hulls		9.5	4.0
		Rice Bran		9.3	3.9
St. Landry Parish, LA 1998 901	0.28	Grain (from processor)	35	0.82	NA
		Polished Rice		<0.05	0.06
		Rice Hulls		3.4	4.1
		Rice Bran		1.9	2.3
	1.40	Grain (from processor)	35	3.7	NA
		Polished Rice		0.28	0.08
		Rice Hulls		11.0	3.0
		Rice Bran		6.3	1.7

[2] DAT = days after treatment.
NA = not applicable

TABLE C.4. Summary of Average Processing factors			
Processed Commodity	Processing Factors	Harvest Interval DAT [2]	Average processing Factors
Polished Rice	0.16	35	0.12
	0.19		
	0.06		
	0.08		
Rice Hulls	4.1	35	3.8
	4.0		
	4.1		
	3.0		
Rice Bran	3.5	35	2.9
	3.9		
	2.3		
	1.7		

D. CONCLUSION

The rice processing data are adequate and indicate that combined propiconazole residues are reduced on average by 0.12x in polished rice and concentrate on average by 3.8x in rice hulls, and 2.9x in rice bran.

E. REFERENCES

DP Barcode: D240856
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
From: Thurston G. Morton,
To: Patrick Dobak/Susan Lewis
Dated: 02/23/05
MRID: 44411201, 44411202, 44411203, 44411204, 44411205, 44411206, 44411207, 44411208

DP Barcode: D279300
Subject: Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From: Y. Donovan
To: S. Lewis/J. Guerry
Dated: 8/18/05
MRID: None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): PP#2F6371
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED	Date: 06/30/06
	Yan Donovan	
Approved by	Susan Hummel, Senior Scientist, RRB4/HED	Date: 06/30/06
	Susan Hummel	

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 6/12/2006). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

44757210 Ediger, K. (1998) Propiconazole and CGA-279202--Magnitude of the Residues in or on Almonds: Final Report: Lab Project Number: 143-98: 02-FR-001-98: 0W-FR-402-98. Unpublished study prepared by Novartis Crop Protection, Inc. 202 p.

45215806 Ediger, K. (2000) CGA-279202 and Propiconazole-Magnitude of the Residues in or on Almond: Final Report: Lab Project Number: 18-99. Unpublished study prepared by Novartis Crop Protection AG. 79 p.

EXECUTIVE SUMMARY:

In five field trials conducted during 1998 and 1999 in CA, propiconazole was applied to almonds in side-by-side tests comparing the use of 45% WP and 3.6 lb/gal EC formulations. Applications were made as dilute sprays (160-207 gal/A) at two sites, as concentrated sprays (10 gal/A) at two sites, and as both dilute (150 gal/A) and concentrated (75 gal/A) sprays at the fifth site. In each test, propiconazole (EC or WP) was applied four times to almonds as foliar applications during nut development at 0.22-0.25 lb ai/A/application, at retreatment intervals (RTIs) of 6-14 days, for a total of 0.88-0.91 lb ai/A/season. All applications were made using ground equipment and adjuvants were not added to the spray mix. Single control and duplicate treated samples of nutmeats and hulls were collected from each test at normal maturity, 53-63 days after the final application (DAT). In one test, duplicate treated samples of nutmeats and hulls were collected at 40, 49, 55, 63, and 68 DAT to examined residue decline. Samples were stored frozen from collection to analysis for up to 10 months, an interval supported by available storage stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on almond nutmeats and hulls were determined using adequate GC/ECD methods (Methods AG-454B and AG-626). For these methods, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization with $KMnO_4$. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and cleaned-up using an acidic alumina cartridge. Methylated DBCA is determined by GC/ECD using external standards, and

residues are expressed in parent equivalents. The validated method LOQ is 0.05 ppm for nutmeats and 0.10 ppm for hulls, and a LOD was not reported.

Although the concurrent recoveries from nutmeat and hulls were generally low (60-80%), the recoveries were relatively consistent. Therefore, the method is deemed adequate for data collection. Although the raw data (instead of corrected data) were used to report residue values, the data collection method detects parent plus all metabolites containing DCBA, and yet the Agency's tolerance expression for propiconazole will be established at parent only, there fore, tolerances will not under represent the real residue levels.

Application volume and formulation type had no apparent effect on residue levels. For samples treated with the WP, combined residues range from <0.05-0.07 ppm in/on 12 samples of nutmeats and 0.57-4.60 ppm in/on 12 samples of hulls, For samples treated with the EC formulation , combined residues range from <0.05-0.09 ppm in/on 12 samples of nutmeats and 0.85-4.20 ppm in/on 12 samples of hulls. For the WP and EC formulations, average residues were respectively 0.035 and 0.041 ppm in/on nutmeats and 1.78 and 2.06 ppm in/on hulls. When data from both formulations are pooled, average residues are 0.038 ppm in/on nutmeats and 1.92 ppm in/on hulls.

In the residue decline test, residues in/on nutmeats declined slightly from an average of 0.07 ppm at 40 DAT to <0.05 ppm by 68 DAT. However, residue levels in/on hulls were variable over time. Given the variability of residues in/on hulls at a single sampling interval (1.92 ± 1.20 ppm; 53-63 DAT), the decline data most likely represent the variability in hulls residues rather than any trend in hull residue levels.

The number of trials and the geographic representation of the trials are adequate. These data will support the use of propiconazole (EC or WP) on almonds as up four foliar applications during nut development at 0.22 lb ai/A/application, at a minimum RTI of 7 days, for a total of 0.88 lb ai/A/season, with a 60-day PHI.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the almond field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited several minor deviations from GLP requirements relating to collection of weather data and characterization of the spray mix. However, none of deviations were serious enough to adversely affect the conclusions of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities [40 CFR §180.434].

Syngenta previously submitted a petition (PP#9F3740) supporting the use of propiconazole, formulated as an EC, on almonds. This petition has been superseded by a more recent petition (PP#2F6371), which includes new or amended use directions for tree nut crops, of which almond is a representative crop. The current submission includes side-by-side field trials on almonds comparing residues resulting from EC and WP formulations using both dilute and concentrate spray volumes.

TABLE A.1. Nomenclature of Propiconazole

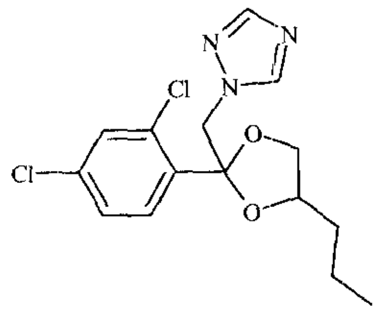
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EP	3.6 lb/gal EC (Tilt Fungicide, EPA Reg. No. 100-617) 45% WP (Tilt 45W Fungicide, EPA Reg. No. 100-780)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.		
Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. Hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK_a)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K_{OW})	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Almond trees in established orchards (7-21 years old) were maintained using typical agricultural practices for the region (Table B.1.1). Monthly rainfall and average temperature data were provided for the entire growing season from the 1999 test, but only weather data from the first half of the growing season was reported for the 1998 tests. No usual or adverse weather conditions were reported. Information was provided on maintenance chemicals and other pesticides used.

At each test site, propiconazole was applied in side-by-side tests comparing the 3.6 lb/gal EC and 45% WP formulations (Table B.1.2). Two sites used only dilute spray volumes and two sites used only concentrated spray volumes. The final site had plots comparing both dilute and concentrated spray volumes.

TABLE B.1.1. Trial Site Conditions.				
Trial Identification (County, State; Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC [2] (meq/g)
Fresno, CA 1998	Sandy loam	0.98	7.1	5.81
Yolo, CA 1998	Clay loam	1.63	7.2	18.24
Tulare, CA 1998	Loam	0.59	7.6	7.48
Stanislaus, CA 1998	Sand	2.18	7.3	3.46
Yolo, CA 1999	Loam	NR	NR	NR

[1] These parameters are optional except in cases where their value affects the use pattern for the chemical.
[2] Cation exchange capacity.
NR = not reported.

TABLE B.1.2. Study Use Pattern on Almonds.

Location (County, State; Year) Trial ID	End-use Product	Application Information [1]				
		Method; Timing	Volume (GPA)	Single Rate (lb ai/A)	RTI [2] (days)	Total Rate (lb ai/A)
Fresno, CA 1998 02-FR-001-98	45% WP	Four foliar applications during nut development, prior to hull split	75	0.22	7, 7, 8	0.88
			150	0.22	7, 7, 8	0.88
	3.6 lb/gal EC	Four foliar applications during nut development, prior to hull split	75	0.22	7, 7, 8	0.88
			150	0.22	7, 7, 8	0.88
Yolo, CA 1998 OW-FR-402-98	45% WP	Four foliar applications during nut development, prior to hull split	10	0.22	7, 8, 6	0.88
	3.6 lb/gal EC	Four foliar applications during nut development, prior to hull split	10	0.22	7, 8, 6	0.88
Tulare, CA 1998 OW-FR-514-98	45% WP	Four foliar applications during nut development, prior to hull split	205-207	0.22	8, 7, 7	0.88
	3.6 lb/gal EC	Four foliar applications during nut development, prior to hull split	205-207	0.22	8, 7. 7	0.88
Stanislaus, CA 1998 OW-FR-515-98	45% WP	Four foliar applications during nut development, prior to hull split	10	0.22-0.25 [3]	7, 7, 7	0.91
	3.6 lb/gal EC	Four foliar applications during nut development, prior to hull split	10	0.22	7, 7, 7	0.88
Yolo, CA 1999 0W-FR-404-99	45% WP	Four foliar applications during nut development, prior to hull split	160	0.22	14, 7, 7	0.88
	3.6 lb/gal EC	Four foliar applications during nut development, prior to hull split	160	0.22	14, 7, 7	0.88

1 No adjuvants were included in any of the spray mixes.
2 RTI = Retreatment Intervals between the four applications.
3 The third application was made at 0.25 lb ai/A; all other applications were at 0.22 lb ai/A.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones[1]	Almonds		
	Submitted	Requested	
		Canada	U.S.
1	---	---	---
2	---	---	---
3	---	---	---
4	---	---	---
5	---	---	---
6	---	---	---
7	---	---	---
8	---	---	---
9	---	---	---
10	5	---	5
11	---	---	---
12	---	---	---
Total	5	NA	5

1 Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the proposed use is for the US only.
NA = Not applicable

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of almond nutmeats and hulls (weights unspecified) were collected from each test at 53-63 DAT. In one of the tests using dilute applications of the 45% WP, single control and duplicate treated samples of nutmeats and hulls were collected also at 40, 49, 55, 63, and 68 DAT, to examine residue decline. All samples from the 1998 tests were placed into freezers after harvest and shipped frozen within ~1 month to the analytical laboratory, Central California Research Laboratories (CCRL), Fresno, CA, where samples were homogenized with dry ice and stored at <0°C until analysis. Samples from the 1999 test were frozen after harvest and shipped by freezer truck to Novartis Crop Protection (Greensboro, NC), where samples were stored at -20°C until analysis.

B.3. Analytical Methodology

Nutmeat and hull samples were analyzed for residues of propiconazole and its DCBA-containing metabolites using related GC/ECD methods (Method AG-454B or AG-626). Both methods are updated versions of the current tolerance enforcement method for propiconazole residues in plant commodities. These methods convert all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents. The basic difference between the two methods is that Method AG-626 uses iodomethane for methylation of DCBA rather than diazomethane as in Method AG-454B.

For these methods, propiconazole residues are extracted by refluxing for 1 hour in NH_4OH/methanol (20:80, v/v), and filtered. Residues are concentrated and oxidized to DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, the $KMnO_4$ is deactivated by the addition of sodium meta-bisulfite, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using either diazomethane (AG-454B) or iodomethane (AG-626). Residues are then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and analyzed by GC/ECD using external standards. The validated method LOQ is 0.05 ppm for nutmeats and 0.1 ppm for hulls; and a LOD was not reported.

Summary tables of the residue data were corrected by the registrant for procedural recoveries of <100%; however, spreadsheets including the uncorrected residue values were available in the raw data and were used by the reviewer to report residue values. Although the raw data (instead of corrected data) were used to report residue values, the data collection method detects parent plus all metabolites containing DCBA, and yet the Agency's tolerance expression for propiconazole will be set at parent only, there fore, tolerances will not under represent the real residue levels.

In conjunction with the analysis of field trial samples, the above methods were validated using control samples of fortified with propiconazole at 0.05-10.0 ppm for nutmeats and at 0.05-20 ppm for hulls.

C. RESULTS AND DISCUSSION

The number and geographic representation of the almond field trial data are adequate. In five field trials conducted during 1998 and 1999 in CA, propiconazole was applied to almonds in side-by-side tests comparing the use of 45% WP and 3.6 lb/gal EC formulations. Applications were made as dilute sprays (160-207 gal/A) at two sites, as concentrated sprays (10 gal/A) at two sites, and as both dilute (150 gal/A) and concentrated (75 gal/A) sprays at the fifth site. In each test, propiconazole (EC or WP) was applied four times to almonds as foliar applications during nut development at 0.22-0.25 lb ai/A/application, at RTIs of 6-14 days, for a total of 0.88-0.91 lb ai/A/season. All applications were made using ground equipment and adjuvants were not added to the spray mix. Single control and duplicate treated samples of nutmeats and hulls were collected from each test at normal maturity, 53-63 DAT. In one test, duplicate treated samples of nutmeats and hulls were collected at 40, 49, 55, 63, and 68 DAT to examined residue decline.

The GC/ECD methods (Methods AG-454B and AG-626) used to determine total propiconazole residues in/on almond nutmeats and hulls were adequately validated in conjunction with the field sample analyses. For Method AG-454B, recoveries of propiconazole were 64-76% from control samples of nutmeats fortified at 0.05-1.0 ppm, and averaged 70 ± 5% (Table C.1). Recoveries of propiconazole were 53-109% from control samples of hulls fortified at 0.1-20 ppm, and averaged 74 ± 16%. Although recoveries from nutmeat and hulls were generally low (60-80%), the recoveries were relatively consistent. Therefore, the method is deemed adequate for data collection. For Method AG-626, the average recovery of propiconazole was 79% from both nutmeats and hulls. For both methods, apparent residues of propiconazole were <LOQ in/on 9 control samples each of nutmeats and hulls. The validated method LOQ for propiconazole is 0.05 ppm in nutmeats and 0.1 ppm in hulls, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided.

Samples of nutmeats and hulls were stored frozen for up to 10 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating that propiconazole is stable for up to 36 months in peanut nutmeats and hulls (DP Barcode D279300, Y. Donovan, 8/18/05). These data will support the frozen storage intervals for the almond trials as the peanut matrices are similar to almond nutmeats and hulls.

Application volume and formulation type had no apparent effect on residue levels (Table C.3). Following four applications of propiconazole totalling 0.88-0.91 lb ai/A, combined propiconazole residues at 53-63 DAT were <0.05-0.07 ppm in/on nutmeats and 0.57-4.60 ppm in/on hulls from trees treated with the WP formulation and <0.05-0.09 ppm in/on nutmeats and 0.85-4.20 ppm in/on hulls from trees treated with the EC formulation. For the WP and EC formulations, average residues at ~60 DAT were respectively 0.035 and 0.041 ppm in/on nutmeats and 1.78 and 2.06 ppm in/on hulls (Table C.4). Including data from both formulations, residues in/on nutmeats were <0.05-0.09 ppm and averaged 0.038 ppm, and residues in/on hulls were 0.57-4.60 ppm and averaged 1.92 ppm.

Results from the residue decline test were variable. Residues in/on nutmeats declined slightly from an average of 0.07 ppm at 40 DAT to <0.05 ppm by 68 DAT. Residues in/on hulls initially remained relatively steadily, averaging 2.0-2.4 ppm from 40-55 DAT, before declining to an average of 0.95 ppm by 63 DAT. However, the highest hull residues were then measured at 5.1 ppm from 68 DAT. Given the variability of residues in/on hulls at a single sampling interval (1.92 ± 1.20 ppm; 53-63 DAT), the decline data most likely represent the variability in hulls residues rather than a trend in hull residue levels.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data

TABLE C.1. Summary of Method Recoveries of Propiconazole from Almonds Using GC/ECD Methods (AG-454B or AG-626).

Analyte	Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Method AG-454B					
Propiconazole	Nutmeats	0.05-1.0	10	67, 76, 70, 76, 69, 65, 66, 64, 73, 74	70 ± 5
	Hulls	0.1-20.0	10	109, 72, 53, 63, 75, 79, 89, 61, 66, 77	74 ± 16
Method AG-626					
Propiconazole	Nutmeats	0.05, 5.0	2	71, 87	79
	Hulls	0.05, 10.0	2	89, 69	79

TABLE C.2 Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1] (months)	Interval of Demonstrated Storage Stability (months)[2]
Almond nutmeats and hulls	-20	2.4-10	36

[1] From harvest to extraction for analysis. Extracts were stored for 0-19 days prior to analysis
[2] DP Barcode D279300, Y. Donovan, 8/18/05.

TABLE C.3. Residue Data from Almond Field Trials Using Propiconazole Formulated as an EC and/or WP and Application as Dilute and/or Concentrated Sprays.

Trial ID (County, State; Year)	Zone	Variety	Total Rate (lb ai/A)	End-use Product	Appl. Volume (GPA)	PHI (days)	Propiconazole Residues (ppm)[1]
Almond Nutmeats							
Fresno, CA 1998 02-FR-001-98	10	Neplus	0.88	45% WP	150	40	0.06, 0.07
						49	0.09, 0.09
						55	<0.05, <0.05
						63	0.07, 0.07
						68	<0.05, <0.05
				45% WP	75	63	<0.05, 0.05
			0.88	3.6 lb/gal EC	150	63	0.09, 0.06
					75		0.07, 0.07
Yolo, CA 1998 OW-FR-402-98	10	Mission	0.88	45% WP	10	62	<0.05, <0.05
			0.88	3.6 lb/gal EC	10		<0.05, <0.05
Tulare, CA 1998 OW-FR-514-98	10	Mission	0.88	45% WP	205-207	63	<0.05, <0.05
			0.88	3.6 lb/gal EC	205-207		<0.05, <0.05
Stanislaus, CA 1998 OW-FR-515-98	10	Carmel	0.91	45% WP	10	62	<0.05, <0.05
			0.88	3.6 lb/gal EC	10		<0.05, <0.05
Yolo, CA 1999 0W-FR-404-99	10	Non Pariel	0.88	45% WP	160	53	<0.05, <0.05
			0.88	3.6 lb/gal EC	160		<0.05, <0.05
Almond Hulls							
Fresno, CA 1998 02-FR-001-98	10	Neplus	0.88	45% WP	150	40	2.2, 2.6
						49	2.3, 2.2
						55	2.1, 1.9
						63	0.97, 0.92
						68	5.1, 5.0
				45% WP	75	63	1.2, 1.2
			0.88	3.6 lb/gal EC	150	63	1.7, 1.8
					75		1.6, 1.9
Yolo, CA 1998 OW-FR-402-98	10	Mission	0.88	45% WP	10	62	4.6, 4.3
			0.88	3.6 lb/gal EC	10		4.2, 3.8
Tulare, CA 1998 OW-FR-514-98	10	Mission	0.88	45% WP	205-207	63	1.7, 1.0
			0.88	3.6 lb/gal EC	205-207		1.8, 1.9
Stanislaus, CA 1998 OW-FR-515-98	10	Carmel	0.91	45% WP	10	62	0.57, 0.59
			0.88	3.6 lb/gal EC	10		0.68, 0.67
Yolo, CA 1999 0W-FR-404-99	10	Non pariel	0.88	45% WP	160	53	2.3, 2.0
			0.88	3.6 lb/gal EC	160		2.6, 2.1

[1] Total propiconazole residues determined as DCBA and expressed in parent equivalents. Reported values were obtained from the raw data and are not corrected procedural recoveries. The LOQ for propiconazole residues is 0.05 ppm in/on nutmeats and 0.1 ppm in/on hulls. The LOD was not reported.

TABLE C.4. Summary of Residue Data from Almond Field Trials with Propiconazole (EC or WP).

Commodity	Total Applic. Rate (lb ai/A)	End-use Product	PHI (days)	Total Residue Levels (ppm)[1]						
				n	Min.	Max.	HAFT[2]	Median (STMdR)[3]	Mean (STMR)[3]	Std. Dev.
Nutmeats	0.88-0.91	45% WP	53-63	12	<0.05	0.07	0.07	0.025	0.035	0.018
		3.6 lb/gal EC		12	<0.05	0.09	0.08	0.025	0.041	0.024
		Both		24	<0.05	0.09	0.08	0.025	0.038	0.021
Hulls	0.88-0.91	45% WP	53-63	12	0.57	4.60	4.45	1.20	1.78	1.36
		3.6 lb/gal EC		12	0.67	4.20	4.00	1.85	2.06	1.06
		Both		24	0.57	4.60	4.45	1.75	1.92	1.20

1 The LOQ is 0.05 ppm. Values are not corrected procedural recoveries. For calculation of the median, mean, and standard deviation, ½LOQ (0.025 ppm) was used for nutmeat samples with residues <LOQ.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

D. CONCLUSION

The almond field trial data are adequate and indicate that the formulation type (WP or EC) and application volume (dilute or concentrate) do not have a notable impact on residue levels in almond nutmeat and hulls. Overall combined residues at 53-63 DAT were <0.05-0.09 ppm in/on almond nutmeats and 0.57-4.60 ppm in/on almond hulls. Average residues were 0.04 and 1.92 ppm in/on nutmeats and hulls, respectively.

E. REFERENCES

DP Barcode: D279300
Subject: Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From: Y. Donovan
To: S. Lewis/J. Guerry
Dated: 8/18/05
MRID: None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 2F6371
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED Yan Donovan	Date: 06/30/06
Approved by	Susan Hummel, Senior Scientist, RRB4/HED Susan Hummel	Date: 06/30/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 6/02/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

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

EXECUTIVE SUMMARY:

In 4 side-by-side field trials conducted in CA, ID, MN and NE in 1998, propiconazole was applied to sugar beets using 45% wettable powder (WP) and 1.04 lb/gal emulsifiable concentrate (EC) formulations. The EC formulation contains both propiconazole and trifoxystrobin. In each test, propiconazole (WP or EC) was applied to sugar beets as three broadcast foliar applications during tuber development at 0.11 lb ai/A/application, at retreatment intervals of 10-11 days, for a total of 0.33 lb ai/A/season. All applications were made using ground equipment at volumes of 20-30 gal/A, and no adjuvants were used. Single control and duplicate treated samples of sugar beet roots and tops were harvested from each site at 0 and 21 DAT. Samples were stored frozen from collection to analysis for up to 9.2 months, an interval supported by available storage stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on sugar beet roots and tops were determined using an adequate GC/ECD method (Method AG-626). For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization with $KMnO_4$. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and cleaned-up using an acidic alumina cartridge. Methylated DBCA is determined by GC/ECD, using external standards, and residues are expressed in parent equivalents. The validated method limit of quantitation (LOQ) is 0.05 ppm, and the limit of quantitation (LOD) is 0.02 ppm.

Following three applications of the WP formulation totaling 0.33 lb ai/A, total propiconazole residues in/on sugar beet roots were <0.05-0.42 ppm at 0 DAT and <0.05-0.23 ppm at 21 DAT, and total residues in/on tops were 2.10-6.10 ppm at 0 DAT and 0.74-2.60 ppm at 21 DAT. Following three applications of the EC formulation totaling 0.33 lb ai/A, total propiconazole residues in/on sugar beet roots were <0.05-0.34 ppm at 0 DAT and 0.05-0.23 ppm at 21 DAT, and total residues in/on tops were 2.70-8.0 ppm at DAT and 0.77-9.20 ppm at 21 DAT. There was no noticeable decline in residues in/on roots between 0 to 21 DAT, but residues did decline in/on tops from 0 to 21 DAT.

Average residues in/on sugar beet roots were similar for both formulations at both 0 and 21 DAT (0.13-0.15 ppm), and average residues in/on sugar beet tops were similar at 0 DAT for the WP (4.05 ppm) and EC (4.44 ppm) formulations. However, average residues in/on tops at 21 DAT were considerably higher for the EC formulation (3.67 ppm) than for the WP formulation (1.67 ppm). This trend toward higher residues from the EC formulation at 21 DAT was evident in 3 out of the 4 field trials.

These data indicate that total propiconazole residues from the WP and EC formulations are similar in/on sugar beet roots harvested at 0 or 21 DAT and in/on sugar beet tops harvested at 0 DAT. However, by 21 days post-treatment, residues in/on tops were substantially higher for the EC formulation than for the WP formulation. (the presence of Trifloxystrobin might have inhibited the break down of residues in top?).

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Although a substantial number of control samples had apparent residues of propiconazole, the sugar beet field trial residue data are classified as scientifically acceptable for purposes of comparing the WP and EC formulations. For sugar beet tops, the low levels of apparent propiconazole residues observed in control samples were considerably lower than residues observed in the treated samples. For sugar beet roots, any additional background residues in control and treated samples will affect the residue levels on both the WP and EC treated samples similarly; therefore, the study is still valid for purposes of comparing residues resulting from the two formulations. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited minor deviations from GLP compliance, pertaining to the collection of weather data, tank mix storage stability data and maintenance chemicals and irrigation application. None of these deviations affect the overall acceptability of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides board spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities [40 CFR §180.434(a)].

Syngenta has submitted at petition (PP#2F6371) proposing tolerances and the use of propiconazole on sugar beets. The current submission includes residue data comparing propiconazole residues resulting from use of a 45% WP formulation with an EC formulation that contains both propiconazole and trifloxystrobin, each at 1.04 lb ai/gal.

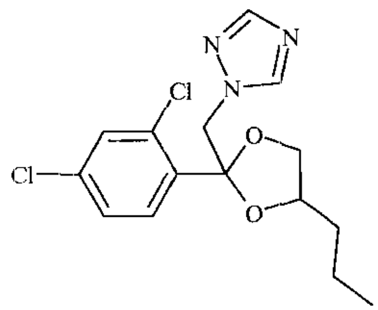
TABLE A.1. Nomenclature of Propiconazole	
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EPs	45% WP (Tilt 45W Fungicide, EPA Reg. No. 100-780) 1.04 lb/gal EC (250EC, MAI containing 1.04 lb/gal each of propiconazole and trifloxystrobin)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.

Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	*Completely miscible in ethanol, acetone,* toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK_a)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K_{OW})	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Sugar beets were grown and maintained at each test site using typical agricultural practices for the respective geographical region (Table B.1.1). Monthly rainfall and irrigation data were provided for each site, along with temperature data. No usual weather conditions were noted that would have an adverse effect on the field trial data. Information was also provided on maintenance chemicals and other pesticides used at each site. Soil types were provided for each site, but no other soil data were provided. At each test site, propiconazole was applied in side-by-side tests comparing 45% WP and 1.04 lb/gal EC formulations of propiconazole (Table B.1.2).

TABLE B.1.1. Trial Site Conditions.

Trial Identification (County, State; Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC[2] (meq/g)
Polk, MN 1988	Silty Clay Loam	NR	NR	NR
Canyon, ID 1998	Loam	NR	NR	NR
Tulare, CA 1998	Sandy Loam	NR	NR	NR
Hall, NE 1998	Silt Loam	NR	NR	NR

[1] These parameters are optional except in cases where their value affects the use pattern for the chemical.
[2] Cation exchange capacity.
NR = Not Reported

TABLE B.1.2. Study Use Pattern on Sugar Beets.						
Location (County, State; Year) Trial ID	End-use Product	Application Information [1]				
		Method; Timing	Volume (GPA)	Rate (lb ai/A)	RTI (days)	Total Rate (lb ai/A)
Polk, MN 1988 216	45% WP 1.04 lb/gal EC	Three broadcast foliar applications during root bulking	20	0.11	11, 10	0.33
Canyon, ID 1998 312	45% WP 1.04 lb/gal EC	Three broadcast foliar applications during vegetative state	29-30	0.11	10	0.33
Tulare, CA 1998 522	45% WP 1.04 lb/gal EC	Three broadcast foliar applications during tuber maturation	30	0.11	10	0.33
Hall, NE 1998 615	45% WP 1.04 lb/gal EC	Three broadcast foliar applications during vegetative state	20	0.11	10	0.33

[1] All applications were made using ground equipment, and no adjuvants were used.

TABLE B.1.3. Trial Numbers and Geographical Locations.			
NAFTA Growing Zones [1]	Sugar Beets		
	Submitted	Requested	
		Canada	U.S.
1	---	---	---
2	---	---	---
3	---	---	---
4	---	---	---
5	1	---	5
6	---	---	---
7	1	---	1
8	---	---	1
9	---	---	1
10	1	---	2
11	1	---	2
12	---	---	---
Total	4	NA	12

[1] Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the use is for only in the U.S.
NA = Not applicable

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of sugar beet roots and tops (weight unspecified) were harvested from each test at 0 and 21 DAT. Samples were frozen shortly after harvest and shipped by freezer truck or overnight courier on dry ice to the analytical laboratory, Novartis Crop Protection (Greensboro, NC), where samples were stored at -20EC until preparation for analysis.

B.3. Analytical Methodology

Sugar beet samples were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-626), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, residues are extracted and base hydrolyzed by refluxing for 1 hour with NH_4OH/MeOH (20:80, v/v) and filtered. Residues are concentrated and oxidized to 2,4-DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, sodium meta-bisulfite is added to deactivate the $KMnO_4$, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using methyl iodide in the presence of tetrabutyl ammonium hydroxide. Residues are partitioned into hexane and then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v). Methylated DCBA is then analyzed by GC/ECD using external standards. Residues are expressed in propiconazole equivalents. The validated method LOQ is 0.05 ppm for residues in/on tops and roots; the LOD is 0.02 ppm.

Summary tables of the residue data were corrected by the registrant for procedural recoveries of <100%; however, spreadsheets including the uncorrected residue values were available in the raw data and were used by the reviewer to report residue values.

In conjunction with the analysis of field trial samples, the above method was validated using control samples fortified with propiconazole at 0.05-20 ppm for roots and at 0.05-10 ppm for tops.

C. RESULTS AND DISCUSSION

In 4 field trials conducted in CA, ID, MN and NE in 1998, propiconazole was applied to sugar beets in side-by-side tests using WP and EC formulations. In each test, propiconazole (WP or EC) was applied to sugar beets as three broadcast foliar applications during tuber development at 0.11 lb ai/A/application, at RTIs 10-11 days, for a total of 0.33 lb ai/A/season. All applications were made using ground equipment at volumes of 20-30 gal/A, and no adjuvants were used. Single control and duplicate treated samples of sugar beet roots and tops were harvested from each site at 0 and 21 DAT.

The GC/ECD method (Method AG-626) used to determine propiconazole residues in/on sugar beet roots and tops was validated in conjunction with the analysis of field trial samples. The recovery of propiconazole averaged 94 ± 10% from roots and 101 ± 5% from tops (Table C.1). Apparent residues of propiconazole were above the LOQ in 5 out of 8 control root samples (0.06-0.15 ppm) and in 5 out of 8 control top samples (0.05-0.24 ppm). Based on data from analysis of reagent blanks, the study author suggested that reagents and/or glassware were the source of background levels. As residues in/on treated tops were considerably higher than in the controls, any background levels in treated samples would have a negligible impact on overall residues. However, the apparent residues in root controls were of a similar magnitude to the residues found in the treated samples. Normally, the residues values in the treated root samples would be considered inadequate; however, the background levels observed in root samples are not a problem for this study, as the objective of the study was to compare the WP and EC formulations and any background levels should alter residue values from both formulations in a similar manner The validated method LOQ for propiconazole is 0.05 ppm, and the LOD is 0.02 ppm. Adequate sample calculations and example chromatograms were provided.

Sugar beet root and top samples were stored frozen for up to 9.2 months prior to extraction for analysis (Table C.2), with the exception of one sample, which was reanalyzed after 11.9 months of storage. Adequate storage stability data are available indicating the fortified residues of propiconazole and its metabolites are stable for up to 10 months at -20° C in carrots (DP Barcode D279300, Y. Donovan, 8/18/05). These data will support the storage intervals and conditions for the current field trials.

Following three applications of the WP formulation totaling 0.33 lb ai/A, total propiconazole residues in/on sugar beet roots were <0.05-0.42 ppm at 0 DAT and <0.05-0.23 ppm at 21 DAT (Table C.3). and total residues in/on tops were 2.10-6.10 ppm at 0 DAT and 0.74-2.60 ppm at 21 DAT. Following three applications of the EC formulation totaling 0.33 lb ai/A, total propiconazole residues in/on sugar beet roots were <0.05-0.34 ppm at 0 DAT and 0.05-0.23 ppm at 21 DAT, and total residues in/on tops were 2.70-8.0 ppm at DAT and 0.77-9.20 ppm at 21 DAT.

Average residues in/on sugar beet roots were similar for both formulations at both 0 and 21 DAT (0.13-0.15 ppm; Table C.4). Average residues in/on sugar beet tops were also similar at 0 DAT for the WP (4.05 ppm) and EC (4.44 ppm) formulations. However, average residues in/on tops at 21 DAT were considerably higher for the EC formulation (3.67 ppm) than for the WP formulation (1.67 ppm). This trend toward higher residues from the EC formulation at 21 DAT was evident in 3 out of the 4 field trials.

HAFT residues in/on sugar beet roots were similar for both formulations and were 0.28-0.30 ppm at 0 DAT and 0.17-0.18 ppm at 21 DAT. HAFT residues in/on sugar beet tops were also similar at 0 DAT for the WP (5.20 ppm) and EC (5.65 ppm) formulations. However, HAFT residues in/on tops at 21 DAT were considerably higher for the EC formulation (7.90 ppm) than for the WP formulation (2.60 ppm).

There was no noticeable decline in residues in/on roots between 0 to 21 DAT, but residues did decline in/on tops from 0 to 21 DAT.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data

TABLE C.1. Summary of Method Recoveries of Propiconazole from Sugar beet Roots and Tops.

Analyte	Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Propiconazole	Roots	0.05-20	9	90, 96, 87, 91, 99, 83, 89, 118, 93	94 ± 10
	Tops	0.05-10	10	110, 102, 94, 105, 99, 99, 105, 100, 98, 99	101 ± 5

TABLE C.2 Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1] (months)	Interval of Demonstrated Storage Stability (months)[3]
Tops and Roots	-20	6.0-9.2, 11.9[2]	10

1 From harvest to extraction for analysis.
2 One sample was reanalyzed after 11.9 months of storage.
3 DP Barcode D279300, Y. Donovan, 8/18/05.

TABLE C.3. Residue Data on Sugar beet from Field Trials with Propiconazole (EC or WP).

Trial ID (County, State; Year)	Zone	Variety	End-use Product	Total Rate (lb ai/A)	Commodity	PHI (days)	Total Propiconazole Residues (ppm)[1]
Polk, MN 1988 216	5	Crystal 222	45% WP	0.33	Roots	0	<0.05, <0.05
						21	<0.05, 0.11
					Tops	0	4.3, 6.1
						21	1.3, 1.3
			1.04 lb/gal EC		Roots	0	0.08, <0.05
						21	0.05, 0.09
					Tops	0	8.0, 3.3
						21	2.3, 2.5
Canyon, ID 1998 312	11	PM9	45% WP	0.33	Roots	0	0.17[2], 0.42[3]
						21	0.10, 0.18
					Tops	0	3.3, 2.1
						21	1.7, 1.9
			1.04 lb/gal EC		Roots	0	0.21[2], 0.34[2]
						21	0.18, 0.15
					Tops	0	3.1, 3.3
						21	3.4, 3.2
Tulare, CA 1998 522	10	SS-KB7R	45% WP	0.33	Roots	0	0.15, 0.11
						21	0.10, 0.23
					Tops	0	3.6, 3.7
						21	2.6[2], 2.6[2]
			1.04 lb/gal EC		Roots	0	0.11, 0.20
						21	0.18, 0.18
					Tops	0	6.3, 4.1
						21	9.2[2], 6.6[2]
Hall, NE 1998 615	7	HMLSR88	45% WP	0.33	Roots	0	0.11, 0.10
						21	0.15, 0.11
					Tops	0	5.5, 3.8
						21	0.74, 1.2
			1.04 lb/gal EC		Roots	0	0.09, 0.11
						21	0.23, 0.09
					Tops	0	2.6, 4.8
						21	1.4, 0.77

1 Total propiconazole residues were determined as DCBA and expressed in parent equivalents. Reported values were obtained from the raw data and are not corrected procedural recoveries. The LOQ for propiconazole residues is 0.05 ppm in/on roots and tops, and the LOD is 0.02 ppm.
2 Sample was reextracted and analyzed. Value is an average of the two analyses
3 Originally extracted sample was lost. Sample was reextracted and analyzed.

TABLE C.4. Summary of Residue Data from Sugar beet Field Trials with Propiconazole (EC or WP).

Commodity	Total Applic. Rate (lb ai/A)	End-use Product	PHI (days)	Residue Levels (ppm)[1]						
				n	Min.	Max.	HAFT[2]	Median (STMdR)[3]	Mean (STMR)[4]	Std. Dev.
Roots	0.33	45% WP	0	8	<0.05	0.42	0.30	0.11	0.14	0.12
			21	8	<0.05	0.23	0.17	0.11	0.13	0.06
Tops			0	8	2.10	6.10	5.20	3.75	4.05	1.26
			21	8	0.74	2.60	2.60	1.50	1.67	0.67
Roots	0.33	1.04 lb/gal EC	0	8	<0.05	0.34	0.28	0.11	0.15	0.10
			21	8	0.05	0.23	0.18	0.17	0.14	0.06
Tops			0	8	2.60	8.00	5.65	3.70	4.44	1.86
			21	8	0.77	9.20	7.90	2.85	3.67	2.84

1 The LOQ is 0.05 ppm. Residue data are not corrected for procedural recoveries. For calculation of the median, mean and standard deviation, ½LOQ (0.025 ppm) was used for root samples with residues <LOQ.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

D. CONCLUSION

The sugar beet field trial data are adequate for comparing residues resulting from use of WP and EC formulations of propiconazole. The data indicated that total propiconazole residues from the WP and EC formulations are similar in/on sugar beet roots harvested at 0 or 21 DAT and in/on sugar beet tops harvested at 0 DAT. However, by the 21 days post-treatment, residues in/on tops were substantially higher for EC formulation than for the WP formulation.

E. REFERENCES

DP Barcode: D279300
Subject: Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From: Y. Donovan
To: S. Lewis/J. Guerry
Dated: 8/18/05
MRID: None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 2F6371
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED	Date: 06/30/06
	Yan Donovan	
Approved by	Susan Hummel, Senior Scientist, RRB4/HED	Date: 06/30/06
	Susan Hummel	

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 6/15/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

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

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

EXECUTIVE SUMMARY:

In a total of 28 field trials conducted throughout the U.S. during 1998 and 1999, propiconazole (1.04 lb/gal EC) was applied to field corn (24 trials) and popcorn (4 trials). With a few exceptions, each field corn trial included one treated plot for the collection of forage and another plot for the collection of grain and stover, and the four popcorn field trials each had a single treated plot for the collection of only grain and stover. Propiconazole (EC) was applied to the forage plots as two broadcast foliar applications during early vegetative development at a rate of 0.11 lb ai/A/application, for a total of 0.22 lb ai/A. The retreatment interval (RTI) for the forage applications ranged from 3-8 days, but was typically 7 days. For the grain and stover plots, propiconazole (EC) was applied to the corn as four broadcast foliar applications from flowering through grain development at rates of 0.09-0.14 lb ai/A/application, for a total of 0.42-0.47 lb ai/A. The RTIs ranged from 6-9 days, but were typically 7 days. All applications were made using ground equipment in volumes of 5-25 gal/A, and no adjuvants were included in the spray mixtures. At two of the field corn sites, propiconazole was also applied as four broadcast foliar applications during grain development at 0.55 lb ai/A/application, for a total of 2.2 lb ai/A (5x rate). In four of the 1998 field trials, propiconazole was misapplied to the forage and/or stover and grain plots at a reduced rate (0.05-0.06 lb ai/A/application); these field trials were replaced by the subsequent 1999 field trials.

Single control and duplicate treated samples of forage were harvested at 29-32 days after the last treatment (DAT), except in three tests in which forage was collected at 15, 51 or 67 DAT. Single control and duplicate treated samples of corn stover and grain were harvested at 28-35

DAT from all tests, with most samples being collected at 29-30 DAT. To examine residue decline, repeated control and treated samples were also collected at two sites at 0, 9, 16, 23, 30 and 36/37 DAT for forage and stover and at 9, 16, 23, 30 and 36 DAT for grain. Samples were stored frozen from collection to analysis for up to 15.9 months, an interval supported by available storage stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on corn forage, grain and stover were determined using adequate GC/ECD methods (Methods AG-454B and AG-626). For these methods, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization with $KMnO_4$. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and cleaned-up using an acidic alumina cartridge. Methylated DBCA is determined by GC/ECD using external standards, and residues are expressed in parent equivalents. The validated method limit of quantitation (LOQ) is 0.05 ppm, and the limit of detection (LOD) was not reported. Concurrent recoveries of propiconazole averaged 93 ± 11% from forage, 89 ± 13 % from stover and 90 ± 15% from grain

Following the two early-season broadcast foliar applications totaling 0.22 lb ai/A, combined propiconazole residues range from <0.05-1.90 ppm and averaged 0.45 ppm in/on 36 samples of forage harvested at 29-32 DAT. Following the four broadcast foliar applications during flowering through grain development at rates totaling 0.42-0.47 lb ai/A, combined residues range from 0.92-19.6 ppm in/on 48 samples of stover and <0.05-0.15 ppm in/on 48 samples of grain harvested at 28-35 DAT. Average residues were 6.87 in/on stover and 0.037 ppm in/on grain, and the highest average field trial (HAFT) residues were 15.9 ppm in/on stover and 0.10 ppm in/on grain. In the two 5x rate tests, combined residues were 23.2-77 ppm in/on four samples of stover and <0.05-0.062 ppm in/on four samples of grain harvested at 29-30 DAT. Data from the two residue decline trials indicated that residues in/on forage and stover decreased at longer post-treatment intervals. However, residue decline could not be determined in grain as residues in grain were < LOQ in all but two samples from the declined trials.

The number of trials and geographic representation of the trials are adequate. These data support the use of up to four broadcast foliar applications of propiconazole (EC) to field or pop corn through grain development at 0.11 lb ai/A/application, at a minimum RTI of 7 days, for a total of 0.44 lb ai/A/season. The data also support a PHI of 30 days for harvest of forage, grain and stover. However, the data will only support the use of two early-season applications prior to the harvest of forage.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the corn field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited minor deviations from GLP compliance, pertaining to the collection of weather data, tank mix storage stability data, maintenance chemicals, irrigation application, a reference standard for 2,4-DCBA past its reassay date and weight documentation.. None of these deviations adversely affect the overall acceptability of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-DCBA (expressed as parent) in/on a variety of plant and animal commodities, including time-limited tolerances of 0.1 ppm on sweet corn (K+CWHR) and field corn grain and 12 ppm on field corn forage and stover [40 CFR §180.434(a)].

In conjunction with PP#2F6371, Syngenta is proposing new tolerances of residues in/on corn commodities. The current submission includes residue data on field corn forage, stover and grain.

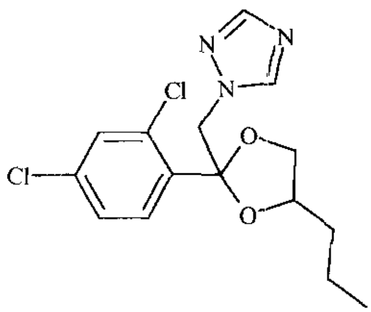
TABLE A.1. Nomenclature of Propiconazole	
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EP	1.04 lb/gal EC (MAI formulation also containing trifloxystrobin at 1.04 lb/gal)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.

Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK$_a$)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K$_{OW}$)	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Corn was grown and maintained at each test site using typical agricultural practices for the respective geographical regions (Table B.1.1). Monthly rainfall and irrigation data were provided for each site, along with temperature data. No usual weather conditions were noted that would have an adverse effect on the field trial data. Information was also provided on maintenance chemicals and other pesticides used at each site. Soil types were provided for each site, but no other soil data were provided. However, as the application to corn was foliar, additional information on soil characteristics are not required.

Propiconazole (1.04 lb/gal EC) was applied to field corn in 24 trials and to popcorn in 4 trials (Table B.1.2). Each field corn trial generally included one treated plot for the collection of forage and a second treated plot for the collection of grain and stover, and each popcorn field trial had only a single treated plot for the collection of grain and stover. In the forage plots, propiconazole (EC) was applied as two broadcast foliar applications during early vegetative development at a target rate of 0.11 lb ai/A/application. In the grain and stover plots, propiconazole (EC) was applied as four broadcast foliar applications from flowering through grain development at target rates of 0.11 lb ai/A/application, for a total of 0.44 lb ai/A. The target RTI for all applications was 7 days. Two of the field corn trials also included plots for applications at exaggerated rates of 0.55 lb ai/A/application (5x rate).

TABLE B.1.1. Trial Site Conditions.

Trial Identification (County, State: Year)	*Soil characteristics* [1] Type	%OM	pH	CEC[2] (meq/g)
Champaign IL 1998	Silty Clay Loam	NR	NR	NR
Burleson, TX 1998	Clay	NR	NR	NR
Sampson, NC 1998	Loamy Sand	NR	NR	NR
Madera, CA 1998	Loamy Sand	NR	NR	NR
Jefferson, IA 1998	Silty Clay Loam	NR	NR	NR
Hamilton, IA 1998	Clay Loam	NR	NR	NR
Adair, MO 1998	Silty Clay Loam	NR	NR	NR
Sedgwick, KS 1998	Clay Loam	NR	NR	NR
Clinton, IL 1998	Silt Loam	NR	NR	NR
Sioux, IA 1998	Silty Clay Loam	NR	NR	NR
Clay, SD 1998	Loam	NR	NR	NR
York, NE 1998	Silt Loam	NR	NR	NR
Polk, NE 1998	Loamy Sand	NR	NR	NR
Walworth, WI 1998	Silt Loam	NR	NR	NR
Freeborn, MN 1998	Clay Loam	NR	NR	NR
Steele, MN 1998	Clay Loam	NR	NR	NR
Hamilton, IN 1998	Loam	NR	NR	NR
Hamilton, IN 1998	Clay Loam	NR	NR	NR
Fayette, OH 1998	Cay Loam	NR	NR	NR
Ingham, MI 1998	Sandy Loam	NR	NR	NR
Ingham, MI 1998	Sandy Loam	NR	NR	NR
Wayne, NY 1998	Sandy Loam	NR	NR	NR
Sedgewick, KS 1998	Clay Loam	NR	NR	NR
York, NE 1998	Silt Loam	NR	NR	NR
Hamilton, IN 1998	Silt Loam	NR	NR	NR
Fayette, OH 1999	Loam	NR	NR	NR
Sedgwick, KS 1999	Loam	NR	NR	NR
Sedgwick, KS 1999	Loam	NR	NR	NR

[1] These parameters are optional except in cases where their value affects the use pattern for the chemical.
[2] Cation exchange capacity.
NR = Not Reported.

TABLE B.1.2. Study Use Pattern on Field and Pop Corn [1].

Location (County, State, Year) Trial ID	End-use Product [2]	Application Information [3] Method; Timing	Volume (GPA)	Single Rate (lb ai/A)	RTI (days)	Total Rate (lb ai/A)
Champaign IL 1998 04-FR-004-98	1.04 lb/gal EC	Two broadcast foliar applications at crop heights of 20-30" and 36-35"	22	0.11	8	0.22
		Four broadcast foliar applications at crop heights of 8-9'	21-24	0.11-0.14	7, 7, 7	0.47
				0.55		2.20
Burleson, TX 1998 0S-FR-201-98	1.04 lb/gal EC	Two broadcast foliar applications at seedling and preboot stages	5	0.11	8	0.22
		Four broadcast foliar applications from milk to black layer stage	5	0.11	7, 7, 7	0.44
Sampson, NC 1998 0S-FR-609-98	1.04 lb/gal EC	Two broadcast foliar applications at 4 collar and 5 collar	20	0.11	7	0.22
		Four broadcast foliar applications at tasseling to early dough stages	20	0.11	7, 7, 7	0.44

TABLE B.1.2. Study Use Pattern on Field and Pop Corn [1].

Location (County, State, Year) Trial ID	End-use Product [2]	Application Information [3]				
		Method; Timing	Volume (GPA)	Single Rate (lb ai/A)	RTI (days)	Total Rate (lb ai/A)
Madera, CA 1998 0W-FR-107-98	1.04 lb/gal EC	Two broadcast foliar applications at crop heights of 8" and 12-16"	25	0.11	7	0.22
		Four broadcast foliar applications at crop heights of 5' to 7'	25	0.11	7, 7, 7	0.44
Jefferson, IA 1998 MW-FR-150-98	1.04 lb/gal EC	Two broadcast foliar applications at 8 leaf and 10 collar stages	28-34	0.11	6	0.22
		Four broadcast foliar applications at early dough to dent stage	21-23	0.11	7, 7, 8	0.44
Hamilton, IA 1998 MW-FR-151-98	1.04 lb/gal EC	Two broadcast foliar applications at crop heights of 12" and 17"	25	0.11	8	0.22
		Four broadcast foliar applications at crop height around 110"	25	0.11 0.55	7, 9, 5	0.44 2.20
Adair, MO 1998 MW-FR-201-98	1.04 lb/gal EC	Two broadcast foliar applications at 4 and 6 collar stages	22-23	0.11	8	0.22
		Four broadcast foliar applications at mid dough to dent stage	21-22	0.11	7, 7, 7	0.44
Sedgwick, KS 1998 MW-FR-308-98	1.04 lb/gal EC	Two broadcast foliar applications at V9 and V10 stages	20	0.05	7	0.10
		Four broadcast foliar applications at VT to R2 stage	17-20	0.05	9, 7, 9	0.20
Clinton, IL 1998 MW-FR-405-98	1.04 lb/gal EC	Two broadcast foliar applications at crop heights of 12-16" and 16-20"	21-23	0.11	7	0.22
		Four broadcast foliar applications at dent to black layer stage	26-28	0.11	7, 7, 7	0.44
Sioux, IA 1998 MW-FR-501-98	1.04 lb/gal EC	Two broadcast foliar applications at crop heights of 8-10" and 15"	21-22	0.11	8	0.22
		Four broadcast foliar applications at crop height of 9'	20-26	0.11	7, 7, 7	0.44
Clay, SD 1998 MW-FR-502-98	1.04 lb/gal EC	Two broadcast foliar applications at crop heights of 12" and 16"	22-24	0.11	7	0.22
		Four broadcast foliar applications at late dough to fully dented stage	20-26	0.11	8, 6, 9	0.44
York, NE 1998 MW-FR-610-98	1.04 lb/gal EC	Two broadcast foliar applications during vegetative development	20	0.11	3	0.22
		Four broadcast foliar applications at late milk to hard dough stage	20-25	0.11	7, 7, 7	0.44
Polk, NE 1998 MW-FR-611-98	1.04 lb/gal EC	Two broadcast foliar applications during vegetative development	20	0.11	7	0.22
		Four broadcast foliar applications at early milk to late dough stage	20	0.11	7, 7, 7	0.44
Walworth, WI 1998 MW-FR-701-98	1.04 lb/gal EC	Two broadcast foliar applications at 6 and 7 leaf stages	25	0.11	7	0.22
		Four broadcast foliar applications at late dough to early dent stage	23-25	0.11	7, 7, 7	0.44
Freeborn, MN 1998 MW-FR-801-98	1.04 lb/gal EC	Two broadcast foliar applications during vegetative development	21	0.11	7	0.22
		Four broadcast foliar applications at late dough to dent stage	21-22	0.11	7, 7, 7	0.44
Steele, MN 1998 MW-FR-802-98	1.04 lb/gal EC	Two broadcast foliar applications during vegetative development	21-22	0.11	7	0.22
		Four broadcast foliar applications at late milk to hard dough stage	21-22	0.11	7, 7, 7	0.44

TABLE B.1.2. Study Use Pattern on Field and Pop Corn [1].

Location (County, State; Year) Trial ID	End-use Product [2]	Application Information [3]				
		Method; Timing	Volume (GPA)	Single Rate (lb ai/A)	RTI (days)	Total Rate (lb ai/A)
Hamilton, IN 1998 NE-FR-103-98	1.04 lb/gal EC	Two broadcast foliar applications at 4 and 7 collar stages	5	0.11	7	0.22
		Four broadcast foliar applications at milk to dent stage	5	0.11	7, 7, 7	0.44
Hamilton, IN 1998 NE-FR-104-98	1.04 lb/gal EC	Two broadcast foliar applications at 6 and 8 collar stages	20-21	0.11	8	0.22
		Four broadcast foliar applications at milk to early dent stage	20	0.11	7, 7, 8	0.44
Fayette, OH 1998 NE-FR-203-98	1.04 lb/gal EC	Two broadcast foliar applications at early to mid whorl stages	20-23	0.055	6	0.11
		Four broadcast foliar applications at soft dough to mature stage	20	0.055	7, 7, 7	0.22
Ingham, MI 1998 NE-FR-710-98	1.04 lb/gal EC	Two broadcast foliar applications at crop heights of 6" and 10"	33	0.06	6	0.12
		Four broadcast foliar applications at crop heights of 7'	22-25	0.09-0.11	8, 7, 7	0.42
Ingham, MI 1998 NE-FR-721-98	1.04 lb/gal EC	Two broadcast foliar applications at crop heights of 12" and 20"	25	0.11	7	0.22
Wayne, NY 1998 NE-FR-802-98	1.04 lb/gal EC	Two broadcast foliar applications during vegetative development	25	0.11	7	0.22
		Four broadcast foliar applications at Early milk to early dough stage	25	0.11	7, 7, 7	0.44
Sedgwick, KS 1998 MW-FR-309-98 (popcorn)	1.04 lb/gal EC	Four broadcast foliar applications at V16 to R2 stage	17-20	0.05	9, 7, 9	0.20
York, NE 1998 MW-FR-612-98 (popcorn)	1.04 lb/gal EC	Four broadcast foliar applications at early dough to hard dough stage	20-25	0.11	7, 7, 7	0.44
Hamilton, IN 1998 NE-FR-105-98 (popcorn)	1.04 lb/gal EC	Four broadcast foliar applications at silking to dough stage	5	0.11	7, 7, 7	0.44
Fayette, OH 1999 NE-FR-203-99	1.04 lb/gal EC	Two broadcast foliar applications at V4 and V5-V6 stages	21-22	0.11	7	0.22
		Four broadcast foliar applications at dough to dent stage	20-21	0.11	8, 6, 7	0.44
Sedgwick, KS 1999 MW-FR-317-99	1.04 lb/gal EC	Two broadcast foliar applications at V5 and V8 stages	20	0.11	7	0.22
		Four broadcast foliar applications at VT to R5 stage	20	0.11	7, 7, 8	0.44
Sedgwick, KS 1999 MW-FR-318-99 (popcorn)	1.04 lb/gal EC	Four broadcast foliar applications at VT to R3 stage	20-21	0.11	7, 7, 8	0.44

1 Field trials used field corn unless otherwise indicated.

2 The end-use product was a multiple active ingredient formulation (EC) containing both propiconazole and trifloxystrobin, each at 1.04 lb ai/gal.

3 All applications were made using ground equipment and no adjuvants were included in the spray mixtures.

TABLE B.1.3.	Trial Numbers and Geographical Locations.		
NAFTA Growing Zones[1]	Corn		
	Submitted	Requested	
		Canada	U.S.
1	1	---	1
2	1	---	1
3	---	---	---
4	---	---	---
5	24	---	17
6	1	---	1
7	---	---	---
8	---	---	---
9	---	---	---
10	1	---	---
11	---	---	---
12	---	---	---
Total	28 [2]	NA	20

1 Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the use is for only in the U.S.
2 Twenty four field trials used field corn and four field trials used popcorn.
NA = Not applicable

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of corn forage were harvested at 29-32 DAT, except in three tests in which forage was collected at 15, 51 or 67 DAT. Single control and duplicate treated samples of corn stover and grain were harvested at 28-35 DAT from all tests. Repeated control and treated samples were also collected at two sites to examine residue decline. In these tests, forage was sampled at 0, 9, 16, 23, 30 and 37 DAT, stover was sampled at 0, 9, 16, 23, 30 and 36 DAT, and grain was sampled at 9, 16, 23, 30 and 36 DAT. After collection, samples were placed in frozen storage (temperature unspecified) at the field sites and later shipped by freezer truck to Novartis Crop Protection (Greensboro, NC), where samples were stored at -20EC until preparation for analysis. Samples were analyzed either directly by Novartis or were shipped frozen to EPL Bio-Analytical Services (Harristown, IL), where samples were stored frozen until analysis.

B.3. Analytical Methodology

Corn samples were analyzed for residues of propiconazole and its DCBA-containing metabolites using two related GC/ECD methods (Methods AG-454B and AG-626), which are updated versions of the current tolerance enforcement method for propiconazole residues in plant commodities. Both methods convert all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents. The basic difference between the two methods is that Method AG-626 uses iodomethane for methylation of DCBA rather than diazomethane as in Method AG-454B.

For both methods, propiconazole residues were extracted by refluxing for 1 hour in NH_4OH/methanol (20:80, v/v), and filtered. Residues were concentrated and oxidized to DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract was diluted with water, the $KMnO_4$ was deactivated by the addition of sodium meta-bisulfite, and the extract was acidified by the addition of 6N HCl. Residues of DCBA were partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using either diazomethane (Method AG-454B) or iodomethane in tetrabutyl ammonium hydroxide (Method AG-626). After methylation, residues were either concentrated and redissolved in hexane (Method AG-454B) or partitioned directly into hexane (Method AG-626). Residues were then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and analyzed by GC/ECD using external standards. The validated method LOQ is 0.05 ppm for corn forage, grain and stover, and a LOD was not reported.

Summary tables of the residue data were corrected by the registrant for procedural recoveries of <100%; however, spreadsheets including the uncorrected residue values were available in the raw data and were used by the reviewer to report residue values.

In conjunction with the analysis of field trial samples, the above method was validated using control samples fortified with propiconazole at 0.05-10 ppm for forage, 0.05-100 ppm for stover, and 0.05-5.0 ppm for grain.

C. RESULTS AND DISCUSSION

In a total of 28 field trials conducted throughout the U.S. during 1998 and 1999, propiconazole (1.04 lb/gal EC) was applied to field corn (24 trials) and popcorn (4 trials). With a few exceptions, each field corn trial included two separate treated plots, one for the collection of forage samples and the other for the collection of grain and stover; whereas, the four popcorn field trials each had a single treated plot for the collection of only grain and stover. Propiconazole (EC) was applied to the forage plots as two broadcast foliar applications during early vegetative development at a target rate of 0.11 lb ai/A/application, for a total of 0.22 lb ai/A. The RTI for forage ranged from 3-8 days, but was typically 7 days. For the grain and stover plots, propiconazole (EC) was applied to the corn as four broadcast foliar applications from flowering through grain development at target rates of 0.11 lb ai/A/application, for a total of 0.44 lb ai/A. The RTIs ranged from 6-9 days, but were typically 7 days. All applications were made using ground equipment in volumes of 5-25 gal/A, and no adjuvants were included in the spray mixtures. At two of the field corn sites, propiconazole was also applied as four broadcast foliar applications during grain development at 0.55 lb ai/A/application, for a total of 2.2 lb ai/A. In four of the 1998 field trials, propiconazole was misapplied to the forage and/or stover and grain plots at a reduced rate (0.05-0.06 lb ai/A/application); these field trials were replaced by the subsequent 1999 field trials.

Single control and duplicate treated samples of corn forage were harvested at 29-32 DAT, except in three tests in which forage was collected at 15, 51 or 67 DAT. Single control and duplicate treated samples of corn stover and grain were harvested at 28-35 DAT from all tests, with most samples being collected at 29-30 DAT. To examine residue decline, repeated control and treated samples were also collected at two sites. In these tests, forage was sampled at 0, 9, 16, 23, 30 and 37 DAT, stover was sampled at 0, 9, 16, 23, 30 and 36 DAT, and grain was sampled at 9, 16, 23, 30 and 36 DAT.

The GC/ECD methods (Methods AG-454B and AG-626) used to determine propiconazole residues in/on corn forage, stover and grain were adequately validated in conjunction with the analysis of field trial samples. Concurrent recoveries of propiconazole averaged 93 ± 11% from forage, 89 ± 13 % from stover and 90 ± 15% from grain (Table C.1). Apparent propiconazole residues were <LOQ in/on 30 of 33 control samples of forage, 34 of 39 control samples of stover and 33 of 37 control samples of grain, but apparent residues were ≥LOQ in/on 3 control samples of forage (0.05-0.12 ppm), 5 control samples of stover (0.05-0.08 ppm), and 4 control samples of grain (0.05-0.11 ppm). Given the small number of control samples with residues ≥LOQ and the low residue levels observed in these controls, apparent residues in these control samples did not adversely impact the field trial data. The validated method LOQ for propiconazole in/on corn forage, stover and grain is 0.05 ppm, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided. Although the study author reported residue values corrected for concurrent recoveries of <100%, uncorrected residues values were used and reported in this review.

Corn forage, stover and grain samples were stored frozen for up to 15.9 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating that weather residues of propiconazole are stable at -20°C for up to 38 months in grass forage, seeds and straw (DP Barcode D279300, Y. Donovan, 8/18/05). As these matrices are similar to corn grain, forage and stover, these storage stability data will support the storage intervals and conditions for the current corn field trials.

TABLE C.1. Summary of Concurrent Method Recoveries of Propiconazole from Corn Matrices using GC/ECD Methods AG-626 and AG-454B.

Analyte	Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Propiconazole	Forage	0.05-10.0	33	75, 111, 100, 84, 98, 95, 87, 82, 106, 77, 100, 95, 83, 87, 110, 66, 99, 107, 105, 93, 95, 92, 96, 100, 89, 85, 99, 79, 103, 104, 82, 98, 90	93 ± 11
	Stover	0.05-100	43	78, 100, 98, 72, 74, 88, 95, 107, 70, 75, 78, 96, 68, 108, 80, 95, 90, 93, 88, 74, 89, 98, 74, 76, 79, 104, 67, 85, 92, 93, 94, 94, 83, 101, 72, 108, 98, 113, 96, 106, 77, 78, 102	89 ± 13
	Grain	0.05-5.0	36	71, 74, 110, 80, 89, 100, 100, 79, 82, 98, 131, 84, 84, 90, 86, 80, 87, 106, 118, 97, 91, 98, 76, 86, 60, 62, 96, 109, 92, 98, 74, 102, 124, 88, 87, 80, 85	90 ± 15

TABLE C.2 Summary of Storage Conditions.			
Matrix	Storage Temperature (°C)	Actual Storage Duration[1] (months)	Interval of Demonstrated Storage Stability (months)[2]
Forage	-20	3.5-15.9	36
Stover		2.2-12.4	
Grain		2.2-12.7	

1 Interval from harvest to extraction for analysis. Extracts were stored for 0-29 days prior to analysis.
2 DP Barcode D279300, Y. Donovan, 8/18/05.

Following two early-season broadcast foliar applications of propiconazole (EC) during vegetative development at rates totaling 0.22 lb ai/A, combined propiconazole residues were <0.05-1.90 ppm in/on 36 samples of forage harvested 29-32 DAT (Tables C.3), and average residues in/on forage were 0.45 ppm (Table C.4.1).

Following four broadcast foliar applications of propiconazole (EC) during flowering through grain development at rates totaling 0.42-0.47 lb ai/A, combined residues were 0.92-19.6 ppm in/on 48 samples of stover and <0.05-0.15 ppm in/on 48 samples of grain harvested at 28-35 DAT. Average residues were 6.87 in/on stover and 0.037 ppm in/on grain, and HAFT residues were 15.9 ppm in/on stover and 0.10 ppm in/on grain. In the two exaggerated rate tests (5x), combined residues were 23.2-77 ppm in/on four samples of stover (ave. 58 ppm) and <0.05-0.062 ppm in/on four samples of grain harvested at 29-30 DAT.

In the two field trials examining residues over time, average residues in/on forage declined steadily from 11.3 ppm at 0 DAT to 0.05 ppm by 37 DAT (Table C.4.2, and Figure C.1), and average residues in/on stover declined erratically from 7.0 ppm at 0 DAT to 3.9 ppm by 36 DAT. Residue decline could not be determined in grain as only two samples from one interval had residues ≥LOQ.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data

TABLE C.3. Residue Data on Corn from Field Trials with Propiconazole (1.04 lb/gal EC).

Trial ID (County, State; Year)	Zone	Variety [1]	Total Rate (lb ai/A)	Commodity	PHI (days)	Total Propiconazole Residues (ppm) [2]
Champaign IL 1998 04-FR-004-98	5	NK4640 BT	0.22	Forage	29	1.1, 1.8
			0.47	Stover	29	12.2, 19.6 [3]
				Grain		<0.05, <0.05
			2.20	Stover	29	74, 77
				Grain		<0.05, <0.05
Burleson, TX 1998 0S-FR-201-98	6	N7590	0.22	Forage	31	0.51, 0.72
			0.44	Stover	28	3.0, 1.6 [4]
				Grain		<0.05, <0.05
Sampson, NC 1998 0S-609-98	2	DK592SR	0.22	Forage	30	0.47, 0.36
			0.44	Stover	34	0.92, 0.98 [4]
				Grain		<0.05, <0.05 [5]
Madera, CA 1998 0W-107-98	10	4138 Hybrid	0.22	Forage	30	0.50, 0.23
			0.44	Stover	35	6.0, 5.8
				Grain		0.15, 0.05 [5]
Jefferson, IA 1998 MW-FR-150-98	5	Pioneer 3335	0.22	Forage	51	0.73, 1.0
			0.44	Stover	29	3.2, 2.3
				Grain		<0.05, <0.05
Hamilton, IA 1998 MW-FR-151-98	5	NK4640 BT	0.22	Forage	30	0.13, 0.16
			0.44	Stover	30	4.7, 5.7
				Grain		<0.05, <0.05
			2.20	Stover	30	23.2, 56.9
				Grain		<0.05, 0.062
Adair, MO 1998 MW-FR-201-98	5	Fielders Choice 9211	0.22	Forage	67	<0.05, <0.05
			0.44	Stover	30	4.9, 3.0
				Grain		0.05, 0.08
Sedgwick, KS 1998 MW-FR-308-98	5	33R87	0.10 [7]	Forage	15	0.91, 1.31
			0.20 [7]	Stover	29	2.1, 2.4
				Grain		<0.05, <0.05
Clinton, IL 1998 MW-FR-405-98	5	Pioneer 33V08	0.22	Forage	29	0.10, 0.20 [6]
			0.44	Stover	30	3.2, 3.5
				Grain		<0.05, <0.05
Sioux, IA 1998 MW-FR-501-98	5	Midwest Seed Genetics	0.22	Forage	0	7.5, 8.6
					9	1.1, 1.1
					16	0.37, 0.29
					23	0.10, 0.18
					30	0.08, <0.05
					37	0.08, 0.08
			0.44	Stover	0	10.5, 13.0
					9	9.2, 13.8
					16	4.0, 4.9
					23	6.8, 4.4
					30	2.5, 4.4
					36	2.7, 4.5
				Grain	9	<0.05, <0.05
					16	<0.05, <0.05
					23	<0.05, <0.05
					30	0.08, 0.06
					36	<0.05, <0.05

TABLE C.3. *Residue Data on Corn from Field Trials with Propiconazole (1.04 lb/gal EC).*

Trial ID (County, State; Year)	Zone	Variety [1]	Total Rate (lb ai/A)	Commodity	PHI (days)	Total Propiconazole Residues (ppm) [2]
Clay, SD 1998 MW-FR-502-98	5	N52-B2	0.22	Forage	30	<0.05, 0.08 [6]
			0.44	Stover	29	8.6, 8.8 [4]
				Grain		<0.05, <0.05 [5]
York, NE 1998 MW-FR-610-98	5	Hybrid 34R06	0.22	Forage	30	0.05, 0.06
			0.44	Stover	30	8.3, 10.2 [3]
				Grain		0.07, <0.05
Polk, NE 1998 MW-FR-611-98	5	34R06	0.22	Forage	30	0.35, 0.44
			0.44	Stover	30	9.3, 6.5
				Grain		<0.05, <0.05
Walworth, WI 1998 MW-FR-701-98	5	RK657	0.22	Forage	30	0.71, 0.41 [6]
			0.44	Stover	30	6.6, 8.0 [4]
				Grain		<0.05, <0.05
Freeborn, MN 1998 MW-FR-801-98	5	Mycogen 2500	0.22	Forage	0	12.5, 16.6
					9	1.0, 1.1
					16	0.18, 0.49
					23	<0.05, <0.05
					30	<0.05, <0.05
					37	<0.05, <0.05
			0.44	Stover	0	2.7, 1.8
					9	20.0, 12.4
					16	1.9, 3.8
					23	6.0, 11.0
					30	6.3, 5.5
					37	4.2, 4.2
				Grain	9	<0.05, <0.05
					16	<0.05, <0.05
					23	<0.05, <0.05
					30	<0.05, <0.05
					37	<0.05, <0.05
Steele, MN 1998 MW-FR-802-98	5	Mycogen 2500	0.22	Forage	30	<0.05, 0.06
			0.44	Stover	30	3.5, 4.7
				Grain		0.06, 0.07 [5]
Hamilton, IN 1998 NE-FR-103-98	5	Pioneer 33A14	0.22	Forage	29	0.06, 0.16
			0.44	Stover	30	3.7, 3.4
				Grain		<0.05, <0.05
Hamilton, IN 1998 NE-FR-104-98	5	Pioneer 34G-81	0.22	Forage	30	1.1, 1.3
			0.44	Stover	30	8.4, 8.0
				Grain		<0.05, <0.05
Fayette, OH 1998 NE-FR-203-98	5	DK580 RR	0.11 [7]	Forage	29	0.27, 0.07
			0.22 [7]	Stover	28	2.8, 3.1
				Grain		<0.05, <0.05
Ingham, MI 1998 NE-FR-710-98	5	DK 471	0.12 [7]	Forage	32	<0.05, <0.05
			0.42	Stover	29	14.4, 15.4
				Grain		0.06, <0.05
Ingham, MI 1998 NE-FR-721-98	5	DK 471	0.22	Forage	29	0.43, 0.63
Wayne, NY 1998 NE-FR-802-98	1	Agway 257	0.22	Forage	30	0.78, 0.39
			0.44	Stover	30	1.99, 1.52
				Grain		<0.05, 0.08
Sedgewick, KS 1998 NE-FR-309-98	5	Purdue 410 (popcorn)	0.20 [7]	Stover	29	1.7, 2.6
				Grain		<0.05, 0.06

TABLE C.3. Residue Data on Corn from Field Trials with Propiconazole (1.04 lb/gal EC).						
Trial ID (County, State; Year)	Zone	Variety [1]	Total Rate (lb ai/A)	Commodity	PHI (days)	Total Propiconazole Residues (ppm) [2]
York, NE 1998 NE-FR-612-98	5	M-212 (popcorn)	0.44	Stover	30	10.6, 17.8
				Grain		<0.05, <0.05
Hamilton, IN 1998 NE-FR-105-98	5	Snow Puff (popcorn)	0.44	Stover	30	15.6, 16.6 [4]
				Grain		<0.05, <0.05
Fayette, OH 1999 NE-FR-203-99	5	SC 1097LL	0.44	Stover	30	12.4, 10.8
				Grain		<0.05, <0.05
Sedgwick, KS 1999 MW-FR-317-99	5	NC 4880	0.22	Forage	31	1.9, 0.85
			0.44	Stover	29	5.6, 2.9
				Grain		<0.05, <0.05
Sedgwick, KS 1999 MW-FR-318-99	5	Yellow Purdue 410 (popcorn)	0.44	Stover	29	2.8, 3.9
				Grain		<0.05, <0.05

1 The field trials used field corn varieties, with the exception of the four trials which used popcorn varieties.
2 Total propiconazole residues were determined as DCBA and expressed in parent equivalents. Reported values were obtained from the raw data and are not corrected procedural recoveries. The LOQ for propiconazole residues in/on corn commodities is 0.05 ppm. The LOD was not reported.
3 Residue values are the average of duplicate analyses
4 Associated control samples of stover had apparent residues at 0.05-0.08 ppm.
5 Associated control samples of grain had apparent residues at 0.05-0.11 ppm.
6 Associated control samples of forage had apparent residues at 0.05-0.12 ppm.
7 Applications in several tests were made at ~0.5x the target application rate.

TABLE C.4.1. Summary of Residue Data from Corn Field Trials with Propiconazole.										
Commodity	Total Applic. Rate (lb ai/A)	End-use Product	PHI (days)	Residue Levels (ppm) [1]						
				n	Min.	Max.	HAFT [2]	Median (STMdR)[3]	Mean (STMR)[4]	Std. Dev.
Forage	0.22	1.04 lb/gal EC	29-32	36	<0.05	1.90	1.45	0.36	0.45	0.49
Stover	0.42-0.47		28-35	48	0.92	19.60	15.9	5.65	6.87	4.75
Grain				48	<0.05	0.15	0.10	0.025	0.037	0.024

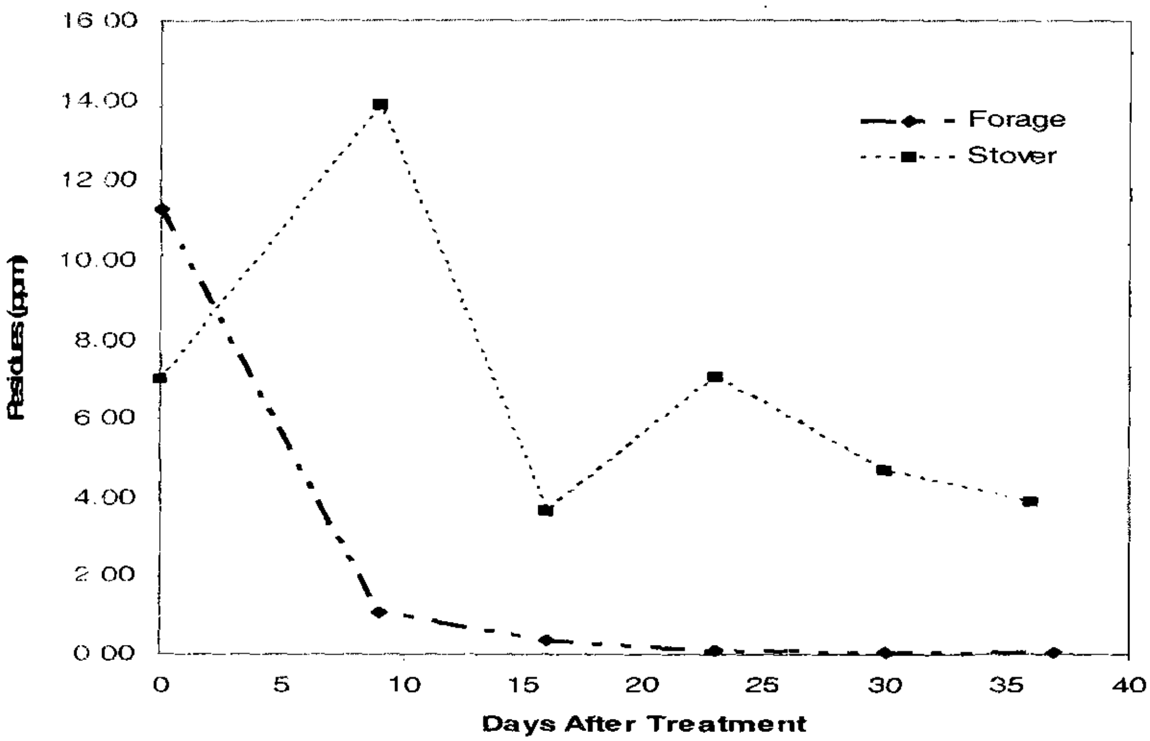
1 The LOQ is 0.05 ppm. Values are not corrected procedural recoveries. For calculation of the median, mean, and standard deviation, ½LOQ (0.025 ppm) was used for samples with residues <LOQ.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

TABLE C.4.2. Summary of Residue Decline Data from Corn Field Trials with Propiconazole (EC).

Commodity	Total Applic. Rate (lb ai/A)	End-use Product	PHI (days)	Residue Levels (ppm)[1]						
				n	Min.	Max.	HAFT[2]	Median (STMdR)[3]	Mean (STMR)[4]	Std. Dev.
Forage	0.22	1.04 lb/gal EC	0	4	7.50	16.6	14.55	10.55	11.30	4.13
			9	4	1.00	1.10	1.10	1.10	1.08	0.05
			16	4	0.18	0.49	0.34	0.33	0.33	0.13
			23	4	<0.05	0.18	0.14	0.06	0.08	0.07
			30	4	<0.05	0.08	0.05	0.03	0.04	0.03
			37	4	<0.05	0.08	0.08	0.05	0.05	0.03
Stover	0.44	1.04 lb/gal EC	0	4	1.80	13.0	11.75	6.60	7.00	5.59
			9	4	9.20	20.0	16.20	13.10	13.85	4.53
			16	4	1.90	4.90	4.45	3.90	3.65	1.26
			23	4	4.40	11.0	8.50	6.40	7.05	2.82
			30	4	2.50	6.30	5.90	4.95	4.68	1.65
			36	4	2.70	4.50	4.20	4.20	3.90	0.81
Grain	0.44	1.04 lb/gal EC	9	4	<0.05	<0.05	<0.05	0.025	0.025	0.00
			16	4	<0.05	<0.05	<0.05	0.025	0.025	0.00
			23	4	<0.05	<0.05	<0.05	0.025	0.025	0.00
			30	4	<0.05	0.080	0.07	0.043	0.048	0.027
			36	4	<0.05	<0.05	<0.05	0.025	0.025	0.00

1 The LOQ is 0.05 ppm. Values are not corrected procedural recoveries. For calculation of the median, mean, and standard deviation, ½LOQ (0.025 ppm) was used for samples with residues <LOQ.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

Figure C 1: Average Residues in or on Corn Forage and Stover Over Time



D. CONCLUSION

The corn field trial data are adequate and will support the use of up to four broadcast foliar applications of propiconazole (EC) to field or pop corn through grain development at 0.11 lb ai/A/application, at a minimum RTI of 7 days, for a total of 0.44 lb ai/A/season. The data also support a PHI of 30 days for harvest of forage, grain and stover. However, the data will only support the use of two early-season applications prior to the harvest of forage.

E. REFERENCES

DP Barcode:	D279300
Subject:	Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From:	Y. Donovan
To:	S. Lewis/J. Guerry
Dated:	8/18/05
MRID:	None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 2F6371
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED Yan Donovan	Date: 06/30/06
Approved by	Susan Hummel, Senior Scientist, RRB4/HED Susan Hummel	Date:06/30/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B; Durham, NC 27713; submitted 6/15/2006). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

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

EXECUTIVE SUMMARY:

In two field trials conducted in IL and IA during 1998, propiconazole (1.04 lb/gal EC) was applied to two plots of field corn at each site as four broadcast foliar applications during grain development at 0.11 or 0.55 lb ai/A/application at retreatment intervals (RTIs) of 5-9 days, for totals of 0.44 or 2.20 lb ai/A/season (1x and 5x rates). All applications were made using ground equipment in volumes of 21-25 gal/A, and no adjuvants were included in the spray mixtures. Single control and treated bulk samples of corn grain were harvested from each test at normal crop maturity, 29 or 30 days after the final treatment (DAT). The grain was cleaned to generate aspirated grain fractions (AGF) and then processed using simulated wet- and dry-milling procedures into meal, grits, flour, starch and refined oil. Prior to analysis, the grain and processed fractions were stored frozen for up to 10 months, an interval supported by the available stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on grain, AGF and processed fractions were determined using an adequate GC/ECD method (Method AG-454B). For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization with $KMnO_4$. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, and methylated. Methylated DBCA is determined by GC/ECD using external standards, and residues are expressed in parent equivalents. The validated method limit of quantitation (LOQ) is 0.05 ppm, and the limit of detection (LOD) was not reported.

Total combined propiconazole residues in/on bulk samples of corn grain harvested at 29 or 30 DAT were <0.05 ppm from the 1x rate tests and 0.062 and 0.081 ppm for the 5x rate tests. Except for AGF, residues in processed fractions were <0.05 ppm in samples from the 1x rate tests. Residues in AGF from the 1x rate tests were 0.159-0.208 ppm from the IL test and 0.173 ppm from the IA test. These data suggest the potential for concentration of residues in corn grain

AGF. However, due to residues being <LOQ in the RAC at 1x, reliable processing factors for AGF from the 1x rate tests could not be calculated.

For the 5x rate tests, residues were also <0.05 ppm in meal, grits, flour and starch and were <0.05-0.097 ppm in refined oil. Processing factors for corn meal, grits, flour and starch were <0.6x-<0.8x and averaged <0.7x, and the processing factors for refined oil were <0.6x-1.6x and averaged ~1x. Residues in/on AGF from the 5x tests were 0.250-0.266 ppm in the IL test and 1.04 ppm in the IA test. As the control sample of AGF from the IL test had apparent residues (0.233-0.264 ppm) of similar magnitude to the treated samples, a processing factor was not calculated for AGF from the test in IL. The processing factor for AGF from the 5x test in IA was 12.8x.

The corn processing trial is adequate and indicates that propiconazole residues are reduced by at least 0.8x in corn meal, grits, flour and starch. Residues in refined oil were variable, but the average processing factor for oil was 1x. Based on data from the only test with grain residues >LOQ and no interferences in the associated AGF sample, residues concentrated in AGF by 12.8x.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the corn processing study residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited minor deviations from GLP compliance, pertaining to the collection of weather data, tank mix storage stability data, maintenance chemicals, irrigation application, a reference standard for 2,4 DCBA past its reassay date and weight documentation.. None of these deviations affect the overall acceptability of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-DCBA (expressed as parent) in/on a variety of plant and animal commodities, including time-limited tolerances of 0.1 ppm on sweet corn (K+CWHR) and field corn grain and 12 ppm on field corn forage and stover [40 CFR §180.434(a)].

In conjunction with PP#2F6371, Syngenta is proposing new tolerances of residues in/on corn commodities. The current submission includes residue data from a field corn processing study.

TABLE A.1. Nomenclature of Propiconazole

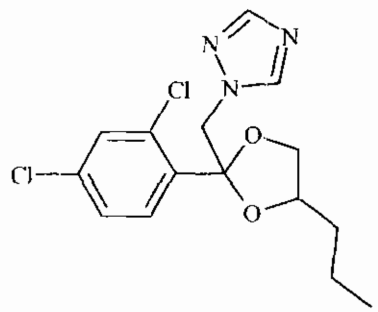
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EP	1.04 lb/gal EC (MAI formulation also containing 1.04 lb/gal of trifloxystrobin)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.

Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK$_a$)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K$_{OW}$)	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

To produced field corn grain of processing, two field trials were conducted in IL and IA during 1998 (Table B.1.1). At each site, propiconazole (EC) was applied to separate plots of field corn during grain development as four broadcast foliar applications at either 0.11 or 0.55 lb ai/A, for totals of 0.44 and 2.20 lb ai/A/season.

B.1. Application and Crop Information

TABLE B.1.1. Study Use Pattern

Location (County, State; Year) Trial ID	End-use Product [1]	Application Information [2]				
		Method; Timing	Volume (GPA)	Single Rate (lb ai/A)	RTI [3] (days)	Total Rate (lb ai/A)
Champaign, IL 1998 04-FR-004-98	1.04 lb/gal EC	Four broadcast foliar at crop height of 8-9'	21-24	0.11	7, 7, 7	0.44
				0.55		2.20
Hamilton, IA 1998 MW-FR-151-98	1.04 lb/gal EC	Four broadcast foliar at crop height of ~9'	25	0.11	7, 9, 5	0.44
				0.55		2.20

1 The end-use product was a multiple active ingredient formulation (EC) containing both propiconazole and trifloxystrobin, each at 1.04 lb ai/gal.
2 All applications were made using ground equipment and no adjuvants were included in the spray mixtures.
3 RTI = Retreatment Interval

B.2. Sample Handling and Processing Procedures

Single control and treated bulk samples of corn grain (>500 lb/sample) were harvested from each test at 29 or 30 DAT and stored frozen (temperature unspecified) at each field site until shipment by freezer truck to the processing facility, the Food Protein Research and Development Center (Bryan, TX), where samples were stored at ≤-12°C until processing. Samples were processed within 2-4 months of harvest. At the processing facility, samples of whole grain were initially dried to a moisture content of 10-13%, and samples of corn AGF were then generated and collected using procedures that simulate the movement of grain during transport and storage. Cleaned grain was then processed using simulated wet- and dry-milling procedures to yield samples of meal, grits (large, medium and small), flour, starch, and refined oil (wet- and dry-milled). Samples were frozen after collection and later shipped on dry ice by overnight courier to Novartis Crop Protection (Greensboro, NC), where samples were prepared (homogenized) and stored at -20EC. Samples were later shipped frozen to the analytical laboratory, EPL Bio-Analytical Services (Harristown, IL), where samples were stored frozen until analysis.

B.3. Analytical Methodology

Samples of corn grain, AGF and corn processed fractions were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-454B), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. This method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, propiconazole residues were extracted by refluxing for 1 hour in NH_4OH/methanol (20:80, v/v), and filtered. Residues were concentrated and oxidized to DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract was diluted with water, the $KMnO_4$ was deactivated by the addition of sodium meta-bisulfite, and the extract was acidified by the addition of 6N HCl. Residues of DCBA were partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using diazomethane. After methylation, residues were concentrated, redissolved in hexane, and cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v). Residues were then analyzed by GC/ECD using external standards. The validated method LOQ is 0.05 ppm for corn commodities, and a LOD was not reported.

Summary tables of the residue data were corrected by the registrant for procedural recoveries of <100%; however, spreadsheets including the uncorrected residue values were available in the raw data and were used by the reviewer to report residue values.

In conjunction with the analysis of the processing study samples, the above method was validated using control samples of each matrix fortified with propiconazole at 0.05 and 0.50 ppm.

C. RESULTS AND DISCUSSION

The GC/ECD method (Method AG-454B) used to determine propiconazole residues in/on corn grain and processed products was adequately validated in conjunction with the analysis of processing study samples. Average recoveries of propiconazole were 91-114% from samples of grain, AGF, and processed fractions fortified at 0.05 and 0.5 ppm. Apparent residues were <LOQ in/on all control samples of grain and processed fractions and in the control sample of AGF from the test in IA, but apparent residues were detected at 0.233-0.264 ppm in the control sample of AGF from the test in IL. As the apparent residues in this control AGF sample were similar to residues in the treated samples (0.159-0.266 ppm) from the same trial, processing factors for corn AGF were not calculated for the IL tests. The validated method LOQ for propiconazole is 0.05 ppm, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided. Although the study author reported residue values corrected for concurrent recoveries of <100%, uncorrected residues values are used and reported in this review.

Prior to analysis, samples of corn grain, AGF, and processed corn fractions were stored frozen for up to 10 months (Table C.2). Adequate storage stability data are available indicating that residues of propiconazole are stable at -20°C for up to 36 months in wheat grain and corn meal and oil (DP Barcode D279300, Y. Donovan, 8/18/05). These storage stability data will support the storage intervals and conditions for the corn processing study.

Following four broadcast foliar applications during grain development, total <u>uncorrected</u> propiconazole residues in/on bulk samples of corn grain harvested at 29-30 DAT were <0.05 ppm from the two tests at the 1x rate and 0.062 and 0.081 ppm from the two tests at the 5x rate.

Except for AGF, residues in processed fractions were <0.05 ppm in samples from the 1x rate tests. Residues in AGF from the 1x rate tests were 0.159-0.208 ppm from the IL test and 0.173 ppm from the IA test. These data suggest the potential for concentration of residues in corn grain AGF. However, due to residues being <LOQ in the RAC at 1x, reliable processing factors for AGF from the 1x rate tests could not be calculated.

For the 5x rate tests, residues were also <0.05 ppm in meal, grits, flour and starch and were <0.05-0.097 ppm in refined oil. Processing factors for meal, grits, flour and starch were <0.6x-<0.8x and averaged <0.7x, and the processing factors for refined oil were <0.6x-1.6x and averaged ~1x. Residues in/on AGF from the 5x tests were 0.250-0.266 ppm in the IL test and 1.04 ppm in the IA test. As the control sample of AGF from the IL test had apparent residues (0.233-0.264 ppm) of similar magnitude to the treated samples, a processing factor was not calculated for AGF from the IL test. The processing factor for AGF from the 5x test in IA was 12.8x. The maximum theoretical processing factor for corn grain is 25x for corn oil.

TABLE C.1. Summary of Concurrent Recoveries of Propiconazole from Corn and its Processed Products.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%) [1]
Whole Grain	0.05, 0.5	2	101, 109	105
AGF	0.05, 0.5	3	103, 85, 95	94
Meal	0.05, 0.5	2	113, 109	111
Grits	0.05, 0.5	6	121, 95, 87, 74, 85, 83	91 ± 16
Flour	0.05, 0.5	2	116, 112	114
Refined oil	0.05, 0.5	4	125, 106, 90, 93	104 ± 16
Starch	0.05, 0.5	3	92, 108, 96	99

[1] Standard deviations were only calculated for matrices with over 3 values.

TABLE C.2. Summary of Storage Conditions.

<table>
<tr><th>Matrix</th><th>Storage Temperature (°C)</th><th>Actual Storage Duration (days) [1]</th><th>Interval of Demonstrated Storage Stability (months) [2]</th></tr>
<tr><td>Grain</td><td rowspan="7"><-12</td><td>9.0-9.3</td><td rowspan="7">36</td></tr>
<tr><td>AGF</td><td>9.0-10.1</td></tr>
<tr><td>Meal</td><td>9.1-9.4</td></tr>
<tr><td>Grits</td><td>9.1-9.4</td></tr>
<tr><td>Flour</td><td>9.2-9.4</td></tr>
<tr><td>Refined oil</td><td>9.2-9.5</td></tr>
<tr><td>Starch</td><td>9.3-9.5</td></tr>
</table>

[1] Reported interval from harvest of whole grain to extraction for analysis, actual storage intervals for processed fractions would be 2-4 months less. Extracts were stored for 0-20 days prior to analysis.
[2] DP Barcode D279300, Y. Donovan, 8/18/05.

TABLE C.3. Residue Data from Corn Processing Study with Propiconazole (EC).

Location	RAC	Processed Commodity	Total Rate (lb ai/A) [1]	PHI (days)	Combined Residues (ppm) [2]	Processing Factor [3]
Champaign, IL 1998 04-FR-004-98	Grain (1x)	NA	0.44	29	(0.048) [4]	NA
		AGF			0.208, 0.159 [5]	NC
		Meal			<0.05	NC
		Grits (large, med., small)			<0.05, <0.05, <0.05	NC
		Flour			<0.05	NC
		Refined oil (dry-milled)			<0.05	NC
		Refined oil (wet-milled)			<0.05	NC
		Starch			<0.05	NC
	Grain (5x)	NA	2.20	29	0.062	NA
		AGF			0.266, 0.250 [5]	NC
		Meal			<0.05	<0.8x
		Grits (large, med., small)			<0.05, <0.05, <0.05	<0.8x
		Flour			<0.05	<0.8x
		Refined oil (dry-milled)			0.097	1.6x
		Refined oil (wet-milled)			<0.05	<0.8x
		Starch			<0.05	<0.8x
Hamilton, IA 1998 MW-FR-151-98	Grain (1x)	NA	0.44	30	(0.034) [4]	NA
		AGF			0.173	NC
		Meal			<0.05	NC
		Grits (large, med., small)			<0.05, <0.05, <0.05	NC
		Flour			<0.05	NC
		Refined oil (dry-milled)			<0.05	NC
		Refined oil (wet-milled)			<0.05	NC
		Starch			<0.05	NC
	Grain (5x)	NA	2.20	30	0.081	NA
		AGF			1.039	12.8x
		Meal			<0.05	<0.6x
		Grits (large, med., small)			<0.05, <0.05, <0.05	<0.6x
		Flour			<0.05	<0.6x
		Refined oil (dry-milled)			<0.05	<0.6x
		Refined oil (wet-milled)			0.081	1x
		Starch			<0.05	<0.6x

1 The application rates were reported to be at 1x and 5x the use rate for corn.
2 Total propiconazole residues were determined as DCBA and expressed in parent equivalents. Reported values were obtained from the raw data and are not corrected procedural recoveries. The LOQ for propiconazole residues is 0.05 ppm in/on grain, AGF and processed fractions. The LOD was not reported.
3 Processing factors were calculated by the reviewer using uncorrected residues.
4 Values for whole grain in parentheses are <LOQ.
5 The associated control sample of AGF had apparent residues of 0.233-0.264 ppm, which were similar to the levels in the treated samples.

NA = not applicable
NC = not calculated

TABLE C.4. Summary of Corn Processing Study with Propiconazole (EC).

RAC	Processed Commodity	Total Rate (lb ai/A)	PHI (days)	Processing Factor (Hamilton, IA 1998)	Processing Factor (Champaign, IL 1998)	Average Processing Factor
Grain (5x)	NA	2.20	29-30	NA	NA	
	AGF			12.8x	NC	12.8x
	Meal			<0.6x	<0.8x	<0.7x
	Grits (large, med., small)			<0.6x	<0.8x	<0.7x
	Flour			<0.6x	<0.8x	<0.7x
	Refined oil (dry-milled)			<0.6x	1.6x	1.0x
	Refined oil (wet-milled)			1x	<0.8x	
	Starch			<0.6x	<0.8x	<0.7x

D. CONCLUSION

The corn processing trial is adequate and indicates that propiconazole residues are reduced by at least 0.8x in corn meal, grits, flour and starch. Residues in refined oil were variable, but the average processing factor for oil was 1x. Based on data from the only test with grain residues >LOQ and no interferences in the associated AGF sample, residues concentrated in AGF by 12.8x.

E. REFERENCES

DP Barcode: D279300
Subject: Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From: Y. Donovan
To: S. Lewis/J. Guerry
Dated: 8/18/05
MRID: None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 2F6371
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED	Date: 06/30/06
	Yan Donovan	
Approved by	Susan Hummel, Senior Scientist, RRB4/HED	Date: 06/30/06
	Susan Hummel	

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 5/26/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

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

EXECUTIVE SUMMARY:

A total 16 field trials were conducted on rice in 1998 in the major rice production areas of the U.S. At each site, propiconazole (3.6 lb/gal EC) was applied to rice as a single broadcast foliar application at 0.28 lb ai/A during heading. Four of the trial sites also included another treatment, in which propiconazole (1.04 lb/gal EC) was applied as split broadcast foliar applications around heading at 0.154 lb ai/A/application, at retreatment intervals (RTIs) of 14 days, for a total of 0.31 lb ai/A/season. All applications were made using ground equipment at volumes of 5-25 gal/A. Single control and duplicate treated samples of rice straw and grain were harvested from each site at 34-49 days after treatment (DAT), with 14 sites having harvest intervals of 34-37 days. To examine residue decline, additional samples were collected from two test sites at 14, 21, 27-28, 34-38, and 42-45 DAT. Samples were stored frozen from collection to analysis for up to 11.2 months, an interval supported by the available storage stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on rice grain and straw were determined using an adequate GC/ECD method (Method AG-626). For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization with $KMnO_4$. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and cleaned-up using an acidic alumina cartridge. Methylated DBCA is determined by GC/ECD, using external standards, and residues are expressed in parent equivalents. Concurrent recoveries from rice straw showed averaged 91 ± 13% and from rice grain 91 ± 7%. The validated method LOQ is 0.05 ppm, and an LOD was not reported.

Following a single application of propiconazole (EC) at 0.28 lb ai/A, total propiconazole residues ranged from 0.97-17.0 ppm in/on 32 samples of straw and 0.03-6.50 ppm in/on 32 samples of grain harvested at 34-49 DAT. Average residues were 4.50 ppm for straw and 1.76

ppm for grain. At the four sites where the single application at 0.28 lb ai/A was compared to the split application totaling 0.31 lb ai/A, residues were similar between the two treatments. Average residues in/on grain and straw were 1.34 and 4.27 ppm, respectively, following the single application, and 1.17 and 4.04 ppm, respectively, following the two split applications.

In the two residue decline tests, residues in/on rice grain remained relatively steadily over time, averaging 1.45 ppm at 14 DAT and 1.22 ppm at ~45 DAT. Residues in/on straw showed a slight increase at longer post-treatment intervals, but the trend could not be verified due to the variability in the residue data on straw. Average residues in/on straw were 3.05 ppm at 14 DAT and 4.45 ppm by ~45 DAT. The slight increase in straw residues may be the result of drying down of the foliage as the crop matures.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the rice field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited minor deviations from GLP compliance, pertaining to the collection of weather data, tank mix storage stability data and maintenance chemicals and irrigation application. None of these deviations affect the overall acceptability of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities, including tolerances of 0.1 and 3.0 ppm on rice grain and straw [40 CFR §180.434(a)].

Under PP#2F6371, Syngenta is requesting revised tolerances on rice commodities in conjunction with a proposal to modify the current use directions for rice to include an application later in the season. The current submission includes field trial data on rice.

TABLE A.1. Nomenclature of Propiconazole

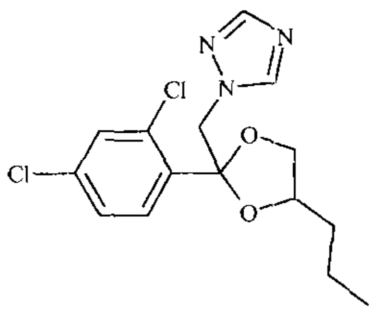
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EPs	3.6 lb/gal EC (Tilt 3.6E Fungicide, EPA Reg. No. 100-617)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.

Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK$_a$)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K$_{OW}$)	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Rice was grown and maintained at each test site using typical agricultural practices for the respective geographical region (Table B.1.1). Monthly rainfall and irrigation data were provided for each site, along with temperature data. No usual weather conditions were noted that would have an adverse effect on the field trial data. Information was also provided on maintenance chemicals and other pesticides used at each site. Soil types were provided for each site, but no other soil data were provided. However, as the application to rice was foliar, additional information on soil characteristics are not required.

The study use pattern for propiconazole (3.6 lb/gal EC) on rice is reported in Table B.1.2. Propiconazole was applied as a single broadcast foliar application at 0.28 lb ai/A during heading at each trial site. Four of the trial sites also included another treatment, in which propiconazole (1.04 lb/gal EC) was applied as two broadcast foliar applications around heading at 0.154 lb ai/A/application, at RTIs of 14 days, for a total of 0.309 lb ai/A/season.

TABLE B.1.1. Trial Site Conditions.

Trial Identification (County, State; Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC[2] (meq/g)
Washington, MI 1998	Silt Loam	NR	NR	NR
Crittenden, AR 1998	Silty Clay Loam	NR	NR	NR
Jackson, AR 1998	Loam	NR	NR	NR
Independence, AR 1998	Silty Clay	NR	NR	NR
Drew, AR 1998	Clay Loam	NR	NR	NR
Arkansas, AR 1998	Loam	NR	NR	NR
Pemiscot, MO 1998	Sandy Loam	NR	NR	NR
Stoddard, MO 1998	Silt Loam	NR	NR	NR
Wharton, TX 1998	Sandy Loam	NR	NR	NR
Colorado, TX 1998	Sandy Clay Loam	NR	NR	NR
St. Landry Parish, LA 1998	Silty Clay Loam	NR	NR	NR
Jeff Davis Parish, LA 1998	Loam	NR	NR	NR
Allen Parish, LA 1998	Silt Loam	NR	NR	NR
Washington, MS 1998	Clay	NR	NR	NR
Merced, CA 1998	Clay Loam	NR	NR	NR
Butte, CA 1998	Clay	NR	NR	NR

1 These parameters are optional except in cases where their value affects the use pattern for the chemical.
2 Cation exchange capacity.
NR = Not Reported

TABLE B.1.2. Study Use Pattern on Rice.

Location (County, State; Year) Trial ID	End-use Product	Application Information [1]				
		Method; Timing	Volume (GPA)	Single Rate (lb ai/A)	RTI (days)	Total Rate (lb ai/A)
Washington, MI 1998 001	3.6 lb/gal EC	One broadcast foliar application at soft dough	14	0.28	--	0.28
Crittenden, AR 1998 104	3.6 lb/gal EC	One broadcast foliar application at heading	12	0.28	--	0.28
	1.04 lb/gal EC	Two broadcast foliar applications at 10 % heading and Heading		0.154	14	0.31
Jackson, AR 1998 105	3.6 lb/gal EC	One broadcast foliar application at 30% headed	20	0.28	--	0.28
Independence, AR 1998 106	3.6 lb/gal EC	One broadcast foliar application at headed	20	0.28	--	0.28
Drew, AR 1998 107	3.6 lb/gal EC	One broadcast foliar application at 90% head	5	0.28	--	0.28
Arkansas, AR 1998 108	3.6 lb/gal EC	One broadcast foliar application at headed	11	0.28	--	0.28
Pemiscot, MO 1998 109	3.6 lb/gal EC	One broadcast foliar application at heading	13	0.28	--	0.28
Stoddard, MO 1998 110	3.6 lb/gal EC	One broadcast foliar application at 1% heading	12	0.28	--	0.28
	1.04 lb/gal EC	Two broadcast foliar applications at jointing and 1% heading		0.154	14	0.31
Wharton, TX 1998 204	3.6 lb/gal EC	One broadcast foliar application at 1-2% heading	13	0.28	--	0.28
	1.04 lb/gal EC	Two broadcast foliar applications at panicle development to 1-2% heading	12-13	0.154	14	0.31
Colorado, TX 1998 206	3.6 lb/gal EC	One broadcast foliar application at 1-2% heading	12	0.28	--	0.28
St. Landry Parish, LA 1998 901	3.6 lb/gal EC	One broadcast foliar application at 60% heading	21	0.28	--	0.28
Jeff Davis Parish, LA 1998 902	3.6 lb/gal EC	One broadcast foliar application at full boot	5	0.28	--	0.28
Allen Parish, LA 1998 903	3.6 lb/gal EC	One broadcast foliar application at full boot	11	0.28	--	0.28
Washington, MS 1998 904	3.6 lb/gal EC	One broadcast foliar application at 80% heading	12	0.28	--	0.28
Merced, CA 1998 401	3.6 lb/gal EC	One broadcast foliar application at maturing heads	25	0.28	--	0.28
Butte, CA 1998 408	3.6 lb/gal EC	One broadcast foliar application at heading	14	0.28	--	0.28
	1.04 lb/gal EC	Two broadcast foliar applications at tillering and heading		0.154	14	0.31

[1] All applications were made using ground equipment, and did not include the use of an adjuvant.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones[1]	Rice		
	Submitted	Requested	
		Canada	U.S.
1	---	---	---
2	---	---	---
3	---	---	---
4	11	---	11
5	1	---	1
6	2	---	2
7	---	---	---
8	---	---	---
9	---	---	---
10	2	---	2
11	---	---	---
12	---	---	---
Total	16	NA	16

[1] Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the use is for only in the U.S.
NA = Not applicable

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of grain and straw (3 lb/sample) were harvested from each test at 34-49 DAT, with all but two sites having harvest intervals for 34-37 DAT. Additional samples were collected from two test sites at 14, 21, 27-28, 34-38, and 42-45 DAT. After collection, samples were placed in frozen storage (temperature unspecified) at the field sites and later shipped by freezer truck to the analytical laboratory, Novartis Crop Protection (Greensboro, NC), where samples were stored at -20° C until preparation for analysis.

B.3. Analytical Methodology

Rice samples were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-626), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, residues are extracted and base hydrolyzed by refluxing for 1 hour with NH_4OH/MeOH (20:80, v/v) and filtered. Residues are concentrated and oxidized to 2,4-DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, sodium meta-bisulfite is added to deactivate the $KMnO_4$, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using methyl iodide in the presence of tetrabutyl ammonium hydroxide. Residues are partitioned into hexane and then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v). Methylated DCBA is then analyzed by GC/ECD, using external standards. Residues are expressed in propiconazole equivalents. The validated method LOQ is 0.05 ppm for residues in/on rice grain and straw; the LOD was not reported.

In conjunction with the analysis of the rice processing study samples, the above method was validated using control samples fortified with propiconazole at 0.05-10 ppm for grain and 0.05-25 ppm for straw.

C. RESULTS AND DISCUSSION

The number and geographic representation of the rice field trials are adequate. A total 16 field trials were conducted on rice in 1998 in the major rice production areas of the U.S. At each site, propiconazole (3.6 lb/gal EC) was applied to rice as a single broadcast foliar application at 0.28 lb ai/A during heading. Four of the trial sites also included another treatment, in which propiconazole (1.04 lb/gal EC) was applied as two broadcast foliar applications around heading at 0.154 lb ai/A/application, at RTIs of 14 days, for a total of 0.31 lb ai/A/season. All applications were made using ground equipment at volumes of 5-25 gal/A. Single control and duplicate treated samples of rice straw and grain were harvested from each site 34-49 DAT, with 14 sites having harvest intervals of 34-37 days. To examine residue decline, additional duplicate samples were collected from two test sites at 14, 21, 27-28, 34-38, and 42-45 DAT.

The GC/ECD method (Method AG-626) used to determine propiconazole residues in/on rice straw and grain was adequately validated in conjunction with the analysis of field trial samples. The recovery of propiconazole averaged 91 ± 13% from rice straw and 91 ± 7% from rice grain (Table C.1). Apparent residues of propiconazole were < LOQ in/on 30 control samples. The validated method LOQ for propiconazole is 0.05 ppm, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided.

Rice straw and grain samples were stored frozen for up to 11.2 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating the weathered residues of propiconazole and its metabolites are stable for up to 39 months at -20° C in grass forage, straw and seeds (DP Barcode D210742, 3/15/95, M. Rodriguez). These data will support the storage intervals and conditions for the current field trials.

Following a single application of propiconazole (3.6 lb/gal EC) at 0.28 lb ai/A, total propiconazole residues ranged from 0.97-17.0 ppm in/on 32 samples of straw and 0.03-6.50 ppm in/on 32 samples of grain harvested 34-49 DAT (Table C.3). Average residues were 4.50 ppm for straw and 1.76 ppm for grain (Table C.4.1). In the two residue decline tests, residues in/on rice grain remained relatively steady overtime up to 45 DAT (Table C.4.2), averaging 1.45 ppm at 14 DAT, 1.1 ppm at ~28 DAT and 1.22 ppm at ~45 DAT. Residues in/on straw showed a slight increase at longer post-treatment intervals (Figure C.1), possibly due to the drying down of the straw as the crop matured. Average residues in/on straw were 3.05 ppm at 14 DAT and increased to 4.45 ppm by ~45 DAT. However, a definitive conclusion about the potential for increased residues can not be made given the degree of variability in the residue data on straw.

In the side-by-side tests comparing the single application at 0.28 lb ai/A vs. the split applications totaling 0.31 lb ai/A, residues levels in/on grain and straw were similar for the two treatments. Total propiconazole residues ranged from 1.10-12.0 ppm in/on 8 samples of straw and 0.09-2.50 on 8 samples of grain harvested 34-49 DAT following the second of two applications of propiconazole (EC) totaling 0.31 lb ai/A, and residues ranged from 0.97-12.0 ppm in/on 8 samples of straw and 0.13-3.90 on 8 samples of grain harvested 34-49 DAT following a single application at 0.28 lb ai/A. Average residues for the single and split applications were respectively 1.34 and 1.17 ppm in/on grain and 4.27 and 4.04 ppm in/on straw.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data

TABLE C.1. Summary of Method Recoveries of Propiconazole from Rice Grain and Straw Using GC/ECD Method AG-626.

Analyte	Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Propiconazole	Rice straw	0.05-25	27	64, 68, 70-109, 122	91 ± 13
	Rice grain	0.05-10	28	66, 69, 69, 71-119, 123, 123	91 ± 17

TABLE C.2 Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1] (months)	Interval of Demonstrated Storage Stability (months)[2]
Rice Straw	-20	11.2	39
Rice Grain		11.1	

[1] From harvest to extraction for analysis.
[2] DP Barcode D210742, 3/15/95, M. Rodriguez.

TABLE C.3. Residue Data on Rice from Field Trials with Propiconazole (EC).

Trial ID (County, State; Year)	Zone	Variety	EP	Total Rate (lb ai/A)	Commodity	PHI (days)	Total Propiconazole Residues (ppm)[1]
Washington, MI 1998 001	4	Lemont	3.6 lb/gal EC	0.28	Straw	14	2.9, 7.4
						21	4.6, 7.5
						27	6.6, 5.3
						34	1.5, 2.1
						42	7.2, 8.3
					Grain	14	1.8, 2.1
						21	1.4, 1.4
						27	1.7, 2.1
						34	1.1, 1.7
						42	1.8, 2.1
Crittenden, AR 1998 104	4	Bengal	3.6 lb/gal EC	0.28	Straw	36	11, 12
					Grain		3.9, 3.3
			1.04 lb/gal EC	0.31	Straw	36	12, 8.0
					Grain		2.4, 2.5
Jackson, AR 1998 105	4	Cypress	3.6 lb/gal EC	0.28	Straw	35	4.0, 4.1
					Grain		2.6, 1.5

TABLE C.3. Residue Data on Rice from Field Trials with Propiconazole (EC).

Trial ID (County, State; Year)	Zone	Variety	EP	Total Rate (lb ai/A)	Commodity	PHI (days)	Total Propiconazole Residues (ppm)[1]
Independence, AR 1998 106	4	Jefferson	3.6 lb/gal EC	0.28	Straw	14	1.7, 0.21
						21	0.82, 1.8
						28	1.6, 1.9
						35	2.7, 2.2
						45	0.89, 1.4
					Grain	14	1.1, 0.78
						21	0.17, 0.76
						28	0.57, 0.086
						35	0.90, 0.85
						45	0.35, 0.62
Drew, AR 1998 107	4	Cypress	3.6 lb/gal EC	0.28	Straw	35	2.6, 1.4
					Grain		0.11, 0.71
Arkansas, AR 1998 108	4	Jefferson	3.6 lb/gal EC	0.28	Straw	34	4.1, 3.3
					Grain		5.0, 5.0
Pemiscot, MO 1998 109	4	Cypress	3.6 lb/gal EC	0.28	Straw	35	16, 17
					Grain		6.1, 6.5
Stoddard, MO 1998 110	5	Drew	3.6 lb/gal EC	0.28	Straw	35	1.0, 0.97
					Grain		0.14, 0.13
			1.04 lb/gal EC	0.31	Straw	35	1.1, 1.1
					Grain		0.13, 0.093
Wharton, TX 1998 204	6	Drew	3.6 lb/gal EC	0.28	Straw	40	1.9, 2.6
					Grain		0.31, 0.64
			1.04 lb/gal EC	0.31	Straw	40	1.8, 1.4
					Grain		0.53, 0.36
Colorado, TX 1998 206	6	Drew	3.6 lb/gal EC	0.28	Straw	37	2.0, 1.5
					Grain		0.13, 0.15
St. Landry Parish, LA 1998 901	4	Cypress	3.6 lb/gal EC	0.28	Straw	35	1.4, 1.4
					Grain		0.68, 0.81
Jeff Davis Parish, LA 1998 902	4	Cypress	3.6 lb/gal EC	0.28	Straw	35	3.4, 2.2
					Grain		1.0, 0.88
Allen Parish, LA 1998 903	4	Cypress	3.6 lb/gal EC	0.28	Straw	35	2.6, 4.0
					Grain		1.0, 1.0
Washington, MS 1998 904	4	Lemont	3.6 lb/gal EC	0.28	Straw	49	1.7, 1.6
					Grain		0.13, <0.05
Merced, CA 1998 401	10	NFD-181	3.6 lb/gal EC	0.28	Straw	35	17, 9.9
					Grain		3.5, 4.3
Butte, CA 1998 408	10	M204	3.6 lb/gal EC	0.28	Straw	35	2.4, 2.3
					Grain		1.5, 0.80
			1.04 lb/gal EC	0.31	Straw	35	3.0, 3.9
					Grain		0.85, 2.5

1 Total propiconazole residues were determined as DCBA and expressed in parent equivalents. The LOQ for propiconazole residues in/on rice grain and straw is 0.05 ppm. The LOD was not reported.

TABLE C.4.1 Summary of Residue Data from Rice Field Trials with Propiconazole (EC).

Commodity	Total Applic. Rate (lb ai/A)[1]	End-use Product	PHI (days)	Residue Levels (ppm)[1]						
				n	Min.	Max.	HAFT[2]	Median (STMdR)[3]	Mean (STMR)[4]	Std. Dev.
Straw	0.28	3.6 lb/gal EC	34-49	32	0.97	17.00	16.50	2.50	4.50	4.81
Grain	0.28	3.6 lb/gal EC	34-49	32	0.03	6.50	6.30	0.95	1.76	1.89
Straw[5]	0.28	3.6 lb/gal EC	35-40	8	0.97	12.00	11.50	2.35	4.27	4.51
	0.31	1.04 lb/gal EC		8	1.10	12.00	10.00	2.40	4.04	3.95
Grain[5]	0.28	3.6 lb/gal EC	35-40	8	0.13	3.90	3.60	0.72	1.34	1.47
	0.31	1.04 lb/gal EC		8	0.09	2.50	2.45	0.69	1.17	1.10

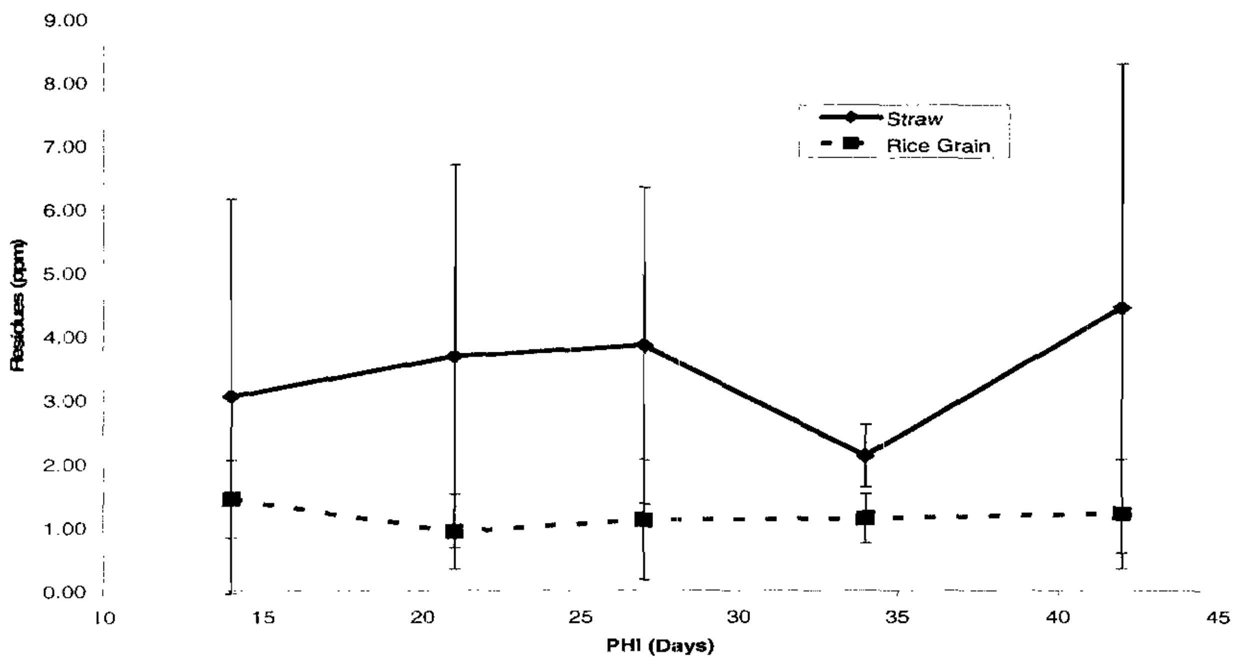
1 The higher application rate reflects two applications at 0.154 lb ai/A.
2 Residues are expressed in propiconazole equivalents. The LOQ is 0.05 ppm, and the LOD was not reported. Residues <LOQ were estimated to be 2 LOQ, for calculation of mean, median and standard deviation.
3 HAFT = Highest Average Field Trial.
4 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.
5 Comparison of residues in grain and straw from side-by-side tests using either one application at 0.28 lb ai/A or two applications totaling 0.31 lb ai/A

TABLE C.4.2 Summary of Residue Decline Data from Rice Field Trials with Propiconazole (EC).

Commodity	Total Applic. Rate (lb ai/A)	End-use Product	PHI (days)	Residue Levels (ppm)[1]						
				n	Min.	Max.	HAFT[2]	Median (STMdR)[3]	Mean (STMR)[4]	Std. Dev.
Rice Straw	0.28	3.6 lb/gal EC	14	4	0.21	7.40	5.15	2.30	3.05	3.10
			21	4	0.82	7.50	6.05	3.20	3.68	3.01
			27-28	4	1.60	6.60	5.95	3.60	3.85	2.49
			34-38	4	1.50	2.70	2.45	2.15	2.13	0.49
			42-45	4	0.89	8.30	7.75	4.30	4.45	3.85
Rice Grain	0.28	3.6 lb/gal EC	14	4	0.78	2.10	1.95	1.45	1.45	0.61
			21	4	0.17	1.40	1.40	1.08	0.93	0.59
			27-28	4	0.09	2.10	1.90	1.14	1.11	0.94
			34-38	4	0.85	1.70	1.40	1.00	1.14	0.39
			42-45	4	0.35	2.10	1.95	1.21	1.22	0.86

1 The LOQ is 0.05 ppm.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

Figure C.1. Total Propiconazole Residues in/on Rice Grain and Straw Overtime Following a Single Application at 0.28 lb ai/A.



D. CONCLUSION

The rice field trial data are adequate and will support the use of a single application of propiconazole (EC) to rice during heading at up to 0.28 lb ai/A. The data support a PHI of 35 days for rice grain and straw.

E. REFERENCES

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

DP Barcode:	D279300
Subject:	Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From:	Y. Donovan
To:	S. Lewis/J. Guerry
Dated:	8/18/05
MRID:	None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): PP#2F6371
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED Yan Donovan	Date: 06/30/06
Approved by	Susan Hummel, Senior Scientist, RRB4/HED Susan Hummel	Date:06/30/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 6/23/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

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

EXECUTIVE SUMMARY:

In a total of 21 field trials conducted throughout the U.S. during 1997, propiconazole (3.6 lb/gal EC) was applied to at least three separate plots of winter or spring wheat at each site. In two plots at each site, propiconazole was applied as a single broadcast foliar application at 0.11-0.12 lb ai/A at either Feekes Growth Stage (FGS) 5 or FGS 10.5. The early-season application at FGS 5 was used for the collection of forage and hay, and the late-season application at FGS 10.5 was used for collection of grain and straw. In the third plot, propiconazole was applied as two late-season, broadcast foliar applications at FGS 10 and 10.5, at 0.11-0.12 lb ai/A/application, for a total of 0.22-0.23 lb ai/A. This plot was used for the collection of grain and straw samples. Two addition plots were also established at two sites using two late-season applications at exaggerated rates at 0.33 and 0.55 lb ai/A/application (3x and 5x rates), for totals of 0.66 and 1.1 lb ai/A. All applications were made using ground equipment at spray volumes of 11-25 gal/A, and no adjuvants were included in the tank mixtures. For the plots that received two applications, the retreatment interval (RTI) was 13-22 days, with most tests having a RTI of 14 days.

Single control and duplicate treated samples of forage were harvested at 29-32 days after treatment (DAT), and hay samples were cut at 43-50 DAT, with most hay samples being cut at 45 DAT. Single control and duplicate treated samples of mature wheat grain and straw were harvested at 27-50 DAT, with most samples being collected around 40 DAT. To examine residue decline, repeated control and treated samples were collected at two sites from 0-37 DAT for forage, 29-59 DAT for hay, and 21-73 DAT for grain and straw. Samples were stored frozen from collection to analysis for up to 16.3 months, an interval supported by available storage stability data

T

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on wheat commodities were determined using a GC/ECD method (Method AG-454 B). This method is an updated version of the current tolerance enforcement method and was adequately validated in conjunction with the analysis of field trial samples. For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and cleaned-up using an acidic alumina cartridge. Methylated DBCA is determined by GC/ECD, using external standards, and residues are expressed in parent equivalents. The validated method limit of quantitation (LOQ) is 0.05 ppm, and a limit of detection (LOD) was not reported.

Samples were also analyzed for residues of propiconazole, *per se*, using a GC/NPD method from PAM Vol. I (Method 302 E4 + DG5). This method was also adequately validated in conjunction with the analysis of field trial samples. For this method, residues are extracted with aqueous acetone, partitioned into dichloromethane:petroleum ether, and cleaned up using a Florisil column. Residues of parent are then analyzed by GC/NPD using external standards. The validated method LOQ is 0.05 ppm, and a LOD was not reported. For both total combined residues and parent residues, the reported residues values were corrected for concurrent recoveries of < 100%; however, the uncorrected residues values were used and reported in this review.

Following an application at FGS 5 at 0.11 lb ai/A, total combined residues were <0.05-1.91 ppm in/on forage harvested at 29-32 DAT and <0.05-1.10 ppm in/on hay cut at 43-50 DAT, and average combined residues were 0.33 and 0.30 ppm in/on forage and hay, respectively. Residues of parent propiconazole were <0.05-0.49 ppm in/on forage and <0.05-0.20 ppm in/on hay, and averaged 0.06 and 0.04 ppm, respectively. Following a single application at FGS 10.5 at 0.11-0.12 lb ai/A, total combined residues were 0.41-6.21 ppm in/on straw and <0.05-0.13 ppm in/on grain harvested at maturity, 27-57 DAT, and combined residues averaged 2.02 and 0.04 ppm in/on straw and grain, respectively. Residues of parent propiconazole were <0.05-1.63 ppm in/on straw and <0.05 ppm in/on grain, and averaged 0.45 and 0.025 ppm, respectively.

Following two broadcast applications at FGS 10 and 10.5 totaling 0.22 lb ai/A, total combined residues were 0.20-8.27 ppm in/on straw and <0.05-0.20 ppm in/on grain harvested at 27-57 DAT. Combined residues averaged 3.31 and 0.07 ppm in/on straw and grain, respectively. Residues of parent were <0.05-3.49 ppm in/on straw and <0.05 ppm in/on grain, and averaged 0.73 and 0.025 ppm, respectively.

Regardless of the application timing or rate, residues levels of parent in forage, hay and straw were approximately 0.2x the residue levels of total combined residues. For grain, a comparison of parent and combined residues was not meaningful as most samples of grain had residues levels <LOQ for both parent and combined residues.

In the two residue decline trials, substantial decreases in levels of both parent residues and total combined residues were observed in forage from 0 to 32 DAT, and more gradual declines were observed in hay from 29 to 59 DAT. Residues of parent and total residues in grain and straw either remained relatively steady or declined slightly at longer post-treatment intervals.

In the four tests conducted at exaggerated application rates of 0.66 or 1.1 lb ai/A (3x and 5x rates), total combined residues in/on straw harvested at 36 or 47 DAT were 3.11-5.20 ppm for the 3x rate and 4.79-14.7 ppm for the 5x rate, and parent residues were 0.30-0.38 ppm for the 3x rate and 0.66-1.64 ppm for the 5x rate. For grain harvested at 36 or 47 DAT, total combined residues were 0.08-0.15 ppm for the 3x rate and 0.12-0.23 ppm for the 5x rate, and parent residues were <0.05 ppm for both the 3x and 5x rates.

These data would support the use of propiconazole (EC) on wheat as either one or two broadcast foliar applications at 0.11 lb ai/A/application at up to FGS 10.5, for a total of 0.22 lb ai/A/season. However, any labels should allow only a single application prior to the harvest of forage or hay. The data support a minimum RTI of 14 days and pre-harvest intervals (PHIs) of 30 days for forage, 45 days for hay, and 40 days for grain and straw.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the wheat field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited deviations from GLP compliance pertaining to weather data, tank mix storage stability data and the application of maintenance chemicals.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities, including permanent tolerances of 0.1 and 1.5 ppm on wheat grain and straw [40 CFR §180.434(a)].

Syngenta has submitted at petition (PP#2F6371) proposing new tolerances and the use of propiconazole on a variety of cereal grains, including wheat. The current submission includes residue data from wheat field trials comparing residues in/on forage, hay, grain and straw from one or two applications at various developmental stages.

TABLE A.1. Nomenclature of Propiconazole

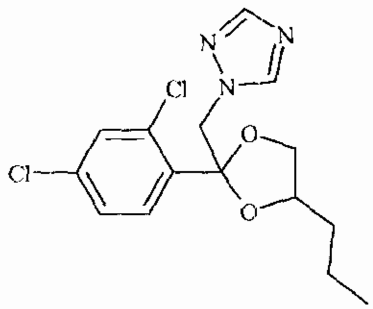
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EPs	3.6 lb/gal EC (Tilt 3.6E Fungicide, EPA Reg. No. 100-617)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.

Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm³ at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2×10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK_a)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K_{OW})	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Wheat was grown and maintained at each test site using typical agricultural practices for the respective geographical regions (Table B.1.1). Monthly rainfall and irrigation data were provided for each site, along with temperature data. No usual weather conditions were noted that would have an adverse effect on the field trial data. Information was also provided on maintenance chemicals and other pesticides used at each site. Soil types and chemical characteristics were provided for each site.

Propiconazole (3.6 lb/gal EC) was applied to at least three separate plots at each site (Table B.1.2). One plot received a single broadcast foliar application of propiconazole at approximately FGS 5 at a target rate of 0.11 lb ai/A and was used for the collection of forage and hay. The second plot received a single broadcast foliar application of propiconazole at approximately FGS 10.5 at a target rate of 0.11 lb ai/A and was used for the collection of grain and straw. The third plot received two broadcast foliar applications of propiconazole at approximately FGS 10 and 10.5 at a target rate of 0.11 lb ai/A/application and was used for the collection of grain and straw. Two addition plots were also established at two sites for exaggerated application rates at 0.33 and 0.55 lb ai/A/application (3x and 5x rates) to produce grain for processing.

TABLE B.1.1. Trial Site Conditions.

Trial Identification (County, State; Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC[2] (meq/g)
Jackson AR 1997	Loamy Sand	0.65	5.0	2.35
Fresno, CA 1997	Sandy Loam	0.65	6.1	4.32
Weld, CO 1997	Sandy Clay Loam	1.14	8.1	13.23
Champaign, IL 1997	Clay Loam	3.35	5.8	8.3
Reno, KS 1997	Clay Loam	1.89	8.3	18.33
Finney, KS 1997	Loam	1.57	6.5	10.85
Pawnee, KS 1997	Loam	1.84	6.6	8.6
Polk, MN 1997	Silty Clay	5.68	7.7	35.94
Lafayette, MO 1997	Silt Loam	2.81	5.6	11.19
Fergus, MT 1997	Clay Loam	4.05	7.4	25.77
Judith Basin, MT 1997	Clay Loam	2.81	7.8	22.58
Hall, NE 1997	Silt Loam	3.57	6.8	15.5
Curry, NM 1997	Clay Loam	1.08	7.8	18.77
Sampson, NC 1997	Loamy Sand	0.86	4.6	6.15
Grand Forks, ND 1997	Silt Loam	5.73	6.2	26.83
McHenry, ND 1997	Loam	4.65	5.8	18.77
Payne, OK 1997	Loam	1.84	6.7	11.97
Caddo, OK 1997	Loamy Sand	0.54	4.7	2.99
Charles Mix, SD 1997	Clay Loam	4.43	7.5	22.24
Lubbock, TX 1997	Sandy Loam	0.65	8.0	6.66
Grant, WA 1997	Sandy Clay Loam	0.97	5.6	11.25

1 These parameters are optional except in cases where their value affects the use pattern for the chemical.
2 Cation exchange capacity.
NR = Not Reported

TABLE B.1.2. Study Use Pattern on Wheat.

Location (County, State; Year) Trial ID	End-use Product	Application Information [1]				
		Method; Timing	Volume (GPA)	Rate (lb ai/A)	RTI (days)	Total Rate (lb ai/A)
Fresno, CA 1997 02-FR-002-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	20	0.11	--	0.11
		One broadcast foliar application at FGS 10.5	20	0.11	--	0.11
		Two broadcast foliar applications at FGS10.1 and 10.5	20	0.11	14	0.22
Champaign, IL 1997 04-FR-001-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	20	0.11	--	0.11
		One broadcast foliar application at FGS 10.5	20	0.11	--	0.11
		Two broadcast foliar applications at FGS10 and 10.5	20	0.11	16	0.22
Jackson AR 1997 0S-FR-103-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	15	0.11	--	0.11
		One broadcast foliar application at FGS 10.5	15	0.11	--	0.11
		Two broadcast foliar applications at FGS10 and 10.5	15	0.11	13	0.22
Sampson, NC 1997 0S-FR-603-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	15	0.11	--	0.11
		One broadcast foliar application at FGS 10.5	15	0.11	--	0.11
		Two broadcast foliar applications at FGS 10.1 and 10.5	15	0.11	14	0.22
Payne, OK 1997 0S-FR-730-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	15	0.11	--	0.11
		One broadcast foliar application at FGS 10.5	15	0.11	--	0.11
		Two broadcast foliar applications at FGS 8-9 and 10.5	15	0.11	22	0.22

TABLE B.1.2. Study Use Pattern on Wheat.

Location (County, State; Year) Trial ID	End-use Product	Application Information [1]				
		Method; Timing	Volume (GPA)	Rate (lb ai/A)	RTI (days)	Total Rate (lb ai/A)
Caddo, OK 1997 0S-FR-731-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	20	0.11	--	0.11
		One broadcast foliar application at FGS 10.5	20	0.11	--	0.11
		Two broadcast foliar applications at FGS 9 and 10.5	19-20	0.11	16	0.22
				0.33		0.66
				0.55		1.10
Curry, NM 1997 0S-FR-733-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	16	0.11	--	0.11
		One broadcast foliar application at FGS 10	16	0.11	--	0.11
		Two broadcast foliar applications at FGS 10 and 14 days later	15-16	0.11	14	0.22
Lubbock, TX 1997 0S-FR-735-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	15	0.11	--	0.11
		One broadcast foliar application at FGS 10	16	0.11	--	0.11
		Two broadcast foliar applications at FGS 9 and 10	16	0.11	14	0.22
Fergus, MT 1997 0W-FR-204-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	16	0.11	--	0.11
		One broadcast foliar application at FGS 10.5	18	0.11	--	0.11
		Two broadcast foliar applications at FGS10.1 and 10.5	16-18	0.11	14	0.22
Judith Basin, MT 1997 0W-FR-205-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	16	0.11	--	0.11
		One broadcast foliar application at FGS 10.5	17	0.11	--	0.11
		Two broadcast foliar applications at FGS10 and 10.5	17-19	0.11	14	0.22
Grand Forks, ND 1997 0W-FR-219-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	25	0.11	--	0.11
		One broadcast foliar application at FGS 10.5	25	0.11	--	0.11
		Two broadcast foliar applications at FGS 5 and 10.5	25	0.11	17	0.22
Polk, MN 1997 0W-FR-220-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	25	0.11	--	0.11
		One broadcast foliar application at FGS 10.5	25	0.11	--	0.11
		Two broadcast foliar applications at FGS10 and 11	25	0.11	16	0.22
McHenry, ND 1997 0W-FR-221-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	15	0.11	--	0.11
		One broadcast foliar application at FGS 8	15	0.11	--	0.11
		Two broadcast foliar applications at FGS 8 and 10.5	15	0.11	15	0.22
Charles Mix, SD 1997 0W-FR-222-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5-6	19	0.11	--	0.11
		One broadcast foliar application at FGS 10.5	21	0.11	--	0.11
		Two broadcast foliar applications at FGS 8-9 and 10.5	19-21	0.11	15	0.22
Grant, WA 1997 0W-FR-625-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	18	0.11	--	0.11
		One broadcast foliar application at FGS 10.5	18	0.11	--	0.11
		Two broadcast foliar applications at leaf boot and FGS10.5	18	0.11	16	0.22
Lafayette, MO 1997 MW-FR-201-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	20	0.11	--	0.11
		One broadcast foliar application at FGS 10.5	20	0.11	--	0.11
		Two broadcast foliar applications at FGS 8-9 and 10.3-10.5	20	0.11	19	0.22
Reno, KS 1997 MW-FR-308-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	16	0.11	--	0.11
		One broadcast foliar application at FGS 10.5	16	0.11	--	0.11
		Two broadcast foliar applications at FGS 9 and 10.5	16	0.11	16	0.22

TABLE B.1.2. Study Use Pattern on Wheat.

Location (County, State; Year) Trial ID	End-use Product	Application Information [1]				
		Method; Timing	Volume (GPA)	Rate (lb ai/A)	RTI (days)	Total Rate (lb ai/A)
Finney, KS 1997 MW-FR-309-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	18	0.11	--	0.11
		One broadcast foliar application at FGS 10.5	20	0.12	--	0.12
		Two broadcast foliar applications at FGS 10.2 and 10.5	20	0.11-0.12	13	0.23
				0.33-0.37		0.70
				0.55-0.62		1.17
Pawnee, KS 1997 MW-FR-310-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	10.5	0.11	--	0.11
		One broadcast foliar application at FGS 10.5	10.5	0.11	--	0.11
		Two broadcast foliar applications at FGS 10.5	10.5	0.11	14	0.22
Weld, CO 1997 MW-FR-311-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	15	0.11	--	0.11
		One broadcast foliar application at FGS 10.5	15	0.11	--	0.11
		Two broadcast foliar applications at FGS 10 and 10.5	15	0.11	16	0.22
Hall, NE 1997 MW-FR-621-97	3.6 lb/gal EC	One broadcast foliar application at FGS 5	20	0.11	--	0.11
		One broadcast foliar application at FGS 10	20	0.11	--	0.11
		Two broadcast foliar applications at FGS 10 and 10.5	20	0.11	14	0.22

[1] All applications were made using ground equipment, and no adjuvants were included in the spray mixtures.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones[1]	Wheat Forage		
	Submitted	Requested	
		Canada	U.S.
1	---	---	--
2	1	---	1
3	---	---	--
4	1	---	1
5	6	---	5
6	1	---	1
7	4	---	5
8	6	---	6
9	---	---	--
10	1	---	--
11	1	---	1
12	---	---	--
Total	21	NA	20

[1] Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the use is for only in the U.S.
NA = Not applicable

B.2. Sample Handling and Preparation

Single control and duplicate treated samples (weight unspecified) of wheat forage and hay were collected from the plots treated with a single foliar application at FGS 5. Forage samples were harvested at 29-32 DAT, and hay samples harvested at 43-50 DAT with most hay samples being cut at 45 DAT. Forage samples were frozen immediately after collection, but hay samples were allowed to dry under ambient conditions of 1-22 days prior to collection. Single control and duplicate treated samples (weight unspecified) of mature wheat grain and straw were collected at 27-50 DAT from the plots treated with one or two foliar applications around FGS 10-10.5, with most samples being collected around ~40 DAT. Repeated control and treated samples were also collected at two sites to examine residue decline. In these trials, forage was sampled at 0, 15/16, 22/23, 29/30 and 35/37 DAT; hay was sampled at 29/31, 35/38, 43/45 and 52/59 DAT; and straw and grain were sampled at 21, 28, 63 and 73 DAT or 34, 38, 44, and 51 DAT.

After collection, all samples were placed in frozen storage (temperature unspecified) at the field sites and later shipped by freezer truck to Novartis Crop Protection (Greensboro, NC), where samples were stored at -20EC until preparation for analysis. For analysis, samples of forage and hay were shipped frozen to EPL Bio-Analytical Services (Harristown, IL) and samples of grain and straw were shipped frozen to ABC Laboratories (Columbia, MO). Samples were stored at -20°C at the analytical laboratories until analysis.

B.3. Analytical Methodology

All samples were analyzed for both total combined propiconazole residues and for residues of propiconazole, *per se*.

At both analytical laboratories, samples were analyzed for total combined residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-454B), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, residues are extracted and base hydrolyzed by refluxing for 1 hour with NH_4OH/MeOH (20:80, v/v) and filtered. Residues are concentrated and oxidized to 2,4-DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, sodium meta-bisulfite is added to deactivate the $KMnO_4$, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using diazomethane. Residues are then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and analyzed by GC/ECD, using external standards. The validated method LOQ is 0.05 ppm for residues in/on wheat forage, hay, grain and straw, and a LOD was not reported.

Method AG-454B was validated in conjunction with the analysis of field trial samples using control samples fortified with propiconazole at 0.05-0.5 ppm for grain, 0.05-5.0 ppm for hay, and 0.05-10.0 ppm for forage and straw.

To determine residues of only parent both laboratories used a multiresidue method from PAM Vol. I, Section 302, Methods E4 and DG5, which is a GC/NPD method. For analysis of grain and straw samples, ABC Laboratories used the method as described below. For analysis of forage and hay samples, EPL modified the method by deleting the Florisil column clean-up step.

For this method, residues of propiconazole are extracted with water:acetone (35:65, v/v), filtered, and partitioned into dichloromethane:petroleum ether (1:1, v/v). Residues are then filtered through sodium sulfate, concentrated to dryness, redissolved in petroleum ether, and cleaned up using a Florisil column eluted with ethyl ether:petroleum ether (1:1, v/v). Residues are then concentrated to dryness, redissolved in acetone and analyzed by GC/NPD using external standards. The validated method LOQ is 0.05 ppm for residues in/on wheat forage, hay, grain and straw, and a LOD was not reported.

The above GC/NPD method was validated in conjunction with the analysis of field trial samples using control samples fortified with propiconazole at 0.05-1.0 ppm for grain, 0.05-5.0 ppm for hay, and 0.05-10.0 ppm for forage and straw.

Summary tables of the residue data for both "total combined residues" and "parent residues" were corrected by the registrant for procedural recoveries of <100%; however, spreadsheets including the uncorrected residue values were available in the raw data and were used by the reviewer to report residue values.

C. RESULTS AND DISCUSSION

A total of 21 field trials were conducted on both winter and spring wheat throughout the U.S. during 1997, and propiconazole (3.6 lb/gal EC) was applied to at least three separate plots at each site. In two plots, propiconazole was applied as a single broadcast foliar application at 0.11-0.12 lb ai/A at either FGS 5 or FGS 10.5. The early-season application at FGS 5 was used for the collection of forage and hay, and the late-season application at FGS 10.5 was used for collection of grain and straw. In the third plot, propiconazole was applied as two late-season, broadcast foliar applications at FGS 10 and 10.5, at 0.11-0.12 lb ai/A/application, for totals of 0.22-0.23 lb ai/A. This plot was also used for the collection of grain and straw samples. Two addition plots were also established at two sites using two late-season applications at exaggerated rates at 0.33 and 0.55 lb ai/A/application (3x and 5x rates), for totals of 0.66 and 1.1 lb ai/A. All applications were made using ground equipment at spray volumes of 11-25 gal/A, and no adjuvants were included in the tank mixtures. For the plots that received two applications, the RTI was 13-22 days, with most tests having a RTI of 14 days.

Single control and duplicate treated samples of wheat forage were harvested at 29-32 DAT, and hay samples were cut at 43-50 DAT, with most hay samples being cut at 45 DAT. Single control and duplicate treated samples of mature wheat grain and straw were harvested at 27-50 DAT, with most samples being collected around 40 DAT. To examine residue decline, repeated control and treated samples were also collected at two sites from 0-37 DAT for forage, 29-59 DAT for hay, and 21-73 DAT for grain and straw.

The GC/ECD method (Method AG-454 B) used to determine propiconazole residues in/on wheat forage, hay, straw and grain was adequately validated in conjunction with the analysis of field trial samples. The recovery of propiconazole averaged 88 ±12% from forage, 85 ± 10% from hay, 87 ± 12% from straw and 90 ± 16% from grain (Table C.1). Apparent total combined residues were < LOQ in/on all but three control samples of straw (0.06-0.13 ppm) and one control sample of hay (0.06 ppm). As any apparent residues in control samples were substantially below residues in treated samples, residues in the controls had no adverse impact on the residue data. The validated method LOQ is 0.05 ppm for total combined residues, expressed as propiconazole, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided.

The GC/NPD method from PAM Vol. I was also adequately validated in conjunction with the analysis of field trial samples. The recovery of propiconazole averaged 100 ± 6% from forage, 94 ± 10% from hay, 101 ± 14% from straw, and 99 ± 16% from grain (Table C.1). Apparent residues of propiconazole were <LOQ in/on all control samples of forage, hay, grain and straw. The validated method LOQ is 0.05 ppm for residues of propiconazole, *per se*, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided.

For both total combined residues and parent residues, the study authors corrected residues values for concurrent recoveries of <100%; however, the uncorrected residues values were used and reported in this review.

TABLE C.1. Summary of Concurrent Method Recoveries of Propiconazole from Wheat Using GC/ECD Method for Determining "Total Residues" and GC/NPD Method for Determining "Parent" Residues.

Analyte	Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean std dev (%)
GC/ECD Method (AG-454B)					
Propiconazole	Forage	0.05-10.0	29	69-116 (1) [1]	88 ± 12
	Hay	0.05-5.0	27	71-104	85 ± 10
	Straw	0.05-10.0	45	62-108 (2)	87 ± 12
	Grain	0.05-0.50	48	65-124 (4)	90 ± 16
GC/NPD Method (PAM Vol. I, Section 302, E4 + DG5)					
Propiconazole	Forage	0.05-10.0	29	87-117	100 ± 6
	Hay	0.05-5.0	27	67-122 (2)	94 ± 10
	Straw	0.05-10.0	44	51-130 (4)	101 ± 14
	Grain	0.05-1.0	47	74-132 (5)	99 ± 16

[1] The number of recoveries outside the 70-120% range is listed in parentheses. Recoveries outside of 70-120% ranges were not associated with a particular fortification level.

Wheat forage, hay, straw and grain samples were stored frozen for up to 11.7 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating that the residues of propiconazole and its metabolites are stable at -20° C for up to 38 months in grass forage, straw and seed (DP Barcode D279300, Y. Donovan, 8/18/05). As these matrices are similar to wheat matrices, these data will support the storage intervals and conditions for the wheat field trials. Although several extracts were stored for >30 days prior to analysis, data are also available from corn forage and soybeans indicating that residues are stable in extracts at 4°C for at least 3 months.

TABLE C.2 Summary of Storage Conditions for Wheat Matrices.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1] (months)	Interval of Demonstrated Storage Stability (days)[2]
Analysis of Total Propiconazole Residues			
Forage	-20	7.0-11.7	36
Hay		6.4-10.3	
Straw		4.5-10.0	
Grain		4.3-10.8	
Analysis of Parent Residues			
Forage	-20	11.5-16.3	36
Hay		10.9-15.2	
Straw		4.8-11.2	
Grain		4.8-10.0	

[1] From harvest to extraction for analysis. Samples were analyzed for "total" residues within 1-12 days of extraction. For analysis of parent residues, extracts were generally analyzed within 0-22 days of extraction, with the exception of selected straw extracts which were analyzed from 38-46 days after extraction.

[2] DP Barcode D279300, Y. Donovan, 8/18/05.

Following a single broadcast application of propiconazole (EC) to wheat at FGS 5 at 0.11 lb ai/A, total combined residues were <0.05-1.91 ppm in/on forage harvested at 29-32 DAT and <0.05-1.10 ppm in/on hay cut at 43-50 DAT (Table C.3). Average residues were 0.33 and 0.30 ppm in/on forage and hay, respectively (Table C.4.1). Residues of parent propiconazole were <0.05-0.49 ppm in/on forage and <0.05-0.20 ppm in/on hay, and averaged 0.06 and 0.04 ppm, respectively. In both forage and hay, residues levels of parent were approximately 0.2x the residue levels of total combined residues.

Following a single broadcast application at 0.11 lb ai/A at approximately FGS 10.5, total combined residues were 0.41-6.21 ppm in/on straw and <0.05-0.13 ppm in/on grain harvested at maturity, 27-57 DAT, and combined residues averaged 2.02 and 0.04 ppm in/on straw and grain, respectively. Residues of parent propiconazole were <0.05-1.63 ppm in/on straw and <0.05 ppm in/on grain, and averaged 0.45 and 0.025 ppm, respectively. As with forage and hay, residues levels of parent in straw were approximately 0.2x the residue levels of total combined residues. A comparison of parent and combined residues was not meaningful for grain as most samples of grain had residues levels <LOQ for both parent and combined residues.

Compared to the single late season application, total combined residues and residues of parent were higher in/on wheat straw and grain following two late season applications. Following two broadcast applications at FGS 10 and 10.5 totaling 0.22 lb ai/A, total combined residues were 0.20-8.27 ppm in/on straw and <0.05-0.20 ppm in/on grain harvested at 27-57 DAT. Combined residues averaged 3.31 and 0.07 ppm in/on straw and grain, respectively. Residues of parent were <0.05-3.49 ppm in/on straw and <0.05 ppm in/on grain, and averaged 0.73 and 0.025 ppm, respectively. Residues levels of parent in straw were approximately 0.2x the residue levels of total combined residues.

In the two residue decline trials, total combined residues in/on forage declined rapidly from an average of 6.7 ppm at 0 DAT to 1.26 ppm by ~15 DAT (Table 4.2 and Figure C.1), and combined residues declined more slowly thereafter to an average of 0.32 ppm by ~36 DAT. A similar pattern of decline was observed for residues of parent in forage, with parent residues declining from 7.6 ppm at 0 DAT to 0.05 ppm by ~36 DAT. In hay, levels of both total combined residues and parent residues showed the same gradual decline at longer post-treatment intervals (Figure C.2).

As the harvest intervals for grain and straw were considerably different between the two residue decline trails, trends in average residues from the two studies could not be determined. However, the data from the two application rates in both trails indicate that there is a general decline in both total combined residues and parent residues in straw at longer post-treatment intervals (Figure C.3), although the decline in parent residues is slight. Similarly, total combined residues decreased in grain overtime; however, the low levels of parent residues in grain (<LOQ) precluded any examination of decline in parent residues.

In the two field trials that included exaggerated application rates at 0.66 and 1.1 lb ai/A (3x and 5x rates), total combined residues in/on straw harvested at 36 or 47 DAT were 3.11-5.20 ppm for the 3x rate and 4.79-14.7 ppm for the 5x rate, and parent residues were 0.30-0.38 ppm for the 3x rate and 0.66-1.64 ppm for the 5x rate. For grain harvested at 36 or 47 DAT, total combined residues were 0.08-0.15 ppm for the 3x rate and 0.12-0.23 ppm for the 5x rate, and parent residues were <0.05 ppm for both the 3x and 5x rates.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data

TABLE C.3. Residue Data on Wheat from Field Trials with Propiconazole (3 lb/gal EC).

Trial ID (County. State; Year)	Zone	Wheat Type/ Variety	Total Rate (lb ai/A)	Commodity	PHI (days)	Total Combined Residues (ppm) [1]	Propiconazole Residues (ppm) [1]
Fresno, CA 1997 02-FR-002-97	10	Winter/ Yecora Rojo	0.11	Forage	0	6.23, 4.76	6.94, 3.91
					16	1.40, 0.90	0.81, 0.59
					23	0.77, 0.67	0.15, 0.12
					30	0.48, 0.55	0.09, 0.14
					37	0.57, 0.44	0.08, 0.07
				Hay	31	1.08, 0.76	0.22, 0.15
					38	1.02, 1.02	0.10, 0.09
					45	0.50, 0.37	0.06, <0.05
					52	0.46, 0.24	<0.05, <0.05
			0.11	Straw	21	5.98, 4.15	0.92, 0.68
					28	3.88, 3.52	0.72, 0.51
					63	2.24, 2.87	0.40, 0.55
					70	4.94, 3.85	0.66, 0.48
				Grain	21	0.07, 0.08	<0.05, <0.05
					28	0.05, 0.06	<0.05, <0.05
					63	<0.05, <0.05	<0.05, <0.05
					70	0.05, 0.05	<0.05, <0.05
			0.22	Straw	21	8.50, 8.11	0.96, 1.09
					28	7.49, 7.49	1.06, 1.13
					63	6.08, 5.00	0.60, 0.35
					70	5.44, 4.67	0.40, 0.47
				Grain	21	0.09, 0.05	0.08, 0.08
					28	0.06, <0.05	<0.05, 0.05
					63	<0.05, 0.05	<0.05, <0.05
					70	0.05, <0.05	<0.05, <0.05
Champaign, IL 1997 04-FR-001-97	5	Winter/ Arapahoe	0.11	Forage	29	0.19, 0.25	<0.05, <0.05
				Hay	44	0.26, 0.27	<0.05, <0.05
			0.11	Straw	40	1.33, 1.13	<0.05, <0.05
				Grain	40	0.05, <0.05	<0.05, <0.05
			0.22	Straw	40	3.23, 1.79	0.11, 0.05
				Grain	40	<0.05, 0.05	<0.05, <0.05
Jackson AR 1997 0S-FR-103-97	4	Winter/ Agritech 91	0.11	Forage	30	0.13, 0.17	<0.05, <0.05
				Hay	44	0.11, 0.14	<0.05, <0.05
			0.11	Straw	43	1.91, 2.07	0.54, 0.53
				Grain	43	0.06, 0.06	<0.05, <0.05
			0.22	Straw	43	3.02, 3.03	0.44, 0.68
				Grain	43	0.07, 0.06	<0.05, <0.05
Sampson, NC 1997 0S-FR-603-97	2	Winter/ Coker 9835	0.11	Forage	30	0.55, 0.44	0.09, 0.12
				Hay	45	0.38, 0.55	0.05, 0.09
			0.11	Straw	34	2.17, 1.66	1.32, 1.05
				Grain	34	0.09, 0.09	<0.05, <0.05
			0.22	Straw	34	8.27 [2], 5.59 [2]	2.18, 1.92
				Grain	34	0.16, 0.20	<0.05, <0.05

TABLE C.3. Residue Data on Wheat from Field Trials with Propiconazole (3 lb/gal EC).

Trial ID (County, State; Year)	Zone	Wheat Type/ Variety	Total Rate (lb ai/A)	Commodity	PHI (days)	Total Combined Residues (ppm) [1]	Propiconazole Residues (ppm) [1]
Payne, OK 1997 0S-FR-730-97	6	Winter/ Karl 92	0.11	Forage	0	8.44, 7.41	9.44, 10.1
					15	1.47, 1.27	0.77, 0.79
					22	0.64, 0.49	0.19, 0.16
					29	0.27, 0.21	0.05, <0.05
					35	0.12, 0.13	<0.05, <0.05
				Hay	29	0.16, 0.17	<0.05, <0.05
					35	0.18, 0.21	<0.05, <0.05
					43	0.22, 0.22	<0.05, <0.05
					59	0.19, 0.24	<0.05, <0.05
			0.11	Straw	34	0.74, 0.97	0.19, 0.25
					38	1.24, 1.18	0.23, 0.19
					44	0.65, 0.58	0.19, 0.17
					51	0.76, 0.68	0.22, 0.16
				Grain	34	0.13 [2], 0.11 [2]	<0.05, <0.05
					38	0.10, 0.07	<0.05, <0.05
					44	<0.05, 0.05	<0.05, <0.05
					51	<0.05, 0.05	<0.05, <0.05
			0.22	Straw	34	1.19, 1.35	0.09, 0.13
					38	2.4, 2.29	0.19, 0.16
					44	0.81, 1.05	<0.05, <0.05
					51	1.51, 1.62	<0.05, <0.05
				Grain	34	0.09, 0.08	<0.05, <0.05
					38	0.20, 0.20	<0.05, <0.05
					44	0.12, 0.08	<0.05, <0.05
					51	0.11, 0.10	<0.05, <0.05
Caddo, OK 1997 0S-FR-731-97	8	Winter/ Karl	0.11	Forage	30	0.13, 0.13	<0.05, <0.05
				Hay	48	0.16, 0.16	<0.05, <0.05
			0.11	Straw	47	0.79, 1.30	0.09, 0.11
				Grain	47	0.09, <0.05	<0.05, <0.05
			0.22	Straw	47	1.02, 0.86	0.06, <0.05
				Grain	47	0.05, 0.05	<0.05, <0.05
			0.66 (3x) [3]	Straw	47	3.11	0.38
				Grain	47	0.15	<0.05
			1.1 (5x) [3]	Straw	47	4.79	0.66
				Grain	47	0.23	<0.05
Curry, NM 1997 0S-FR-733-97	8	Winter/ Tam 101	0.11	Forage	32	0.16, 0.12	<0.05, <0.05
				Hay	50	0.11, 0.11	<0.05, <0.05
			0.11	Straw	27	1.27, 1.16	0.17, 0.17
				Grain	27	<0.05, <0.05	<0.05, <0.05
			0.22	Straw	27	4.74, 5.16	0.72, 0.91
				Grain	27	0.13, 0.13	<0.05, <0.05
Lubbock, TX 1997 0S-FR-735-97	8	Winter/ Tam 105	0.11	Forage	30	0.26, 0.22	<0.05, <0.05
				Hay	45	0.47, 0.39	<0.05, <0.05
			0.11	Straw	32	1.70, 2.99	0.78, 0.72
				Grain	32	<0.05, <0.05	<0.05, <0.05
			0.22	Straw	32	5.66, 6.08	1.77, 2.63
				Grain	32	<0.05, <0.05	<0.05, <0.05

TABLE C.3. Residue Data on Wheat from Field Trials with Propiconazole (3 lb/gal EC).

Trial ID (County, State; Year)	Zone	Wheat Type/ Variety	Total Rate (lb ai/A)	Commodity	PHI (days)	Total Combined Residues (ppm) [1]	Propiconazole Residues (ppm) [1]
Fergus, MT 1997 0W-FR-204-97	7	Spring/ Rammel	0.11	Forage	30	0.07, 0.07	<0.05, <0.05
				Hay	45	0.05, 0.05	<0.05, <0.05
			0.11	Straw	36	3.76, 3.79	1.23, 1.51
				Grain	36	<0.05, <0.05	<0.05, <0.05
			0.22	Straw	36	5.38, 4.17	2.22, 1.64
				Grain	36	0.11, 0.07	<0.05, <0.05
Judith Basin, MT 1997 0W-FR-205-97	7	Spring/ Granden	0.11	Forage	30	0.14, 0.17	<0.05, <0.05
				Hay	45	0.41, 0.31	<0.05, <0.05
			0.11	Straw	43	3.22, 3.67	1.13, 1.56
				Grain	43	0.06, 0.05	<0.05, <0.05
			0.22	Straw	43	7.31, 6.63	2.93, 3.49
				Grain	43	0.12, 0.18	<0.05, <0.05
Grand Forks, ND 1997 0W-FR-219-97	5	Spring/ Russ 2375	0.11	Forage	30	0.20, 0.17	<0.05, <0.05
				Hay	45	0.12, 0.13	<0.05, <0.05
			0.11	Straw	57	0.41, 0.43	0.09, 0.10
				Grain	57	<0.05, <0.05	<0.05, <0.05
			0.22	Straw	57	0.20, 0.24	<0.05, <0.05
				Grain	57	<0.05, <0.05	<0.05, <0.05
Polk, MN 1997 0W-FR-220-97	5	Spring/ Grandin	0.11	Forage	30	0.63, 0.66	<0.05, <0.05
				Hay	45	0.75, 0.79	0.06, 0.06
			0.11	Straw	44	2.03, 2.77	0.21, 0.29
				Grain	44	<0.05, <0.05	<0.05, <0.05
			0.22	Straw	44	2.65, 2.46	0.15, 0.27
				Grain	44	<0.05, <0.05	<0.05, <0.05
McHenry, ND 1997 0W-FR-221-97	7	Spring/ AC Barrie	0.11	Forage	30	<0.05, <0.05	<0.05, <0.05
				Hay	45	0.07, 0.05	<0.05, <0.05
			0.11	Straw	40	1.83, 3.15	0.15, 0.32
				Grain	40	0.13[3], <0.05[3]	<0.05, <0.05
			0.22	Straw	40	2.45, 1.31	0.10, 0.05
				Grain	40	<0.05, 0.06	<0.05, <0.05
Charles Mix, SD 1997 0W-FR-222-97	7	Spring/ Russ	0.11	Forage	30	0.64, 0.59	0.05, 0.06
				Hay	45	0.30, 0.13	<0.05, <0.05
			0.11	Straw	31	4.43, 6.21	1.61, 1.63
				Grain	31	0.09, 0.05	<0.05, <0.05
			0.22	Straw	31	5.73, 3.57	1.63, 1.00
				Grain	31	0.05, 0.07	<0.05, <0.05
Grant, WA 1997 0W-FR-625-97	11	Winter/ Madsen	0.11	Forage	30	0.18, 0.14	<0.05, <0.05
				Hay	45	0.14, 0.15	<0.05, <0.05
			0.11	Straw	53	0.88, 1.35	0.06, 0.12
				Grain	53	<0.05, 0.05	<0.05, <0.05
			0.22	Straw	53	1.75, 1.34	0.10, 0.05
				Grain	53	<0.05, <0.05	<0.05, <0.05

TABLE C.3. Residue Data on Wheat from Field Trials with Propiconazole (3 lb/gal EC).

Trial ID (County, State, Year)	Zone	Wheat Type/ Variety	Total Rate (lb ai/A)	Commodity	PHI (days)	Total Combined Residues (ppm) [1]	Propiconazole Residues (ppm) [1]
Lafayette, MO 1997 MW-FR-201-97	5	Winter/ Coker	0.11	Forage	31	0.16, 0.24	<0.05, <0.05
				Hay	45	0.32, 0.40	<0.05, <0.05
			0.11	Straw	43	0.92, 0.62	<0.05, <0.05
				Grain	43	<0.05, <0.05	<0.05, <0.05
			0.22	Straw	43	1.14, 0.56	<0.05, <0.05
				Grain	43	<0.05, <0.05	<0.05, <0.05
Reno, KS 1997 MW-FR-308-97	5	Winter/ Karl 92	0.11	Forage	32	1.24, 1.91	0.23, 0.49
				Hay	45	0.98, 1.10	0.11, 0.20
			0.11	Straw	49	2 09, 1.25	0.39, 0.18
				Grain	49	<0.05, <0.05	<0.05, <0.05
			0.22	Straw	49	2.95, 2.37	0.50, 0.46
				Grain	49	0.06, <0.05	<0.05, <0.05
Finney, KS 1997 MW-FR-309-97	8	Winter/ Ogallala	0.11	Forage	30	0.20, 0.23	<0.05, <0.05
				Hay	45	0.12, 0.08	<0.05, <0.05
			0.12	Straw	36	0.94 [2], 2.57 [2]	0.05, 0.06
				Grain	36	0.05,<0.05	<0.05, <0.05
			0.23	Straw	36	2.34, 2.01	0.11, <0.05
				Grain	36	<0.05, <0.05	<0.05, <0.05
			0.70 (3x) [3]	Straw	36	5.22	0.30
				Grain	36	0.08	<0.05
			1.17 (5x) [3]	Straw	36	14.7	1.64
				Grain	36	0.12	<0.05
Pawnee, KS 1997 MW-FR-310-97	8	Winter/ Tam 107	0.11	Forage	30	0.58, 0.65	0.10, 0.12
				Hay	46	0.48, 0.49	0.05, 0.05
			0.11	Straw	35	1.23, 1.11	0.17, 0.17
				Grain	35	0.06, <0.05	<0.05, <0.05
			0.22	Straw	35	2.76, 3.36	0.60, 0.55
				Grain	35	0.10, 0.06	<0.05, <0.05
Weld, CO 1997 MW-FR-311-97	8	Winter/ Hawk	0.11	Forage	30	0.25, 0.20	<0.05, <0.05
				Hay	45	0.24, 0.26	<0.05, <0.05
			0.11	Straw	38	1.50, 0.99	0.13, 0.09
				Grain	38	<0.05, <0.05	<0.05, <0.05
			0.22	Straw	38	0.98, 1.57	0.13, 0.23
				Grain	38	<0.05, <0.05	<0.05, <0.05
Hall, NE 1997 MW-FR-621-97	5	Winter/ Karl 92	0.11	Forage	31	<0.05, 0.05	<0.05, <0.05
				Hay	45	<0.05, 0.05	<0.05, <0.05
			0.11	Straw	33	1.52, 2.73	0.07, 0.20
				Grain	33	<0.05, <0.05	<0.05, <0.05
			0.22	Straw	33	2.42, 3.04	0.17, 0.15
				Grain	33	<0.05, <0.05	<0.05, <0.05

1 Total propiconazole residues were determined as methyl-DCBA and expressed in parent equivalents using GC/ECD Method AG454B, and residues of propiconazole were determined using Method 302 E4 and DG5 from PAM Vol. 1. For both methods, the validated LOQ was 0.05 ppm for combined residues and propiconazole. A LOD was not reported. Reported values were obtained from the raw data and are not corrected procedural recoveries.

2 Residue values are the average of duplicate analyses.

3 At two test sites, exaggerated rate applications were made twice at 0.33 or 0.55 lb ai/A/application, which were reported to be 3x and 5x rates.

TABLE C.4.1. Summary of Residue Data from Wheat Field Trials with Propiconazole (EC).

Commodity	Total Applic. Rate (lb ai/A)	PHI (days) [1]	n	Min.	Max.	HAFT [2]	Median (STMdR) [3]	Mean (STMR) [3]	Std. Dev.
Total Combined Residues (ppm) [4]									
Forage	0.11	29-32	42	<0.05	1.91	1.58	0.20	0.33	0.35
Hay		43-50	42	<0.05	1.10	1.04	0.23	0.30	0.25
Straw	0.11-0.12	27-57	42	0.41	6.21	5.32	1.59	2.02	1.25
Grain		27-57	42	<0.05	0.13	0.09	0.03	0.04	0.03
Straw	0.22-0.23	27-57	42	0.20	8.27	7.49	2.71	3.31	2.17
Grain		27-57	42	<0.05	0.20	0.20	0.05	0.07	0.06
Propiconazole Residues (ppm) [4]									
Forage	0.11	29-32	42	<0.05	0.49	0.36	0.025	0.06	0.08
Hay		43-50	42	<0.05	0.20	0.16	0.025	0.04	0.03
Straw	0.11-0.12	27-57	42	<0.05	1.63	1.62	0.19	0.45	0.51
Grain		27-57	42	<0.05	0.03	0.025	0.025	0.025	0.00
Straw	0.22-0.23	27-57	42	<0.05	3.49	3.21	0.25	0.73	0.91
Grain		27-57	42	<0.05	<0.05	0.025	0.025	0.025	0.00

1 The majority of harvest intervals were around 30 days for forage, 45 days for hay and 40 days for grain and straw.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.
4 The Method LOQs are 0.05 ppm for both total combined residues and residue of propiconazole, *per se*. For calculation of the median, mean, and standard deviation, ½LOQ (0.025 ppm) was used for samples with residues <LOQ. Values are not corrected procedural recoveries.

TABLE C.4.2. Summary of Residue Decline Data of Forage and Hay from Wheat Field Trials with Propiconazole (EC).

Commodity	Total Rate (lb ai/A)	PHI (days)	n	Min.	Max.	HAFT [1]	Median (STMdR) [2]	Mean (STMR) [2]	Std. Dev.
Total Combined Residues (ppm) [3]									
Forage	0.11	0	4	4.76	8.44	7.93	6.82	6.71	1.58
		15-16	4	0.90	1.47	1.37	1.34	1.26	0.25
		22-23	4	0.49	0.77	0.72	0.66	0.64	0.12
		29-30	4	0.21	0.55	0.52	0.38	0.38	0.16
		35-37	4	0.12	0.57	0.51	0.29	0.32	0.23
Hay	0.11	29-31	4	0.16	1.08	0.92	0.47	0.54	0.46
		35-38	4	0.18	1.02	1.02	0.62	0.61	0.48
		43-45	4	0.22	0.50	0.44	0.30	0.33	0.14
		52-59	4	0.19	0.46	0.35	0.24	0.28	0.12
Propiconazole Residues (ppm)									
Forage	0.11	0	4	3.91	10.10	9.77	8.19	7.60	2.81
		15-16	4	0.59	0.81	0.78	0.78	0.74	0.10
		22-23	4	0.12	0.19	0.18	0.16	0.16	0.03
		29-30	4	<0.05	0.14	0.12	0.07	0.08	0.05
		35-37	4	<0.05	0.08	0.08	0.05	0.05	0.03
Hay	0.11	29-31	4	<0.05	0.22	0.19	0.09	0.11	0.10
		35-38	4	<0.05	0.10	0.10	0.06	0.06	0.04
		43-45	4	<0.05	0.06	0.04	0.025	0.025	0.02
		52-59	4	<0.05	<0.05	0.03	0.025	0.025	0.00

1 HAFT = Highest Average Field Trial.
2 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.
3 The Method LOQs are 0.05 ppm for both total combined residues and residue of propiconazole, *per se*. For calculation of the median, mean, and standard deviation, ½LOQ (0.025 ppm) was used for samples with residues <LOQ. Values are not corrected procedural recoveries.

Figure C.1. Average Residue Decline for Wheat Forage from Two Field Trials.

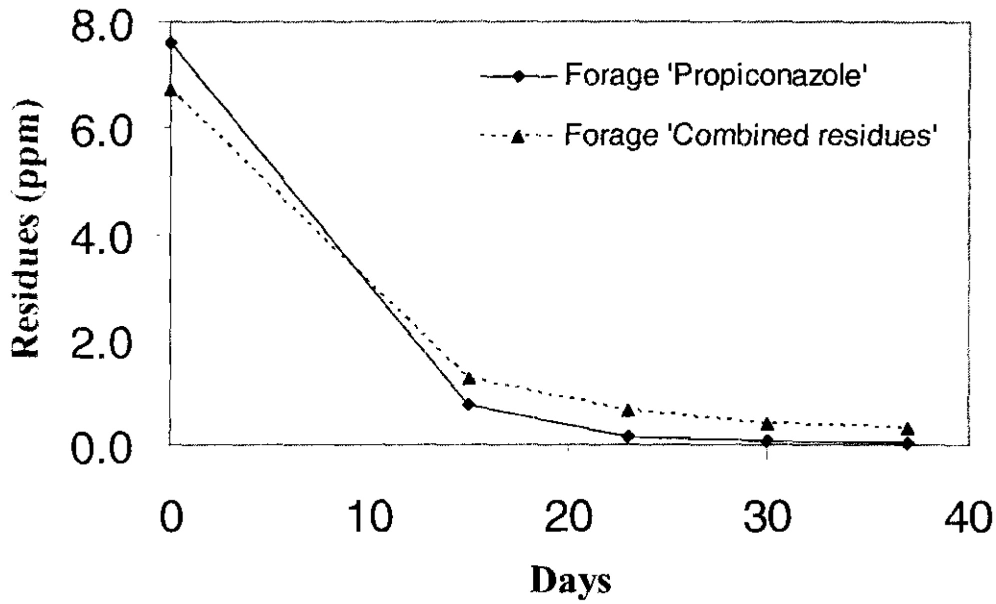


Figure C.2. Average Residue Decline for Wheat Hay from Two Field Trials.

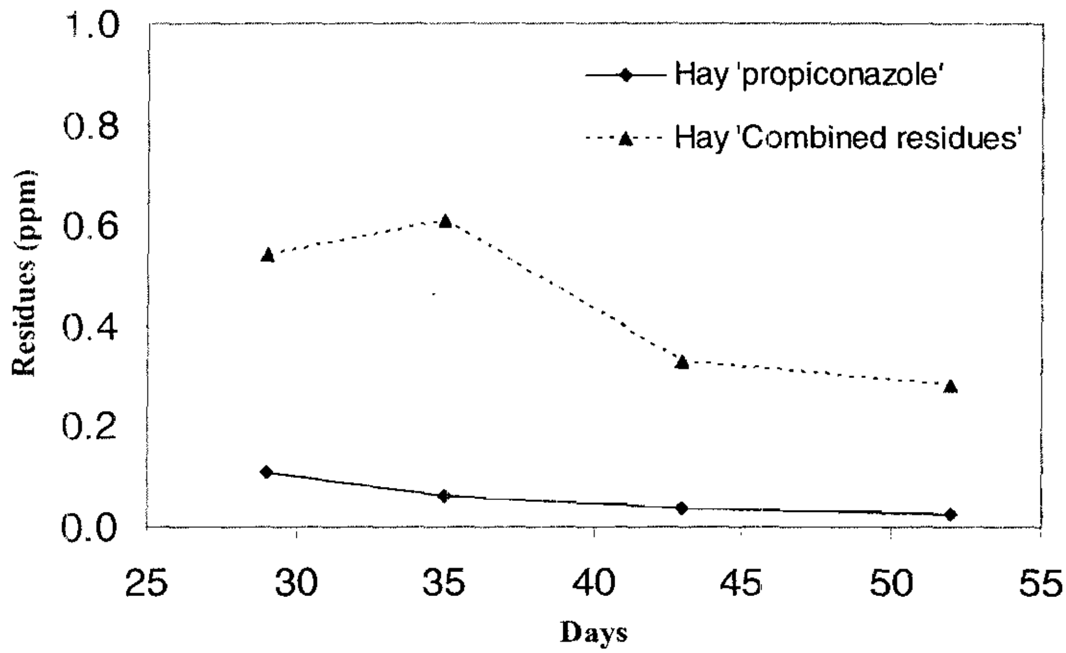
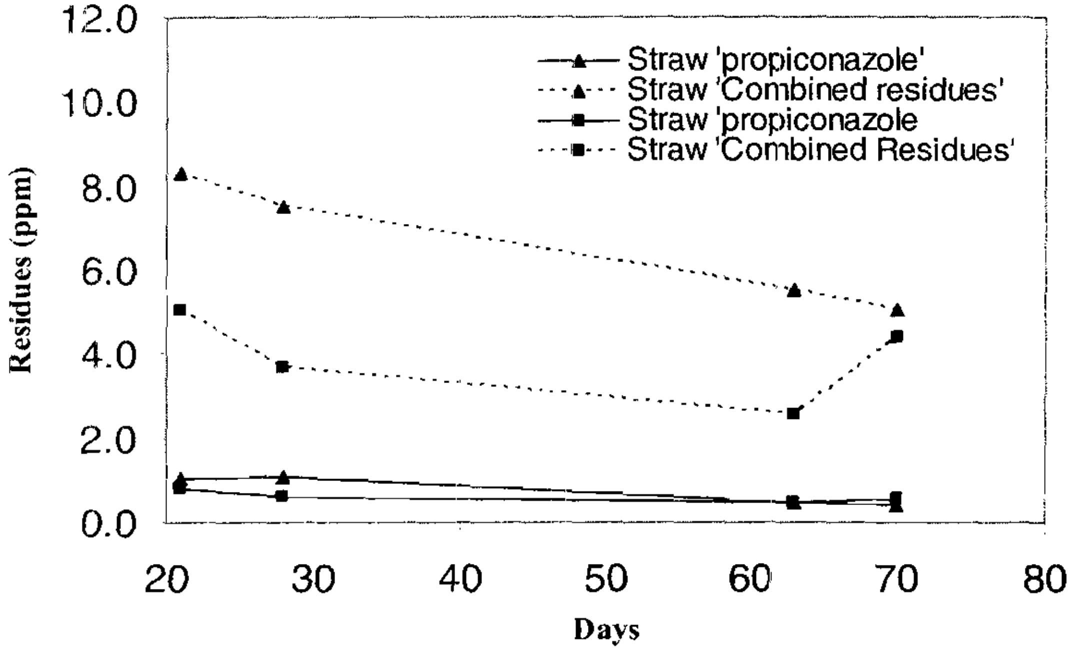


Figure C.3. Residue Decline Data from Two Field Tests on Wheat Straw Treated at 0.11 or 0.22 lb ai/A.



D. CONCLUSION

The wheat field trial data are adequate and support the use of propiconazole (EC) on wheat as either one or two broadcast foliar applications at 0.11 lb ai/A/application at up to FGS 10.5, for a total of 0.22 lb ai/A/season. However, any labels should allow only a single application prior to the harvest of forage or hay. The data support a minimum RTI of 14 days and PHIs of 30 days for forage, 45 days for hay, and 40 days for grain and straw.

E. REFERENCES

DP Barcode:	D279300
Subject:	Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From:	Y. Donovan
To:	S. Lewis/J. Guerry
Dated:	8/18/05
MRID:	None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 2F6371
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED Yan Donovan	Date: 06/30/06
Approved by	Susan Hummel, Senior Scientist, RRB4/HED	Date:06/31/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 6/12/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

44548402 Vincent, T. (1998) Propiconazole--Magnitude of the Residues in or on Wheat, Including Processed Fractions, Following an Application of TILT: Lab Project Number: 46-96: ABR-97143: 411124. Unpublished study prepared by Novartis Crop Protection, Inc. 189 p.

EXECUTIVE SUMMARY:

Two wheat field trials were conducted in ID and ND in 1996 to compare residues in/on wheat grain and straw resulting from a late-season application of propiconazole. At each site, propiconazole (3.6 lb/gal EC) was applied to 4 separate plots of wheat as a single broadcast foliar application at booting (Feekes Growth Stage 10) or at heading (Feekes Growth Stage 10.5) at 0.11-0.12 lb ai/A or 0.55-0.62 lb ai/A (1x and 5x rates). All applications were made using ground equipment in volumes of 15-21 gal/A, and did not include any adjuvants. Single control and single or duplicate treated samples of grain and straw were harvested 41 and 63-67 days following the application at booting and 30-31 and 55-57 days following the application at heading. Samples were stored up to 3.4 months prior to analysis, an interval supported by available storage stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on wheat grain and straw were determined using an adequate GC/ECD method (Method AG-454B). For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization with $KMnO_4$. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and cleaned-up using an acidic alumina cartridge. Methylated DBCA is determined by GC/ECD using external standards, and residues are expressed in parent equivalents. The validated method limit of quantitation (LOQ) is 0.05 ppm, and the limit of detection (LOD) is 0.02 ppm.

Following a single application at 0.11-0.12 lb ai/A (1x), total propiconazole residues in/on grain averaged 0.03 ppm at 41 and 63-67 days after an application at booting (FGS 10). For the application at heading (FGS 10.5), grain residues averaged 0.06 ppm at ~30 days after treatment (DAT) and declined to 0.03 ppm at 55-57 DAT. For straw, average residues following the application at booting were 1.1 ppm at 41 DAT and 0.56 ppm at 63-67 DAT, and average

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residues following the application at heading were 1.6 ppm at ~30 DAT and 0.95 ppm at 55-57 DAT.

Following a single application at 0.55-0.62 lb ai/A (5x) at booting, average residues in/on grain were 0.07 ppm at 41 DAT and 0.03 ppm at 63-67 DAT and average residues in/on straw were 6.1 ppm at 41 DAT and 4.1 ppm at 63-67 DAT. Following the application 5x application at heading, average residues in/on grain were 0.30 ppm at ~30 DAT and 0.18 ppm at 55-57 DAT and average residues in/on straw were 7.8 ppm at ~30 DAT and 5.0 ppm at 55-57 DAT.

The tests conducted at both use rates indicate that propiconazole residues in/on wheat grain and straw are higher following an application at the heading stage then at the booting stage. The tests also indicate that residues in both grain and straw decline at longer post-treatment intervals.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the wheat field trial data are classified as scientifically acceptable for purposes of comparing residues resulting from a late season application to wheat at either booting or heading (FGS 10 or 10.5). The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited minor deviations from GLP compliance, pertaining to the collection of weather data, tank mix storage stability data and maintenance of records. None of these deviations affect the overall acceptability of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities, including permanent tolerances of 0.1 and 1.5 ppm on wheat grain and straw [40 CFR §180.434(a)].

Syngenta has submitted at petition (PP#2F6371) proposing tolerances and the use of propiconazole on a variety of cereal grains, including wheat. The current submission includes residue data from two wheat field trials comparing residues in/on grain and straw resulting from a late season application of propiconazole (EC) at either booting or heading. Propiconazole was applied at 1x and 5x rates to also generate grain samples for processing studies (44548402.der2, under review).

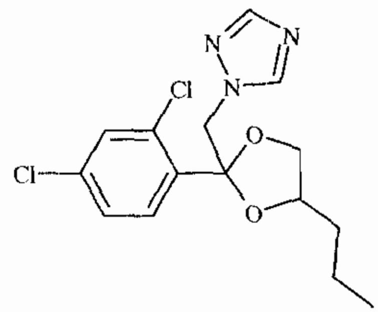
TABLE A.1. Nomenclature of Propiconazole	
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EPs	3.6 lb/gal EC (Tilt 3.6E Fungicide, EPA Reg. No. 100-617)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.		
Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK$_a$)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K$_{OW}$)	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Wheat was grown and maintained at each test site using typical agricultural practices for the two regions (Table B.1.1). Monthly rainfall and irrigation data were provided for each site, along with temperature data. No usual weather conditions were noted that would have an adverse effect on the field trial data. Information was provided on soil characteristics at each site, along with the maintenance chemicals and other pesticides used.

A total of four treated plots were established at each test site (Table B.1.2). At both sites, propiconazole (3.6 lb/gal EC) was applied to wheat as a single broadcast foliar application at either booting (FGS 10) or heading (FGS 10.5) at target rates of 0.11 lb ai/A (1x) and 0.55 lb ai/A (5x).

TABLE B.1.1. Trial Site Conditions.				
Trial Identification (County, State; Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC[2] (meq/g)
Latah, ID 1996	Silt Loam	4.4	5.8	17.10
Foster, ND 1996	Loam	4.3	7.5	15.88

[1] These parameters are optional except in cases where their value affects the use pattern for the chemical.
[2] Cation exchange capacity.

TABLE B.1.2. Study Use Pattern on Wheat.

Location (County, State; Year) Trial ID	End-use Product	Application Information [1]				
		Method; Timing	Volume (GPA)	Rate (lb ai/A)	RTI (days)	Total Rate (lb ai/A)
Latah, ID 1996 0W-FR-672-96	3.6 lb/gal EC	Single broadcast foliar application at Feekes Growth Stage 10 (boot stage)	21	0.12	NA	0.12
			21	0.62	NA	0.62
		Single broadcast foliar application at Feekes Growth Stage 10.5 (heading)	21	0.12	NA	0.12
			21	0.62	NA	0.62
Foster, ND 1996 MW-FR-515-96	3.6 lb/gal EC	Single broadcast foliar application at Feekes Growth Stage 10 (boot stage)	15	0.11	NA	0.11
			15	0.55	NA	0.55
		Single broadcast foliar application at Feekes Growth Stage 10.5 (heading)	15	0.11	NA	0.11
			15	0.55	NA	0.55

[1] All applications were made using ground equipment, and no adjuvants were included in the spray mix.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones[1]	Wheat		
	Submitted	Requested	
		Canada	U.S.
1	---	---	---
2	---	---	1
3	---	---	---
4	---	---	1
5	1	---	5
6	---	---	1
7	---	---	5
8	---	---	6
9	---	---	---
10	---	---	---
11	1	---	1
12	---	---	---
Total	2	NA	20

[1] Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the use is for only in the U.S.
NA = Not applicable

B.2. Sample Handling and Preparation

Single control samples and either single (5x rate) or duplicate (1x rate) treated samples of wheat grain and straw (weights unspecified) were collected from each test at two intervals. Following the application at booting (FGS 10), samples were collected at 41 DAT and 63-67 DAT. Following the application at heading (FGS 10.5), samples were collected at 30-31 DAT and 55-57 DAT. Grain and straw samples were frozen shortly after harvest and shipped by on dry ice by overnight courier to Novartis Crop Protection (Greensboro, NC), where samples were prepared (homogenized) and stored at -20°C. Samples were later shipped frozen to the analytical laboratory, ABC Laboratories (Columbia, MO), where samples were stored at -20°C until analysis.

B.3. Analytical Methodology

Samples were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-454B), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, propiconazole residues are extracted by refluxing for 1 hour in NH_4OH/methanol (20:80, v/v), and filtered. Residues are concentrated and oxidized to DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, the $KMnO_4$ is deactivated by the addition of sodium meta-bisulfite, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using diazomethane. Residues are then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and analyzed by GC/ECD using external standards. The validated method LOQ is 0.05 ppm, and the LOD is 0.02 ppm.

Summary tables of the residue data were corrected by the registrant for procedural recoveries of <100%; however, spreadsheets including the uncorrected residue values were available in the raw data and were used by the reviewer to report residue values.

In conjunction with the analysis of field trial samples, the above method was validated using control samples fortified with propiconazole at 0.05-10.0 ppm for straw and at 0.05-20 ppm for grain.

C. RESULTS AND DISCUSSION

In two wheat field trials conducted in ID and ND in 1996, propiconazole (3.6 lb/gal) was applied to 4 separate plots of wheat as a single broadcast foliar application at booting (FGS 10) or heading (FGS 10.5) at 0.11-0.12 lb ai/A or 0.55-0.62 lb ai/A (1x and 5x rates). All applications were made use ground equipment in volumes of 15-21 gal/A, and did not include the use of any adjuvants. Single control and single or duplicate treated samples of grain and straw were harvested at 41 and 63-67 DAT following the application at booting and at 30-31 and 55-57 DAT following the application at heading.

The GC/ECD method (Method AG-454B) used to determine propiconazole residues in/on grain and straw was adequately validated in conjunction with the analysis of field trial samples. The recovery of propiconazole averaged 85± 15% from grain and 80 ± 9% from straw (Table C.1). Apparent residues of propiconazole were <LOQ on all control samples of grain and straw. The validated method LOQ for propiconazole is 0.05 ppm, and the LOD is 0.02 ppm. Adequate sample calculations and example chromatograms were provided. Although the study author reported residue values corrected for concurrent recoveries of <100%, uncorrected residues values are used and reported in this review.

Grain and straw samples were stored frozen for up to 3.7 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating that the residues of propiconazole and its metabolites are stable at -20° C for up to 39 months in grass forage, straw and seed (DP Barcode D279300, Y. Donovan, 8/18/05). As these matrices are similar to wheat grain and straw, these data will support the storage intervals and conditions for the wheat field trials.

Following a single application at booting at the 1x rate, total residues in/on grain were <0.05 ppm at both sampling intervals, and residues in/on straw were 0.95-1.3 ppm at 41 DAT and 0.31-0.91 ppm at 63-67 DAT (Table C.3). Following an application at heading at the 1x rate, total residues in/on grain were <0.05-0.10 ppm at ~30 DAT and decreased to <0.05 ppm by 55-57 DAT, and residues in/on straw were 1.2-2.2 ppm at ~30 DAT and decreased to 0.75-1.2 ppm by 55-57 DAT. For the 1x applications, average residues in/on grain were 0.03 ppm at 41-67 days after the application at booting and 0.03-0.06 ppm at 30-57 days after the application at heading (Table C.4). Average residues in/on straw following the application at booting were 1.1 ppm at 41 DAT and 0.56 ppm at 63-67 DAT, and average residues in/on straw following the application at heading were 1.6 ppm at 30-31 DAT and 0.95 ppm at 55-57 DAT.

Although residues in/on grain and straw following the 5x application were higher than from the 1x rate, the same trends were observed with regards to residues levels resulting from booting vs. heading applications and for residues at longer post-treatment intervals. Following the application at booting, average residues in/on grain were 0.07 ppm at 41 DAT and 0.03 ppm at 63-67 DAT and average residues in/on straw were 6.1 ppm at 41 DAT and 4.1 ppm at 63-67 DAT. Following the application at heading, average residues in/on grain were 0.30 ppm at ~30 DAT and 0.18 ppm at 55-57 DAT and average residues in/on straw were 7.8 ppm at ~30 DAT and 5.0 ppm at 55-57 DAT.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data

TABLE C.1. Summary of Concurrent Recoveries of Propiconazole from Wheat Straw and Grain.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Grain	0.05	5	101, 75, 73, 61, 77	85 ± 15
	0.10	4	72, 107, 79, 88	
	0.50	2	105, 95	
	20.0	1	86	
Straw	0.05	1	83	80 ± 9
	0.10	5	82, 85, 74, 68, 66	
	0.50	1	93	
	10.0	1	85	

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration [1] (months)	Interval of Demonstrated Storage Stability (months) [2]
Grain and straw	-20	1.2-3.4	39

1 From harvest to extraction for analysis. Samples were analyzed within 1-10 days of extraction.
2 DP Barcode D279300, Y. Donovan, 8/18/05.

TABLE C.3. Residue Data on Wheat Grain and Straw following a Late Season Applications of Propiconazole (EC) at Booting or Heading.

Trial ID (County, State; Year)	Zone	Wheat Variety	Application Timing	Total Rate (lb ai/A) [1]	PHI (days)	Commodity	Total Propiconazole Residues (ppm) [2]
Latah, ID 1996 0W-FR-672-96	11	Walkanz	Feekes Growth stage 10 (booting)	0.12	41	Grain	ND, ND
						Straw	1.3, 0.95
					67	Grain	ND, ND
						Straw	0.91, 0.70
				0.62	41	Grain	0.08
						Straw	7.3
					67	Grain	ND
						Straw	6.8
			Feekes Growth Stage 10.5 (heading)	0.12	31	Grain	(0.05, 0.04) [3]
						Straw	1.2, 1.4
					57	Grain	(0.04, 0.04)
						Straw	1.2, 0.98
				0.62	31	Grain	0.18
						Straw	6.6
					57	Grain	0.30
						Straw	6.5

TABLE C.3. Residue Data on Wheat Grain and Straw following a Late Season Applications of Propiconazole (EC) at Booting or Heading.

Trial ID (County, State; Year)	Zone	Wheat Variety	Application Timing	Total Rate (lb ai/A) [1]	PHI (days)	Commodity	Total Propiconazole Residues (ppm) [2]
Foster, ND 1996 MW-FR-515-96	5	Sharp	Feekes growth stage 10 (booting)	0.11	41	Grain	ND, ND
						Straw	1.1, 0.97
					63	Grain	ND, ND
						Straw	0.33, 0.31
				0.55	41	Grain	0.06
						Straw	4.8
					63	Grain	(0.03)
						Straw	1.4
			Feekes growth Stage 10.5 (heading)	0.11	30	Grain	0.10, 0.09
						Straw	1.6, 2.2
					55	Grain	ND, ND
						Straw	0.75, 0.85
				0.55	30	Grain	0.42
						Straw	9.0
					55	Grain	0.06
						Straw	3.5

1 The application rates were reported to be at 1x and 5x the proposed use rate for wheat.
2 Total propiconazole residues were determined as DCBA and expressed in parent equivalents. Reported values were obtained from the raw data and are not corrected procedural recoveries. The LOQ for propiconazole residues is 0.05 ppm in/on roots and tops, and the LOD is 0.02 ppm.
3 Values in parentheses are residues reported below the LOQ, but ≥LOD.
ND = Not detected, <0.02 ppm.

TABLE C.4. Summary of Residue Data from Wheat Field Trials with Propiconazole (EC) Comparing Late Season Applications.

Commodity	Application Timing	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)[1] n	Min.	Max.	HAFT[2]	Median (STMdR)[3]	Mean (STMR)[3]	Std. Dev.
Grain	Feekes GS 10 (booting)	0.11-0.12	41	4	<0.05	<0.05	<0.05	0.03	0.03	0.00
			63-67	4	<0.05	<0.05	<0.05	0.03	0.03	0.00
		0.55-0.62	41	2	0.06	0.08	0.08	0.07	0.07	0.01
			63-67	2	<0.05	<0.05	<0.05	0.03	0.03	0.00
	Feekes GS 10.5 (heading)	0.11-0.12	30-31	4	<0.05	0.10	0.10	0.06	0.06	0.04
			55-57	4	<0.05	<0.05	<0.05	0.03	0.03	0.00
		0.55-0.62	30-31	2	0.18	0.42	0.42	0.30	0.30	0.17
			55-57	2	0.06	0.30	0.30	0.18	0.18	0.17
Straw	Feekes GS 10 (booting)	0.11-0.12	41	4	0.95	1.3	1.1	1.04	1.1	0.16
			63-67	4	0.31	0.91	0.81	0.52	0.56	0.29
		0.55-0.62	41	2	4.8	7.3	7.3	6.1	6.1	1.8
			63-67	2	1.4	6.8	6.8	4.1	4.1	3.8
	Feekes GS 10.5 (heading)	0.11-0.12	30-31	4	1.2	2.2	1.9	1.5	1.6	0.43
			55-57	4	0.75	1.2	1.1	0.92	0.95	0.19
		0.55-0.62	30-31	2	6.6	9.0	9.0	7.8	7.8	1.7
			55-57	2	3.5	6.5	6.5	5.0	5.0	2.1

1 The LOQ is 0.05 ppm. Residue data are not corrected for procedural recoveries. For calculation of the median, mean and standard deviation, ½LOQ (0.025 ppm) was used for grain samples with residues <LOQ.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

D. CONCLUSION

The two wheat field trials are adequate for the purposes for which they were intended. The tests conducted at both the 1x and 5x rates indicate that propiconazole residues in/on grain and straw are higher following an application at the heading stage then at the booting stage, and that residues in both grain and straw decline at longer post-treatment intervals.

E. REFERENCES

DP Barcode:	D279300
Subject:	Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From:	Y. Donovan
To:	S. Lewis/J. Guerry
Dated:	8/18/05
MRID:	None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 2F6371
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED Yan Donovan	Date: 07/03/06
Approved by	Susan Hummel, Senior Scientist, RRB4/HED Susan Hummel	Date:07/03/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 6/12/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

44548402 Vincent, T. (1998) Propiconazole--Magnitude of the Residues in or on Wheat, Including Processed Fractions, Following an Application of TILT: Lab Project Number: 46-96: ABR-97143: 411124. Unpublished study prepared by Novartis Crop Protection, Inc. 189 p.

EXECUTIVE SUMMARY:

In two wheat field trials conducted in ID and ND in 1996, propiconazole (3.6 lb/gal EC) was applied to four separate plots of wheat at each site as a single broadcast foliar application at booting (Feekes Growth Stage 10) or at heading (Feekes Growth Stage 10.5) at 0.11-0.12 lb ai/A or 0.55-0.62 lb ai/A (1x and 5x rates). All applications were made using ground equipment in volumes of 15-21 gal/A, and did not include the use of any adjuvants. Single control and treated bulk samples of grain were harvested from each test at normal crop maturity, 63-67 days following the application at booting or 55-57 days following the application at heading. The grain was cleaned to generate aspirated grain fractions (AGF) and then processed using simulated commercial procedures into wheat germ, bran, middlings, shorts and flour (low grade and patent). Prior to analysis, the grain and processed fractions were stored frozen for up to 4.9 months, an interval supported by the available stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on wheat grain, straw and processed fractions were determined using an adequate GC/ECD method (Method AG-454B). For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization with $KMnO_4$. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and cleaned-up using an acidic alumina cartridge. Methylated DBCA is determined by GC/ECD using external standards, and residues are expressed in parent equivalents. The validated method limit of quantitation (LOQ) is 0.05 ppm, and the limit of detection (LOD) is 0.02 ppm.

For the tests conducted at the reported 1x rate, total propiconazole residues were <LOQ in/on all samples of grain and all processed fractions, with the exception of AGF. AGF samples from the 1x applications were <LOQ in one test and 0.08-0.14 ppm in the remaining three 1x tests, indicating the potential for concentration of residues in AGF. However, reliable processing factors could not be calculated at residues in the RAC were <LOQ.

V

Residues were also <LOQ in/on grain samples from two of the tests conducted at 5x rates; however, in the remaining two 5x tests, residues in/on grain were 0.16 ppm at 67 days following an application at booting and 0.24 ppm at 57 days following an application at heading. In these tests, residues were 1.3-1.4 ppm in AGF, ≤0.06 ppm in germ, 0.05-0.17 ppm in bran, and <LOQ in middlings, shorts and flour. Calculated processing factors for these tests were 5.8-8.1x for AGF, ≤0.3x for germ, 0.3-0.7x for bran, ≤0.2x for middlings, shorts and flour. Average processing factors were 7.0x for AGF, 0.2x for germ, 0.5x for bran and <0.1x for middlings, shorts and flour.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the wheat processing study data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited minor deviations from GLP compliance, pertaining to the collection of weather data, tank mix storage stability data and maintenance of records. None of these deviations affect the overall acceptability of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities, including permanent tolerances of 0.1 and 1.5 ppm on wheat grain and straw [40 CFR §180.434(a)].

Syngenta has submitted at petition (PP#2F6371) proposing tolerances and the use of propiconazole on a variety of cereal grains, including wheat. The current submission includes residue data from several processing studies on wheat, in which propiconazole (EC) was applied to wheat at up to Feekes Growth Stage 10.5 (heading) at 1x and 5x rates.

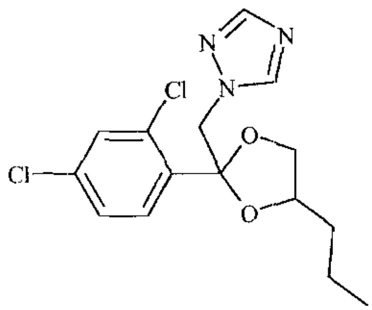
TABLE A.1.	Nomenclature of Propiconazole
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EPs	3.6 lb/gal EC (Tilt 3.6E Fungicide, EPA Reg. No. 100-617)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.		
Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK$_a$)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K$_{OW}$)	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Application and Crop Information

Four treated plots and a control plot were established at each test site (Table B.1.1). At both sites, propiconazole (3.6 lb/gal EC) was applied to wheat as a single broadcast foliar application at either booting (Feekes Growth Stage 10) or heading (Feekes growth stage 10.5) at target rates of 0.11 lb ai/A (1x) and 0.55 lb ai/A (5x).

TABLE B.1.1. Study Use Pattern on Wheat.						
Location (County, State; Year) Trial ID	End-use Product	Application Information [1]				
		Method; Timing	Volume (GPA)[2]	Single Rate (lb ai/A)	RTI[2] (days)	Total Rate (lb ai/A)
Latah, ID 1996 0W-FR-672-96	3.6 lb/gal EC	Single broadcast foliar application at Feekes Growth Stage 10 (boot stage)	21	0.12	NA	0.12
			21	0.62	NA	0.62
		Single broadcast foliar application at Feekes Growth Stage 10.5 (heading)	21	0.12	NA	0.12
			21	0.62	NA	0.62
Foster, ND 1996 MW-FR-515-96	3.6 lb/gal EC	Single broadcast foliar application at Feekes Growth Stage 10 (boot stage)	15	0.11	NA	0.11
			15	0.55	NA	0.55
		Single broadcast foliar application at Feekes Growth Stage 10.5 (heading)	15	0.11	NA	0.11
			15	0.55	NA	0.55

1 All applications were made using ground equipment, and did not include the use of any spray adjuvants.
2 Gallons per acre
3 RTI = Retreatment Interval.
NA = not applicable

B.2. Sample Handling and Processing Procedures

Single bulk samples (weight unspecifed) of control and treated (1x and 5x) wheat grain were harvested at normal crop maturity, which was 63-67 days following the application at booting or 55-57 days following the application at heading. Samples were then shipped by overnight courier under ambient conditions to the processing facility, Food and Protein Research and Development Center, Texas A&M University, Bryan, TX, where samples were stored at ≤-12°C until processing. A subsample of grain was collected at the processing facility, and samples of AGF were then generated and collected using procedures that simulate the movement of grain during transport and storage. Cleaned wheat grain was then processed into flour using simulated commercial procedures, and samples of wheat germ, bran, middlings, shorts, and flour (low grade and patent) were collected during processing. Samples were frozen within ~2 hours of collection and shipped to on dry ice by overnight courier to Novartis Crop Protection (Greensboro, NC), where samples were prepared (homogenized) and stored at -20EC. Samples were later shipped frozen to the analytical laboratory, ABC Laboratories (Columbia, MO), where samples were stored at -20°C until analysis.

B.3. Analytical Methodology

Samples of wheat grain and processed fractions were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-454B), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, propiconazole residues are extracted by refluxing for 1 hour in NH_4OH/methanol (20:80, v/v), and filtered. Residues are concentrated and oxidized to DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, the $KMnO_4$ is deactivated by the addition of sodium meta-bisulfite, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using diazomethane. Residues are then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and analyzed by GC/ECD using external standards. The validated method LOQ is 0.05 ppm for roots and processed fractions, and the LOD is 0.02 ppm.

Summary tables of the residue data were corrected by the registrant for procedural recoveries of <100%; however, spreadsheets including the uncorrected residue values were available in the raw data and were used by the reviewer to report residue values.

In conjunction with the analysis of field trial samples, the above method was validated using control samples fortified propiconazole at 0.05-20 ppm for grain and at 0.05 and 0.10 ppm for AGF and each processed fraction.

C. RESULTS AND DISCUSSION

The GC/ECD method (Method AG-454B) used to determine propiconazole residues in/on wheat grain and processed fractions was adequately validated in conjunction with the analysis of field trial samples. Average recoveries of propiconazole were 85 ± 15% from grain fortified at 0.05-20 ppm (Table C.1). For AGF and grain processed fractions, recoveries averaged 83-86% from samples fortified at 0.05 and 0.10 ppm, with standard deviations of ± 11-21%. Apparent residues of propiconazole were non-detectable (<0.02 ppm) in/on control samples of grain and all processed fractions, with the exception of one control sample of grain, which had apparent residues above the LOD, but <LOQ. The validated method LOQ for propiconazole is 0.05 ppm, and the LOD is 0.02 ppm. Adequate sample calculations and example chromatograms were provided. Although the study author reported residue values corrected for concurrent recoveries of <100%, uncorrected residues values are used and reported in this review.

Samples of wheat grain, AGF and processed fractions were stored frozen for up to 4.9 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating that residues of propiconazole and its metabolites are stable at -20° C for up to 36 months on a wide variety of plant commodities, including wheat grain and corn meal (DP Barcode D279300, Y. Donovan, 8/18/05), which are similar in nature to the matrices in the current processing study. These data will support the storage intervals and conditions for the wheat grain processing study.

TABLE C.1. Summary of Concurrent Recoveries of Propiconazole from Wheat Grain, AGF and Processed Fractions.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Grain	0.05	5	101, 75, 73, 61, 77	85 ± 15
	0.10	4	72, 107, 79, 88	
	0.50	2	105, 95	
	20.0	1	86	
AGF	0.05, 0.10	4	73, 91, 78, 96	85 ± 11
Germ	0.05, 0.10	4	97, 68, 84, 102	88 ± 15
Bran	0.05, 0.10	4	78, 67, 73, 113	83 ± 21
Middlings	0.05, 0.10	4	77, 82, 83, 103	86 ± 11
Shorts	0.05, 0.10	4	77, 68, 84, 102	83 ± 14
Flour (low grade *and patent)*	0.05, 0.10	8	94, 95, 78, 99, 89, 105, 117, 93	96 ± 11

TABLE C.2. Summary of Storage *Conditions.*

Matrix	Storage Temperature (°C)	Actual Storage Duration [1] (months)	Interval of Demonstrated Storage Stability (months) [2]
Grain, AGF and processed fractions	-20	1.2-4.9	36

[1] From harvest to extraction for analysis. Samples were analyzed within 1-10 days of extraction.
[2] DP Barcode D279300, Y. Donovan, 8/18/05.

Following applications at 0.11-0.12 lb ai/A (1x rate), total uncorrected propiconazole residues were <LOQ in/on mature samples of grain harvested at either 63-67 days following an application at booting or 55-57 days following an application at heading (Table C.3). For the tests conducted at 1x, residues were also <LOQ in all wheat processed fractions, with the exception of AGF. AGF samples from the 1x applications were <LOQ in one test and 0.08-0.14 ppm in the remaining three 1x tests. As residues were <LOQ in grain, reliable processing factors could not be calculated from the tests conducted at 1x.

For the applications at 0.55-62 lb ai/A (5x rate), total propiconazole residues were also <LOQ in/on grain samples from the two tests conducted in ND. The data from these tests indicated there is the potential for concentration of residues in AGF and bran, but processing factor were not calculated for these two tests as residues in the RAC were <LOQ. For the two 5x tests conducted in ID, total propiconazole residues in/on grain were 0.16 ppm at 67 days following an application at booting and 0.24 ppm at 57 days following an application at heading. In these two tests, residues were 1.3-1.4 ppm in AGF, ≤0.06 ppm in germ, 0.05-0.17 ppm in bran, and <LOQ in middlings, shorts and flour. The calculated processing factors for these two tests were 5.8-8.1x for AGF, ≤0.3x for germ, 0.3-0.7x for bran, ≤0.2x for middlings, shorts and flour. Average processing factors were 7.0x for AGF, 0.2x for germ, 0.5x for bran and <0.1x for middlings, shorts and flour.

Table C.3. Residue Data from Wheat Processing Studies with Propiconazole (EC) Applied as a Late-season Application at Booting or Heading.

Location (County, State; Year) Trial ID	Application Timing	Total Rate (lb ai/A) [1]	RAC	Processed Commodity	PHI (days)	Total Residues (ppm) [2]	Processing Factors [3]
Latah, ID 1996 0W-FR-672-96	Feekes Growth stage 10 (booting)	0.12	Grain	NA	67	(0.02) [4]	NA
				AGF		0.08	NC
				Germ		(0.03)	NC
				Bran		ND	NC
				Middlings		ND	NC
				Shorts		ND	NC
				Low grade flour		ND	NC
				Patent flour		ND	NC
		0.62	Grain	NA	67	0.16	NA
				AGF		1.3	8.1x
				Germ		(0.03)	<0.2x
				Bran		0.05	0.3x
				Middlings		(0.02)	<0.1x
				Shorts		ND	<0.1x
				Low grade flour		ND	<0.1x
				Patent flour		ND	<0.1x
	Feekes Growth stage 10.5 (heading)	0.12	Grain	NA	57	ND	NC
				AGF		0.14	NC
				Germ		ND	NC
				Bran		(0.02)	NC
				Middlings		ND	NC
				Shorts		ND	NC
				Low grade flour		ND	NC
				Patent flour		ND	NC
		0.62	Grain	NA	57	0.24	NA
				AGF		1.4	5.8x
				Germ		0.06	0.3x
				Bran		0.17	0.7x
				Middlings		(0.03)	0.1x
				Shorts		(0.04)	0.2x
				Low grade flour		ND	<0.1x
				Patent flour		ND	<0.1x

Table C.3. Residue Data from Wheat Processing Studies with Propiconazole (EC) Applied as a Late-season Application at Booting or Heading.

Location (County, State; Year) Trial ID	Application Timing	Total Rate (lb ai/A) [1]	RAC	Processed Commodity	PHI (days)	Total Residues (ppm) [2]	Processing Factors [3]
Foster, ND 1996 MW-FR-515-96	Feekes Growth stage 10 (booting)	0.11	Grain	NA	63	ND	NA
				AGF		(0.02)	NC
				Germ		ND	NC
				Bran		(0.03)	NC
				Middlings		ND	NC
				Shorts		ND	NC
				Low grade flour		ND	NC
				Patent flour		ND	NC
		0.55	Grain	NA	63	(0.03)	NA
				AGF		0.08	NC
				Germ		(0.02)	NC
				Bran		0.09	NC
				Middlings		ND	NC
				Shorts		0.04	NC
				Low grade flour		ND	NC
				Patent flour		ND	NC
	Feekes Growth stage 10.5 (heading)	0.11	Grain	NA	55	ND	NA
				AGF		0.10	NC
				Germ		(0.02)	NC
				Bran		0.07	NC
				Middlings		ND	NC
				Shorts		0.03	NC
				Low grade flour		ND	NC
				Patent flour		ND	NC
		0.55	Grain	NA	55	ND	NA
				AGF		0.32	NC
				Germ		0.14	NC
				Bran		0.30	NC
				Middlings		(0.05)	NC
				Shorts		0.10	NC
				Low grade flour		ND	NC
				Patent flour		(0.02)	NC

1 The application rates were reported to be at 1x and 5x the use rate for wheat.
2 Total propiconazole residues were determined as DCBA and expressed in parent equivalents. Reported values were obtained from the raw data and are <u>not</u> corrected procedural recoveries. The LOQ for propiconazole residues is 0.05 ppm in/on wheat grain and processed fractions, and the LOD is 0.02 ppm.
3 Processing factors were calculated by the reviewer using uncorrected residues.
4 Values in parentheses are residues reported below the LOQ, but ≥LOD.
NA = not applicable
ND = not detected: <0.02 ppm.
NC = not calculated. Processing factors were not calculated for test in which grain residues were <LOQ.

D. CONCLUSION

The wheat grain processing tests are adequate. In the two 5x tests in which residues in/on grain were above the method LOQ, residues were shown to concentrate in wheat AGF by an average of 7x. However, residues were reduced by 0.2x in germ, 0.5x in bran and <0.1x in middlings, shorts and flour

E. REFERENCES

DP Barcode:	D279300
Subject:	Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From:	Y. Donovan
To:	S. Lewis/J. Guerry
Dated:	8/18/05
MRID:	None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 2F6371
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED Yan Donovan	Date: 06/30/06
Approved by	Susan Hummel, Senior Scientist, RRB4/HED Susan Hummel	Date: 06/30/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 6/02/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

44757207 Vincent, T.; Ediger, K. (1998) Propiconazole and CGA-279202--Magnitude of the Residues in or on Sugar Beet: Final Report: Lab Project Number: 35-97: MW-FR-312-97: MW-FR-313-97. Unpublished study prepared by Novartis Crop Protection, Inc. 372 p.

EXECUTIVE SUMMARY:

In 11 field trials conducted throughout the U.S. in 1997, propiconazole (45% WP) was applied to sugar beets as three broadcast foliar applications during tuber development at 0.11 lb ai/A/application, for a total of 0.33 lb ai/A/season. Applications were made at retreatment intervals (RTIs) of 9-12 days, with the exception of one site, which had RTIs of 6 and 14 days. At one field site in MN, two additional plots were also treated similarly with three applications of propiconazole (WP) at 0.33 and 0.55 lb ai/A/application (3x and 5x rates), to provide samples for a processing study. All applications were made using ground equipment at volumes of 5-32 gal/A, and no adjuvants were included in the spray mixes. Single control and duplicate treated samples of sugar beet roots and tops were harvested from each site at 0 and 21-23 days after the third application (DAT). At two sites, duplicate samples of roots and tops were collected at 0, 7, 14, 21 and 28 DAT to examine residue decline.

Sugar beet root and top samples were stored frozen for up to 9.9 months prior to extraction for analysis. Adequate storage stability data are available to support the storage intervals and conditions for the current field trials.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on sugar beet roots and tops were determined using an adequate GC/ECD method (Method AG-454B). For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization with $KMnO_4$. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and cleaned-up using an acidic alumina cartridge. Methylated DBCA is determined by GC/ECD, using external standards, and residues are expressed in parent equivalents. The validated method limit of quantitation (LOQ) is 0.05 ppm, and the limit of detection (LOD) is 0.02 ppm. Concurrent recoveries were conducted and the % recoveries are acceptable.

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Following three applications of propiconazole (WP) to sugar beets totaling 0.33 lb ai/A, total propiconazole residues in/on sugar beet roots were <0.05-0.61 ppm at 0 DAT and <0.05-0.12 ppm at 21-23 DAT, and total residues in/on tops were 0.89-5.2 ppm at 0 DAT and 0.41-2.9 ppm at 21-23 DAT. Average residues in/on roots and tops were respectively 0.09 and 2.52 ppm at 0 DAT and 0.04 and 1.10 ppm at 21-23 DAT. The highest average field trial (HAFT) residues in/on roots and tops were respectively 0.57 and 5.1 ppm at 0 DAT and 0.08 and 2.9 ppm at 21-23 DAT

Residues in/on roots and tops from the 3x rate test were respectively 0.21 and 5.8 ppm at 0 DAT and <0.05 and 1.3 ppm at 23 DAT, and residues in/on roots and tops from the 5x rate test were respectively 0.41 and 13.7 ppm at 0 DAT and 0.10 and 2.0 ppm at 23 DAT.

In the two residue decline tests, residue levels in/on roots were low and remained relatively steady from 0 to 28 DAT, averaging 0.053 ppm at 0 DAT, 0.064 ppm at 14 DAT, and 0.054 ppm at 28 DAT. However, residues in/on tops declined steadily at longer post-treatment intervals, averaging 2.68 ppm at 0 DAT, 1.15 ppm at 14 DAT and 0.68 ppm at 28 DAT.

The number of trials and the geographic representations are adequate. These field trial data will support the use of propiconazole (WP) on sugar beets as up to three boardcast foliar applications at 0.11 lb ai/A/application, at a minimum RTI of 10 days, for a total of 0.33 lb ai/A/season, with either a 0 or 21 day pre-harvest interval.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the sugar beet field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited minor deviations from GLP compliance, pertaining to the collection of weather data, tank mix storage stability data and maintenance chemicals and irrigation application. None of these deviations affect the overall acceptability of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities [40 CFR §180.434(a)].

Syngenta has submitted at petition (PP#2F6371) proposing tolerances and the use of propiconazole on sugar beets. The current submission includes residue data supporting the use on sugar beets of propiconazole, formulated as a 45% WP.

TABLE A.1. Nomenclature of Propiconazole

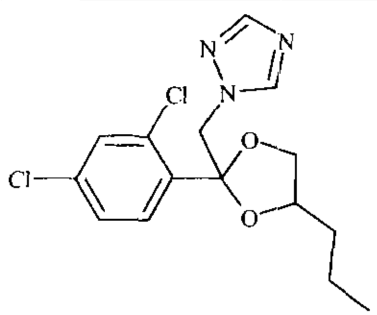
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products EPs	45% WP (Tilt 45W Fungicide, EPA Reg. No. 100-780) 1.04 lb/gal EC (250EC, MAI containing 1.04 lb/gal each of propiconazole and trifloxystrobin)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.		
Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK_a)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K_{OW})	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Sugar beets were grown and maintained at each test site using typical agricultural practices for the respective geographical region (Table B.1.1). Monthly rainfall and irrigation data were provided for each site, along with temperature data. No usual weather conditions were noted that would have an adverse effect on the field trial data. Information was also provided on maintenance chemicals and other pesticides used at each site. Soil types were provided for some sites, but no other soil data were provided. The study use pattern for propiconazole (45% WP) on sugar beets is presented in Table B.1.2.

TABLE B.1.1. Trial Site Conditions.				
Trial Identification (County, State; Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC[2] (meq/g)
Polk, MN 1997	NR	NR	NR	NR
Polk, MN 1997	NR	NR	NR	NR
Grand Forks, ND 1997	NR	NR	NR	NR
Steele, ND 1997	NR	NR	NR	NR
Blaine, ID 1997	NR	NR	NR	NR
Canyon, ID 1997	NR	NR	NR	NR
Hall, NE 1997	NR	NR	NR	NR
Weld, CO 1997	Sandy Clay Loam	NR	NR	NR
Platte, WY 1997	Sandy Clay Loam	NR	NR	NR
Ottawa, MI 1997	Silt Loam	NR	NR	NR
Yollo, CA 1997	Loam	NR	NR	NR

[1] These parameters are optional except in cases where their value affects the use pattern for the chemical.
[2] Cation exchange capacity.
NR = Not Reported.

TABLE B.1.2. Study Use Pattern on Sugar Beets.

Location (County, State; Year) Trial ID	End-use Product	Application Information [1]				
		Method; Timing	Volume (GPA)	Rate (lb ai/A)	RTI (days)	Total Rate (lb ai/A)
Polk, MN 1997 223	45% WP	Three broadcast foliar applications during root enlargement	20	0.11	10	0.33
				0.33		0.99
				0.55		1.65
Polk, MN 1997 224	45% WP	Three broadcast foliar applications during root enlargement	20	0.11	10	0.33
Grand Forks, ND 2251997	45% WP	Three broadcast foliar applications during root enlargement	20	0.11	10	0.33
Steele, ND 1997 226	45% WP	Three broadcast foliar applications during root enlargement	20	0.11	10	0.33
Yolo, CA 1997 402	45% WP	Three broadcast foliar applications during root enlargement	25	0.11	10, 12	0.33
Blaine, ID 1997 626	45% WP	Three broadcast foliar applications during root enlargement	5	0.11	10	0.33
Canyon, ID 1997 627	45% WP	Three broadcast foliar applications to green plants	32	0.11	6, 14	0.33
Weld, CO 1997 312	45% WP	Three broadcast foliar applications during root development	16	0.11	10	0.33
Platte, WY 1997 313	45% WP	Three broadcast foliar applications during root development	16	0.11	9, 10	0.33
Hall, NE 1997 622	45% WP	Three broadcast foliar applications during root development	20	0.11	10	0.33
Ottawa, MI 1997 731	45% WP	Three broadcast foliar applications 41, 31 and 21 days before harvest	5	0.11	10	0.33

[1] All applications were made using ground equipment, and no adjuvants were included in the spray mixes.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones[1]	Sugar Beets		
	Submitted	Requested	
		Canada	U.S.
1	---	---	---
2	---	---	---
3	---	---	---
4	---	---	---
5	5	---	5
6	---	---	---
7	1	---	1
8	1	---	1
9	1	---	1
10	1	---	2
11	2	---	2
12	---	---	---
Total	11	NA	12

[1] Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the use is for only in the U.S.
NA = Not applicable

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of sugar beet roots and tops (weights unknown) were harvested from each test at 0 and 21-23 DAT. At two sites samples were taken at 1, 7, 14, 21 and 28 DAT to examine residue decline. Samples were frozen shortly after harvest and shipped by freezer truck or overnight courier on dry ice to Novartis Crop Protection (Greensboro, NC), where samples were stored at -20EC until preparation for analysis.

B.3. Analytical Methodology

Samples were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-454B), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, propiconazole residues are extracted by refluxing for 1 hour in NH_4OH/methanol (20:80, v/v), and filtered. Residues are concentrated and oxidized to DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, the $KMnO_4$ is deactivated by the addition of sodium meta-bisulfite, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using diazomethane. Residues are then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and analyzed by GC/ECD using external standards. The validated method LOQ is 0.05 ppm for tops and roots, and the LOD is 0.02 ppm.

Summary tables of the residue data were corrected by the registrant for procedural recoveries of <100%; however, spreadsheets including the uncorrected residue values were available in the raw data and were used by the reviewer to report residue values.

In conjunction with the analysis of field trial samples, the above method was validated using control samples fortified with propiconazole at 0.05-0.50 ppm for roots and at 0.05-20 ppm for tops.

C. RESULTS AND DISCUSSION

In 11 field trials conducted throughout the U.S. in 1997, propiconazole (45% WP) was applied to sugar beets during root development as three broadcast foliar applications at 0.11 lb ai/A/application, for a total of 0.33 lb ai/A/season. Applications were made at RTIs of 9-12 days, with the exception of one site, which had RTIs of 6 and 14 days.

At one field site in MN, two additional plots were also treated similarly with propiconazole (WP) at 0.33 and 0.55 lb ai/A/application (3x and 5x rates), to provide samples for a concurrent processing study, which is reported in 44757201.der2. All applications were made using ground equipment at volumes of 5-32 gal/A, and no adjuvants were included in the spray mixtures. Single control and duplicate treated samples of sugar beet roots and tops were harvested from each site at 0 and 21-23 DAT. In the exaggerated use tests (3x and 5x), single bulk treated samples of roots and tops were collected at 0 and 23 DAT. At two sites, samples were collected at 0, 7, 14, 21 and 28 days to examine residue decline.

The GC/ECD method (Method AG-454B) used to determine propiconazole residues in/on sugar beet roots and tops was adequately validated in conjunction with the analysis of field trial samples. The recovery of propiconazole averaged 81± 15% from sugar beet roots and 83 ± 12% from sugar beet tops (Table C.1). Apparent residues of propiconazole were <LOQ on all control samples for roots and tops. The validated method LOQ for propiconazole is 0.05 ppm, and the LOD is 0.02 ppm. Adequate sample calculations and example chromatograms were provided.

Sugar beet root and top samples were stored frozen for up to 9.9 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating the fortified residues of propiconazole and its metabolites are stable for up to 10 months at -20° C in carrots (DP Barcode D279300, Y. Donovan, 8/18/05). These data will support the storage intervals and conditions for the current field trials.

Following three applications of propiconazole (45% WP) to sugar beets totaling 0.33 lb ai/A, total propiconazole residues in/on roots were <0.05-0.61 ppm at 0 DAT and <0.05-0.12 ppm at 21-23 DAT (Table C.3), and total residues in/on tops were 0.89-5.2 ppm at 0 DAT and 0.41-2.9 ppm at 21-23 DAT. Average residues in/on roots and tops were respectively 0.09 and 2.52 ppm at 0 DAT and 0.04 and 1.10 ppm at 21-23 DAT (Table C.4.1).

In 3x rate test, residues in/on roots and tops were respectively 0.21 and 5.8 ppm at 0 DAT and <0.05 and 1.3 ppm at 23 DAT (Table C.3). In the 5x rate test, residues in/on roots and tops were respectively 0.41 and 13.7 ppm at 0 DAT and 0.10 and 2.0 ppm at 23 DAT.

In the two residue decline tests, residue levels in/on roots were low and remained relatively steady from 0 to 28 DAT, averaging 0.053 ppm at 0 DAT, 0.064 ppm at 14 DAT, and 0.054 ppm at 28 DAT (Table C.4.2). However, residues in/on tops declined steadily at longer post-treatment intervals (Figure C.1). Average residues in/on tops were 2.68 ppm at 0 DAT, 1.15 ppm at 14 DAT and 0.68 ppm at 28 DAT.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data

TABLE C.1. Summary of Method Recoveries of Propiconazole from Sugar beet Roots and Tops.

Analyte	Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Propiconazole	Roots	0.05-0.5	29	78, 77, 109, 105, 84, 104, 88, 86, 84, 92, 73, 104, 83, 77, 70, 65, 64, 76, 84, 61, 76, 66, 71, 63, 114, 78, 75, 88, 67	81 ± 15
	Tops	0.05-20	31	72, 86, 90, 95, 88, 70 ,71, 110, 77, 70, 95, 89, 87, 85, 95, 76, 84, 83, 75, 89, 79, 70, 82, 78, 81, 70, 73, 76, 118, 71	83 ± 12

TABLE C.2 Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1] (months)	Interval of Demonstrated Storage Stability (months)
Tops and Roots	-20	9.9	10

[1] From harvest to extraction for analysis.
[2] DP Barcode D279300, Y. Donovan, 8/18/05.

TABLE C.3. Residue Data on Sugarbeet from Field Trials with Propiconazole (EC or WP).

Trial ID (*County, State; Year*)	Zone	Variety	End-use Product	Total Rate (lb ai/A)	Commodity	PHI (days)	Total Propiconazole Residues (ppm)[1]
Polk, MN 1997 223	5	ACH 192	45% WP	0.33	Roots	0	<0.05, 0.17
						23	<0.05, 0.07
					Tops	0	2.6, 2.1
						23	0.57, 0.89
				0.99	Roots	0	0.12
						23	<0.05
					Tops	0	5.8
						23	1.3
				1.65	Roots	0	0.41
						23	0.10
					Tops	0	13.7
						23	2.0
Polk, MN 1997 224	5	ACH 310	45% WP	0.33	Roots	0	0.11, 0.05
						7	<0.05, 0.07
						14	<0.05, 0.05
						21	0.06, <0.05
						28	<0.05, 0.14
					Tops	0	1.7, 2.2
						7	0.75, 1.6
						14	0.73, 0.86
						21	0.67, 0.54
						28	0.43, 0.53
Grand Forks, ND 1997 225	5	ACH 192	45% WP	0.33	Roots	0	<0.05, <0.05
						21	0.07, 0.05
					Tops	0	2.8, 2.4
						21	0.76, 0.56
Steele, ND 1997 226	5	ACH 192	45% WP	0.33	Roots	0	<0.05, <0.05
						21	<0.05, <0.05
					Tops	0	2.3, 2.5
						21	0.41, 0.46

TABLE C.3. Residue Data on Sugarbeet from Field Trials with Propiconazole (EC or WP).

Trial ID (County, State; Year)	Zone	Variety	End-use Product	Total Rate (lb ai/A)	Commodity	PHI (days)	Total Propiconazole Residues (ppm)[1]
Yolo, CA 1997 402	11	SS-102R	45% WP	0.33	Roots	0	<0.05, <0.05
						7	<0.05, <0.05
						14	0.08, 0.10
						21	<0.05, <0.05
						28	<0.05, <0.05
					Tops	0	3.5, 3.3
						7	1.9, 1.8
						14	1.1, 1.9
						21	1.2, 1.1
						28	1.0, 0.75
Blaine, ID 1997 626	11	BETA 8757	45% WP	0.33	Roots	0	<0.05, <0.05
						21	<0.05, <0.05
					Tops	0	1.7, 1.8
						21	0.50, 0.44
Canyon, ID 1997 627	7	WSPM9	45% WP	0.33	Roots	0	0.52, 0.61
						21	0.05, 0.08
					Tops	0	5.2, 4.9
						21	2.9, 2.8
Weld, CO 1997 312	8	Charger	45% WP	0.33	Roots	0	<0.05, <0.05
						21	<0.05, <0.05
					Tops	0	0.89, 1.5
						21	0.54, 0.85
Platte, WY 1997 313	9	Monohikari	45% WP	0.33	Roots	0	<0.05, <0.05
						21	<0.05, <0.05
					Tops	0	1.2, 1.2
						21	1.3, 2.3
Hall, NE 1997 622	5	HMLS RSS	45% WP	0.33	Roots	0	<0.05, <0.05
						21	<0.05, <0.05
					Tops	0	2.0, 2.1
						21	2.2, 2.0
Ottawa, MI 1997 731	10	E-4	45% WP	0.33	Roots	0	<0.05, <0.05
						21	<0.05, <0.05
					Tops	0	3.0, 4.6
						21	0.5, 0.73

[1] Total propiconazole residues were determined as DCBA and expressed in parent equivalents. Reported values were obtained from the raw data and are not corrected procedural recoveries. The LOQ for propiconazole residues is 0.05 ppm in/on roots and tops, and the LOD is 0.02 ppm.

TABLE C.4.1 Summary of Residue Data from Sugar Beet Field Trials with Propiconazole (45% WP).

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)[1]						
			n	Min.	Max.	HAFT[2]	Median (STMdR)[3]	Mean (STMR)[3]	Std. Dev.
Root	0.33	0	22	<0.05	0.61	0.565	0.025	0.086	0.160
		21-23	22	<0.05	0.08	0.065	0.025	0.035	0.018
Tops	0.33	0	22	0.89	5.20	5.05	2.25	2.52	1.17
		21-23	22	0.41	2.90	2.85	0.75	1.10	0.80

[1] The LOQ is 0.05 ppm. Residue data are not corrected for procedural recoveries. For calculation of the median, mean and standard deviation, ½LOQ (0.025 ppm) was used for root samples with residues <LOQ.

[2] HAFT = Highest Average Field Trial.

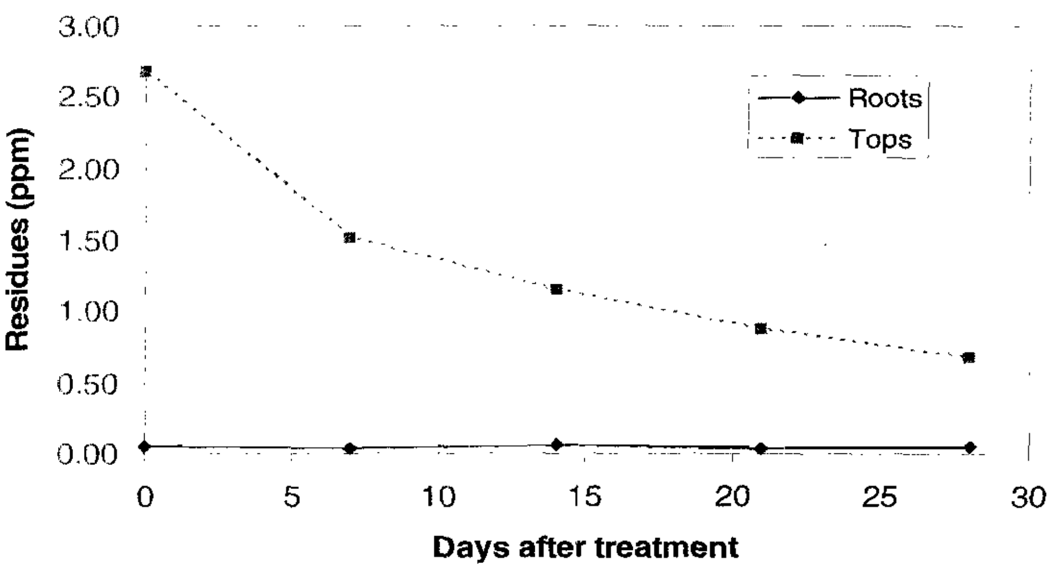
[3] STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

TABLE C.4.2 Summary of Residue Decline Data from Sugar Beet Field Trials with Propiconazole (45% WP).

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)[1]						
			n	Min.	Max.	HAFT[2]	Median (STMdR)[3]	Mean (STMR)[4]	Std. Dev.
Root	0.33	0	4	<0.05	0.11	0.080	0.038	0.053	0.040
		7	4	<0.05	0.07	0.048	0.025	0.036	0.023
		14	4	<0.05	0.10	0.090	0.065	0.064	0.033
		21	4	<0.05	0.06	0.043	0.025	0.034	0.018
		28	4	<0.05	0.14	0.083	0.025	0.054	0.058
Tops	0.33	0	4	1.70	3.50	3.40	2.75	2.68	0.87
		7	4	0.75	1.90	1.85	1.70	1.51	0.52
		14	4	0.73	1.90	1.50	0.98	1.15	0.53
		21	4	0.54	1.20	1.15	0.89	0.88	0.32
		28	4	0.43	1.00	0.88	0.64	0.68	0.25

1 The LOQ is 0.05 ppm. Residue data are <u>not</u> corrected for procedural recoveries. For calculation of the median, mean and standard deviation, ½LOQ (0.025 ppm) was used for root samples with residues <LOQ.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

Figure C.1 Average Residues in or on Sugar Beet Roots and Tops Over Time.



D. CONCLUSION

The sugar beet field trial data are adequate and will support the use of propiconazole (WP) on sugar beets as up to three boardcast foliar applications during root development at 0.11 lb ai/A/application, at a minimum RTI of 10 days, for a total of 0.33 lb ai/A/season, with either a 0 or 21 day pre-harvest interval.

E. REFERENCES

DP Barcode: D279300
Subject: Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From: Y. Donovan
To: S. Lewis/J. Guerry
Dated: 8/18/05
MRID: None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 2F6371
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED Yan Donovan	Date: 06/30/06
Approved by	Susan Hummel, Senior Scientist, RRB4/HED Susan Hummel	Date: 06/30/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 6/02/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

44757207 Vincent, T.; Ediger, K. (1998) Propiconazole and CGA-279202--Magnitude of the Residues in or on Sugar Beet: Final Report: Lab Project Number: 35-97: MW-FR-312-97: MW-FR-313-97. Unpublished study prepared by Novartis Crop Protection, Inc. 372 p.

EXECUTIVE SUMMARY:

In a field trial conducted in MN in 1997, propiconazole (45%WP) was applied to sugar beets as three broadcast foliar applications during root enlargement at either 0.11, 0.33 or 0.55 lb ai/A/application, at retreatment intervals of 10 days, for totals of 0.33, 0.99 and 1.65 lb ai/A/season. These rates were reported to correspond to 1x, 3x and 5x application rates. Sugar beets were grown and harvested at commercial maturity, 23 days after the final application (DAT). Following harvest, sugar beet roots from each rate were processed into refined sugar, dried pulp and molasses using simulated commercial procedures. Prior to analysis, samples were stored up to 4.5 months, an interval supported by available storage stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on sugar beet roots and processed fractions were determined using an adequate GC/ECD method (Method AG-454B). For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization with $KMnO_4$. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and cleaned-up using an acidic alumina cartridge. Methylated DBCA is determined by GC/ECD, using external standards, and residues are expressed in parent equivalents. The validated method limit of quantitation (LOQ) is 0.05 ppm, and the limit of detection (LOD) is 0.02 ppm.

Total residues were 0.03, 0.045 and 0.11 ppm in/on roots treated at the 1x, 3x and 5x rates, respectively. Root residues were above the LOQ only in the 5x treatment. Because residues were above the LOQ in roots from only 5x treatment, the processing factors for refined sugar (<0.2x), molasses (7.4x) and dried pulp (4.9x) from the 5x treatment should be used for determining residues in sugar beet processed fractions.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

X

Under the conditions and parameters used in the study, the processed sugar beet residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited minor deviations from GLP compliance, pertaining to the collection of weather data, tank mix storage stability data and maintenance chemicals and irrigation application. None of these deviations affect the overall acceptability of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities [40 CFR §180.434(a)].

Syngenta has submitted at petition (PP#2F6371) proposing tolerances and the use of propiconazole on sugar beets. The current submission includes residue data from three processing studies on sugar beets treated at 1x, 3x and 5x rates.

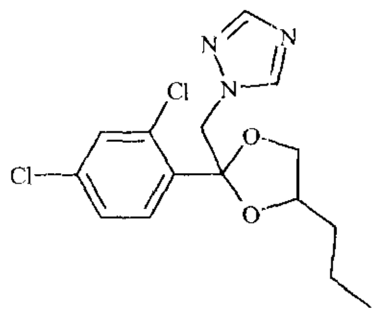
TABLE A.1. Nomenclature of Propiconazole	
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EPs	45% WP (Tilt 45W Fungicide, EPA Reg. No. 100-780) 1.04 lb/gal EC (250EC, MAI containing 1.04 lb/gal each of propiconazole and trifloxystrobin)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.		
Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK$_a$)	1.09	MRID No. 43698701
Octanol/water partition coefficient Log(K$_{OW}$)	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, *nm*)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Application and Crop Information

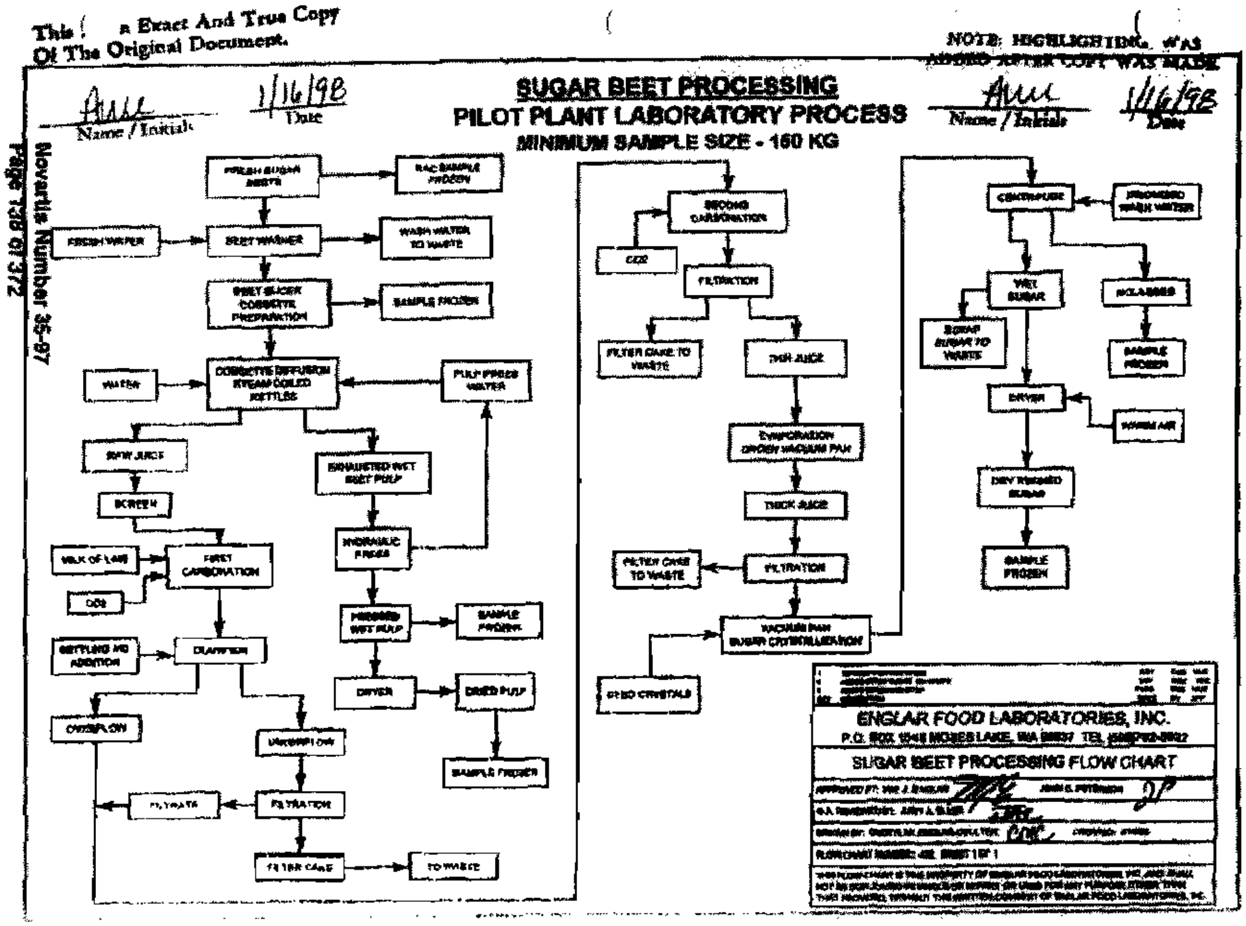
TABLE B.1.1. *Study* Use Pattern on Sugar Beets.						
Location (County, State; Year) *Trial ID*	End-use Product	Application Information				
		Method; Timing	Volume (GPA)[2]	Rate (lb ai/A)	RTI[2] (days)	Total Rate (lb ai/A)
Polk, MN 1997 223	45% WP	Three broadcast foliar applications during root enlargement	20	0.11	10	0.33
				0.33		0.99
				0.55		1.65

[1] Gallons per acre
[2] RTI = Retreatment Interval.

B.2. Sample Handling and Processing Procedures

Single bulk samples (~150 kg/sample) of control and treated (1x, 3x, and 5x) roots were harvested at normal crop maturity, 23 DAT. Samples were frozen and shipped directly to the processing facility, Englar Food Laboratories, Inc. (EFL), Moses Lake, WA, where samples were stored at ≤-17°C until processing. Root samples were processed within 2 months into refined sugar, molasses and dried pulp using simulated processing procedures (Figure B.2). Single samples of roots from each treatment were collected prior to processing, and single samples of each processed fraction were collected after processing and placed in frozen storage. Samples were shipped frozen to the analytical laboratory, Novartis Crop Protection (Greensboro, NC), where samples were stored at -20EC until preparation for analysis.

Figure B.2. Processing Flowchart for Sugar Beet Roots.



B.3. Analytical Methodology

Samples of sugar beet roots and processed fractions were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-454B), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, propiconazole residues are extracted by refluxing for 1 hour in NH_4OH/methanol (20:80, v/v), and filtered. Residues are concentrated and oxidized to DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, the $KMnO_4$ is deactivated by the addition of sodium meta-bisulfite, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using diazomethane. Residues are then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and analyzed by GC/ECD using external standards. The validated method LOQ is 0.05 ppm for roots and processed fractions, and the LOD is 0.02 ppm.

Summary tables of the residue data were corrected by the registrant for procedural recoveries of <100%; however, spreadsheets including the uncorrected residue values were available in the raw data and were used by the reviewer to report residue values.

In conjunction with the analysis of field trial samples, the above method was validated using control samples of roots and each processed fraction fortified with propiconazole at 0.05 ppm.

C. RESULTS AND DISCUSSION

The GC/ECD method (Method AG-454B) used to determine propiconazole residues in/on sugar beet roots and processed fractions was adequately validated in conjunction with the analysis of field trial samples. The recovery of propiconazole fortified at 0.05 ppm was 109% from roots, 95% from refined sugar, 71% from dried pulp and 72% from molasses (Table C.1). Apparent residues of propiconazole were <LOQ on all control samples. The validated method LOQ for propiconazole is 0.05 ppm, and the LOD was 0.02ppm. Adequate sample calculations and example chromatograms were provided.

Sugar beet root and processed samples were stored frozen for up to 4.5 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating the fortified residues of propiconazole and its metabolites are stable at -20° C for up to 10 months in carrots and for up to 36 months on a wide variety of plant commodities (DP Barcode D279300, Y. Donovan, 8/18/05). These data will support the storage intervals and conditions for the sugar beet processing study.

TABLE C.1. Summary of Concurrent Recoveries of Propiconazole from Sugar Beets and its Processed Products.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Roots (RAC)	0.05	1	109	NA
Refined Sugar	0.05	1	95	NA
Dried Pulp	0.05	1	71	NA
Molasses	0.05	1	72	NA

NA = not applicable.

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration [1] (months)	Interval of Demonstrated Storage Stability (months) [2]
Sugar beet roots and processed products	-20	3.8-4.5	10-36

[1] From harvest to extraction for analysis. Samples were analyzed within 1-15 days of extraction.
[2] DP Barcode D279300, Y. Donovan, 8/18/05.

Total propiconazole residues in/on roots were <LOQ for the 1x and 3x applications, but were detectable at 0.03 and 0.045 ppm, respectively (Table C.3). Residues in/on roots from the 5x application were 0.11 ppm. For the 5x treatment, residues in refined sugar, molasses, and dried pulp were non-detectable (<0.02 ppm), 0.54 ppm, and 0.81 ppm, respectively.

Because only the 5x treatment had residues above the LOQ in roots, only the processing factors from this treatment should be used for calculating potential residues in refined sugar, molasses and dried pulp.

TABLE C.3. Residue Data from Sugar Beet Processing Study with Propiconazole.

RAC	Processed Commodity	Total Rate (lb ai/A)	PHI (days)	Total Propiconazole Residues (ppm) [1]	Processing Factor [2]
Sugar Beet Roots	Roots, Processor	0.33 (1x) [4]	23	<0.05 (0.03) [3]	NA
	Refined Sugar			<0.05 (ND)	<0.7x
	Dried Pulp			0.11	3.7x
	Molasses			0.18	6.0x
	Roots, Processor	0.99 (3x)	23	<0.05 (0.045)	NA
	Refined Sugar			<0.05 (ND)	<0.4x
	Dried Pulp			0.26	5.8X
	Molasses			0.76	16.9x
	Roots, Processor	**1.65 (5x)**	**23**	**0.11**	**NA**
	Refined Sugar			**<0.05 (ND)**	**<0.2x**
	Dried Pulp			**0.54**	**4.9x**
	Molasses			**0.81**	**7.4x**

1 Total propiconazole residues were determined as DCBA and expressed in parent equivalents. Reported values were obtained from the raw data and are not corrected procedural recoveries. The LOQ for propiconazole residues is 0.05 ppm in/on roots and tops, and the LOD is 0.02 ppm.

4 Processing factors were calculated by the reviewer using uncorrected residues. For the 1x and 3x application rates, residues <LOQ in roots were used to calculate processing factors.

3 Values in parentheses are residues reported below the LOQ.

4 The application rates were reported to be at 1x, 3x and 5x the proposed use rate for sugar beets.

ND = not detected, <0.02 ppm.

D. CONCLUSION

The sugar beet processing tests are adequate. As residues were above the LOQ in roots from only 5x treatment, the processing factors for refined sugar (<0.2x), molasses (7.4x) and dried pulp (4.9x) from the 5x treatment should be used for determining residues in processed fractions.

E. REFERENCES

DP Barcode:	D279300
Subject:	Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From:	Y. Donovan
To:	S. Lewis/J. Guerry
Dated:	8/18/05
MRID:	None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED.
Petition Number(s): 2F6371
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED	Date: 07/03/06
	Yan Donovan	
Approved by	Susan Hummel, Senior Scientist, RRB4/HED	Date: 07/03/06
	Susan Hummel	

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 6/23/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

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

EXECUTIVE SUMMARY:

In two field trials conducted in OK and KS during 1997, propiconazole (3.6 lb/gal EC) was applied to winter wheat in four separate plots as either a single broadcast foliar application at Feekes Growth Stage 10.5 at 0.11-12 lb ai/A (0.5x rate), or as two broadcast foliar applications around Feekes Growth Stages 10 (booting) and 10.5 (heading) at either 0.11-0.12, 0.33-0.37, or 0.55-0.62 lb ai/A/application, for totals of ~0.22, ~0.66, and ~1.1 lb ai/A/season (1x, 3x and 5x rates). All applications were made using ground equipment in volumes of 19-20 gal/A, and no adjuvants were included in the spray mixture. The retreatment interval (RTI) was 12 or 16 days for plots receiving two applications. Single control and treated bulks samples of grain were harvested from each test at 36 or 47 days after treatment (DAT). Samples were cleaned to generate aspirated grain fractions (AGF) and then processed using simulated commercial procedures into wheat germ, bran, middlings, shorts and flour (low grade and patent). Samples were stored up to 9.3 months prior to analysis, an interval supported by available storage stability data.

Combined residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on wheat commodities were determined using a GC/ECD method (Method AG-454 B). This method is an updated version of the current tolerance enforcement method and was adequately validated in conjunction with the analysis of treated samples. For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and cleaned-up using an acidic alumina cartridge. Methylated DBCA is determined by GC/ECD, using external standards, and residues are expressed in parent equivalents. The validated method limit of quantitation (LOQ) is 0.05 ppm, and the limit of detection (LOD) was 0.02 ppm.

Samples were also analyzed for residues of propiconazole, *per se*, using a GC/NPD method from PAM Vol. I (Method 302 E4 + DG5). This method was also adequately validated in conjunction

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with the analysis of treated samples. For this method, residues are extracted with aqueous acetone, partitioned into dichloromethane:petroleum ether, and cleaned up using a Florisil column. Residues of parent are then analyzed by GC/NPD using external standards. The validated method LOQ is 0.05 ppm, and a LOD was not reported. For both total combined residues and parent residues, the reported residues values were corrected for concurrent recoveries of < 100%; however, the uncorrected residues values were used and reported in this review.

Following a single broadcast application to wheat at 0.11-0.12 lb ai/A (0.5x rate) at FGS 10.5, total combined residues were <LOQ in/on mature samples of grain harvested at either 36 or 47 DAT (Table C.3). Following two broadcast applications at approximately Feekes Growth Stages (FGS) 10 and 10.5, combined residues in/on grain were <0.05 and 0.062 ppm from the 1x rate tests, 0.101 and 0.129 ppm from the 3x rate tests, and 0.107 and 0.183 ppm from the 5x rate tests. Within each test, levels of combined residues were typically highest in AGF and then bran, and residues were lowest in flour. Processing factors were calculated only for those tests in which residues were ≥LOQ in/on whole grain.

For all tests, average processing factors for total combined residues were 0.9x for germ, 3.2x for bran, 0.7x for middlings, 0.9x for shorts, and <0.3x for flour. The maximum theoretical processing factor for wheat is 8.3x. Processing factors for combined residues in AGF varied considerably between the two test sites, averaging 2.7x at the OK site and 34x at the KS site, with an overall processing factor of 23x.

Processing factors for parent residues could not be determined as residues of parent were <LOQ in grain and all processed fractions, except AGF, at rates up to 5x. Assuming parent residues at the LOQ (0.05 ppm) in grain, processing factors for propiconazole in AGF could range from 2.2x-39x.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the wheat field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited deviations from GLP compliance pertaining to weather data, tank mix storage stability data and the application of maintenance chemicals.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides board spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities, including permanent tolerances of 0.1 and 1.5 ppm on wheat grain and straw [40 CFR §180.434(a)].

Syngenta has submitted at petition (PP#2F6371) proposing new tolerances and the use of propiconazole on a variety of cereal grains, including wheat. The current submission includes residue data from wheat grain processing conducted at 0.5x, 1x, 3x and 5x rates.

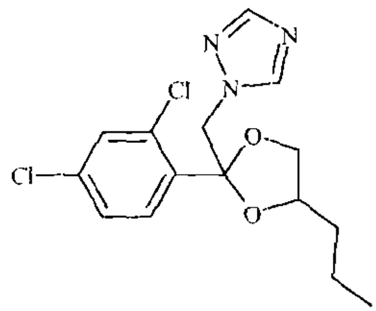
TABLE A.1. Nomenclature of Propiconazole	
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EPs	3.6 lb/gal EC (Tilt 3.6E Fungicide, EPA Reg. No. 100-617)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.

Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK_a)	1.09	MRID No. 43698701
Octanol/water partition coefficient $Log(K_{OW})$	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Application and Crop Information

At two field sites in OK and KS during 1997, propiconazole (EC) was applied to at least four separate plots of winter wheat at each site during grain development as one or two broadcast foliar applications. In one plot, propiconazole (EC) was applied once at 0.11 lb ai/A (0.5x) at heading (FGS 10.5). In the other three plots, propiconazole (EC) was applied twice around booting (FSG 9-10) and heading (FGS 10.5) at target rates of 0.11, 0.33 or 0.55 lb ai/A/application, at RTIs of 12 or 16 days, for totals of 0.22, 0.66, and 1.10 lb ai/A, which were reported to be equivalent to 1x, 3x and 5x rates (Table B.1.1).

TABLE B.1.1. Study Use Pattern for Propiconazole (EC) on Wheat.

Location (County, State, Year) Trial ID	End-use Product	Application Information [1]					Tank Mix/ Adjuvants
		Method; Timing	Volume (GPA)	Single Rate (lb ai/A)	RTI [2] (days)	Total Rate (lb ai/A)	
Caddo, OK 1997 0S-FR-731-97	3.6 lb/gal EC	One broadcast foliar application at Feekes Growth Stage 10.5	20	0.11	--	0.11	None
		Two broadcast foliar applications at Feekes Growth Stages 9 and 10.5	19-20	0.11	16	0.22	
				0.33		0.66	
				0.55		1.10	
Finney, KS 1997 MWFR-309-97	3.6 lb/gal EC	One broadcast foliar application at Feekes Growth Stage 10.5	20	0.12	--	0.12	None
		Two broadcast foliar applications at Feekes Growth Stages 10.2 and 10.5	20	0.11, 0.12	12	0.23	
				0.33, 0.37		0.70	
				0.55, 0.62		1.17	

[1] All applications were made using ground equipment.
[2] RTI = Retreatment Interval

B.2. Sample Handling and Processing Procedures

Single bulk samples (210-501 lb/sample) of control and treated wheat grain were harvested from each test plot at normal crop maturity, which was at 47 DAT at the OK site and 36 DAT at the KS site. Samples were frozen immediately after harvest and stored frozen at the field sites for up to 8 days until shipment by freezer truck to the processing facility, Food and Protein Research and Development Center, Texas A&M University, Bryan, TX, where samples were stored at ≤-12°C until processing.

At the processing facility, grain samples were dried to a moisture content of 10-13% and a subsample of grain was collected. Samples of AGF were then generated and collected using procedures that simulate the movement of grain during transport and storage. Cleaned wheat grain was then processed into flour using simulated commercial procedures, and samples of wheat germ, bran, middlings, shorts, and flour (low grade and patent) were collected during processing. Samples were frozen within ~2 hours of collection and shipped to on dry ice by overnight courier to Novartis Crop Protection (Greensboro, NC), where samples were prepared (homogenized) and stored at -20EC. Samples were later shipped frozen to the analytical laboratory, ABC Laboratories (Columbia, MO), where samples were stored at -20°C until analysis.

B.3. Analytical Methodology

All samples were analyzed for both total combined propiconazole residues and for residues of propiconazole, *per se*. A GC/ECD method (Method AG-454B) was used for determining total combined residues of propiconazole and its DCBA-containing metabolites in/on wheat grain and its processed fractions. This method is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities.

For this method, residues are extracted and base hydrolyzed by refluxing for 1 hour with NH_4OH/MeOH (20:80, v/v) and filtered. Residues are concentrated and oxidized to 2,4-DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, sodium meta-bisulfite is added to deactivate the $KMnO_4$, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using diazomethane. Residues are then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and analyzed by GC/ECD using external standards. The validated method LOQ is 0.05 ppm for residues in/on wheat grain and processed fractions, and a LOD of 0.02 ppm was implied in the raw data spreadsheets. Method AG-454B was validated in conjunction with the analysis of treated samples using control samples of each matrix fortified with propiconazole at 0.05 and 0.10 ppm.

A GC/NPD multiresidue method from PAM Vol. I (Section 302, Methods E4 and DG5) was used to determine residues of only parent. For this method, residues of propiconazole are extracted with water:acetone (35:65, v/v), filtered, and partitioned into dichloromethane: petroleum ether (1:1, v/v). Residues are then filtered through sodium sulfate, concentrated to dryness, redissolved in petroleum ether, and cleaned up using a Florisil column eluted with ethyl ether:petroleum ether (1:1, v/v). Residues are then concentrated to dryness, redissolved in acetone and analyzed by GC/NPD using external standards. The validated method LOQ is 0.05 ppm for residues in/on wheat grain and processed fractions, and a LOD was not reported. This GC/NPD method was validated in conjunction with the analysis of field trial samples using control samples of each matrix fortified with propiconazole at 0.05 and 0.10 ppm.

Summary tables of the residue data for both "total combined residues" and "parent residues" were corrected by the study authors for procedural recoveries of <100%; however, spreadsheets including the uncorrected residue values were available in the raw data and were used by the reviewer to report residue values.

C. RESULTS AND DISCUSSION

The GC/ECD method (Method AG-454 B) used to determine propiconazole residues in/on wheat grain and its processed fractions was adequately validated in conjunction with the analysis of treated samples. Average recoveries of propiconazole were 83-99% from grain, AGF and processed fractions (Table C.1). Apparent total combined residues were <LOD in/on all controls samples. The validated method LOQ is 0.05 ppm for total combined residues, expressed as propiconazole, and the LOD is 0.02 ppm based on data in the spreadsheets. Adequate sample calculations and example chromatograms were provided.

The GC/NPD method from PAM Vol. I was also adequately validated in conjunction with the analysis of treated samples. Average recoveries of propiconazole were 86-111% from grain, AGF and processed fractions, and apparent residues of propiconazole were <LOQ in/on all control samples. The validated method LOQ is 0.05 ppm for residues of propiconazole, *per se*, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided.

For both total combined residues and parent residues, the study authors corrected residues values for concurrent recoveries of <100%; however, the uncorrected residues values were used and reported in this review.

TABLE C.1. Summary of Concurrent Method Recoveries of Propiconazole from Wheat Using GC/ECD Method for Determining "Total Residues" and GC/NPD Method for Determining "Parent" Residues.

Analyte	Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ± Std [1] (%)
GC/ECD Method (AG-454B)					
Propiconazole	Grain	0.05, 0.10	5	73, 83, 100, 83, 82	84 ± 10
	AGF	0.05, 0.10	3	113, 92, 92	99
	Germ	0.05, 0.10	2	90, 94	92
	Bran	0.05, 0.10	2	108, 74	91
	Middlings	0.05, 0.10	2	90, 76	83
	Shorts	0.05, 0.10	2	96, 69	83
	Flour	0.05, 0.10	4	77, 85, 88, 94	86 ± 7
GC/NPD Method (PAM Vol. I, Section 302, E4 + DG5)					
Propiconazole	Grain	0.05, 0.10	5	120, 91, 80, 115, 80	97 ± 19
	AGF	0.05, 0.10	2	66, 117, 74	86
	Germ	0.05, 0.10	2	112, 105	109
	Bran	0.05, 0.10	2	102, 100	101
	Middlings	0.05, 0.10	2	108, 114	111
	Shorts	0.05, 0.10	2	83, 103	93
	Flour	0.05, 0.10	4	100, 108, 89, 97	99 ± 8

[1] Standard deviations were only calculated for matrices with ≥4 recovery values.

Samples of wheat grain, AGF and processed fractions were stored frozen for up to 9.3 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating that residues of propiconazole and its metabolites are stable at -20° C for up to 36 months on a wide variety of plant commodities, including wheat grain and corn meal (DP Barcode D279300, Y. Donovan, 8/18/05), which are similar in nature to the matrices in the current processing study. Although several extracts were stored for >30 days prior to analysis, data are also available from corn forage and soybeans indicating that residues are stable in extracts at 4°C for at least 3 months.

TABLE C.2 Summary of Storage Conditions for Wheat Grain and Processed Matrices.

Matrix	Storage Temperature (°C)	Actual Storage Duration [1] (months)	Interval of Demonstrated Storage Stability (days)[2]
Analysis of Total Propiconazole Residues			
Grain	-20	6.9-9.3	36
AGF		7.2-9.3	
Germ, Middlings, Short, and Flour		8.9-9.2	
Analysis of Parent Residues			
Grain	-20	7.1-8.7	36
AGF		7.6-8.8	
Germ, Middlings, Short, and Flour		8.6-8.8	

[1] From harvest to extraction for analysis. Samples were analyzed for "total" residues within 1-5 days of extraction. For analysis of parent residues, extracts were generally analyzed within 0-14 days of extraction, with the exception of selected germ and AGF extracts which were analyzed 36 days after extraction.
[2] DP Barcode D279300, Y. Donovan, 8/18/05.

Following a single broadcast application to wheat at 0.11-0.12 lb ai/A (0.5x rate) at FGS 10.5, total combined residues were <LOQ in/on mature samples of grain harvested at either 36 or 47 DAT (Table C.3). Following two broadcast applications at approximately FGS 10 and 10.5, combined residues in/on grain were <0.05 and 0.062 ppm from the 1x rate tests, 0.101 and 0.129 ppm from the 3x rate tests, and 0.107 and 0.183 ppm from the 5x rate tests.

Within each test, levels of combined residues were typically highest in AGF and then bran, and residues were lowest in flour. Processing factors were calculated only for those tests in which residues were >LOQ in/on whole grain.

The calculated processing factors for combined residues in AGF were substantially different between the two field sites, but were similar for tests within each site. At the OK field site, processing factors for AGF were 1.6x-4.3x and averaged 2.7x. At the KS field site, processing factors for AGF were 30x and 37x and averaged 34x. No explanation was provided as to why processing factors were so much higher at the KS field site. However, the applications at the KS site were possibly closer to maturity as grain was harvested at 36 DAT; whereas grain at the OK site was harvested at 47 DAT. If processing factors for AGF from all five tests with quantifiable residues in grain are combined, the overall processing factor for wheat grain AGF would be 23x.

In contrast to AGF, processing factors for combined residues from the remaining processed commodities were generally similar between the tests at the two sites. Processing factors were 0.5x-1.2x for germ, 2.0x-4.2x for bran, 0.5x-0.9x for middlings, 0.5x-1.2x for shorts, and <0.2x-0.4x for flour. Average processing factors calculated for combined residues were 0.9x for germ, 3.2x for bran, 0.7x for middlings, 0.9x for shorts, and <0.3x for flour. The maximum theoretical processing factor for wheat is 8.3x.

Residues of parent were <LOQ in/on all samples of grain following late-season applications at up to 5x (Table C.3). Residues of parent were also <LOQ in all samples of wheat processed fractions, with the exception of wheat AGF. Quantifiable residues of parent were detected at 0.133 ppm in the 5x rate test from OK, and at 0.112, 0.398, and 1.93 ppm in the 1x, 3x and 5x tests, respectively, from KS. Although these data indicate the potential for concentration of propiconazole residues in wheat AGF, actually processing factors for parent residues in AGF could not be calculated as parent residues were <LOQ in all grain samples. However, if a value of 0.05 ppm is assumed for residues of parent in grain, processing factors for propiconazole in AGF could range from 2.2-39x.

TABLE C.3. Residue Data from Wheat Processing Study with Propiconazole (EC).

Location	RAC	Processed Commodity	Total Rate (lb ai/A)	PHI (days)	Total Combined Residues [1]		Parent Residues [2]	
					PPM [3]	Processing Factor	PPM [3]	Processing Factor
Caddo, OK 1997 0S-FR-731-97	Grain	NA	0.11 (0.5x)	47	(0.023) [4]	NA	<0.05	NA
		AGF			0.128	NC	<0.05	NC
		Germ			(0.036)	NC	<0.05	NC
		Bran			0.105	NC	<0.05	NC
		Middlings			(0.020)	NC	<0.05	NC
		Shorts			(0.030)	NC	<0.05	NC
		Flour (low grade)			ND	NC	<0.05	NC
		Flour (patent)			ND	NC	<0.05	NC
	Grain	NA	0.22 (1x)	47	0.062	NA	<0.05	NA
		AGF			0.140	2.3x	<0.05	NC
		Germ			(0.045)	0.7x	<0.05	NC
		Bran			0.160	2.6x	<0.05	NC
		Middlings			(0.028)	0.5x	<0.05	NC
		Shorts			(0.033)	0.5x	<0.05	NC
		Flour (low grade)			ND	<0.3x	<0.05	NC
		Flour (patent)			ND	<0.3x	<0.05	NC
	Grain	NA	0.66 (3x)	47	0.129	NA	<0.05	NA
		AGF			0.556	4.3x	<0.05	NC
		Germ			0.120	0.9x	<0.05	NC
		Bran			0.487	3.8x	<0.05	NC
		Middlings			0.091	0.7x	<0.05	NC
		Shorts			0.142	1.1x	<0.05	NC
		Flour (low grade)			(0.045)	0.3x	<0.05	NC
		Flour (patent)			(0.037)	0.3x	<0.05	NC
	Grain	NA	1.10 (5x)	47	0.183	NA	<0.05	NA
		AGF			0.297	1.6x	0.133	2.7x [5]
		Germ			0.178	1.0x	<0.05	NC
		Bran			0.772	4.2x	<0.05	NC
		Middlings			0.151	0.8x	<0.05	NC
		Shorts			0.200	1.1x	<0.05	NC
		Flour (low grade)			0.075	0.4x	<0.05	NC
		Flour (patent)			0.078	0.4x	<0.05	NC

TABLE C.3. Residue Data from Wheat Processing Study with Propiconazole (EC).

Location	RAC	Processed Commodity	Total Rate (lb ai/A)	PHI (days)	Total Combined Residues [1]		Parent Residues [2]	
					PPM [3]	Processing Factor	PPM [3]	Processing Factor
Finney, KS 1997 MW-FR-309-97	Grain	NA	0.12 (0.5x)	36	ND	NA	<0.05	NA
		AGF			0.403	NC	<0.05	NC
		Germ			ND	NC	<0.05	NC
		Bran			(0.046)	NC	<0.05	NC
		Middlings			(0.020)	NC	<0.05	NC
		Shorts			ND	NC	<0.05	NC
		Flour (low grade)			ND	NC	<0.05	NC
		Flour (patent)			ND	NC	<0.05	NC
	Grain	NA	0.23 (1x)	36	(0.031)	NA	<0.05	NA
		AGF			0.654	NC	0.112	2.2x [5]
		Germ			ND	NC	<0.05	NC
		Bran			0.064	NC	<0.05	NC
		Middlings			ND	NC	<0.05	NC
		Shorts			(0.025)	NC	<0.05	NC
		Flour (low grade)			ND	NC	<0.05	NC
		Flour (patent)			ND	NC	<0.05	NC
	Grain	NA	0.70 (3x)	36	0.101	NA	<0.05	NA
		AGF			3.05	30x	0.398	8.0x [5]
		Germ			0.052	0.5x	<0.05	NC
		Bran			0.205	2.0x	<0.05	NC
		Middlings			0.089	0.9x	<0.05	NC
		Shorts			0.076	0.8x	<0.05	NC
		Flour (low grade)			ND	<0.2x	<0.05	NC
		Flour (patent)			ND	<0.2x	<0.05	NC
	Grain	NA	1.17 (5x)	36	0.107	NA	<0.05	NA
		AGF			3.99	37x	1.93	39x [5]
		Germ			0.127	1.2x	<0.05	NC
		Bran			0.389	3.6x	<0.05	NC
		Middlings			0.051	0.5x	<0.05	NC
		Shorts			0.127	1.2x	<0.05	NC
		Flour (low grade)			(0.024)	0.2x	<0.05	NC
		Flour (patent)			(0.024)	0.2x	<0.05	NC

1 Total propiconazole residues were determined as methyl-DCBA and expressed in parent equivalents using GC/ECD Method AG-454B. The validated LOQ is 0.05 ppm for combined residues in each commodity and the LOD is 0.02 ppm.
2 Residues of propiconazole were determined using Method 302 E4 and DG5 from PAM Vol. I. The validated LOQ was 0.05 ppm for propiconazole, and a LOD was not reported.
3 Reported values were obtained from the raw data and are not corrected procedural recoveries.
4 Values in parentheses are <LOQ but ≥LOD.
5 Processing factors for parent in AGF were estimated assuming a value of 0.05 ppm (LOQ) for grain.
NA = not applicable.
NC = not calculated.

D. CONCLUSION

The wheat processing trial is adequate. For all tests with quantifiable residues in the grain (RAC), average processing factors for total combined residues were 0.9x for germ, 3.2x for bran, 0.7x for middlings, 0.9x for shorts, and <0.3x for flour. Processing factors for combined residues in AGF varied considerably between the two test sites, averaging 2.7x at the OK site and 34x at the KS site, with an overall processing factor of 23x.

Processing factors for parent residues could not be determined as residues of parent were <LOQ in grain and all processed fractions, except AGF, at rates up to 5x. Assuming parent residues at the LOQ (0.05 ppm) in grain, processing factors for propiconazole in AGF could range from 2.2x-39x.

E. REFERENCES

DP Barcode:	D279300
Subject:	Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From:	Y. Donovan
To:	S. Lewis/J. Guerry
Dated:	3/18/05
MRID:	None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 2F6371
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED Yan Donovan	Date: 5/31/06
Approved by	Susan Hummel, Branch Senior Scientist, RRB4/HED Susan Hummel	Date:5/31/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 4/26/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

44416501. Thompson, D.C. (1997) Propiconazole: Magnitude of the Residue on Mint. Lab Project Numbers: A4911; A4911.95-EPL01. Unpublished study prepared by IR-4. 630 p.

EXECUTIVE SUMMARY:

In five field trials conducted during 1995 in Regions 5 and 11, propiconazole (3.6 lb/gal EC) was applied twice to established fields of mint as broadcast foliar applications at 0.111-0.114 lb ai/A/application at retreatment intervals (RTIs) of 13-14 days, for a total of 0.224-227 lb ai/A/season. The initial application was made when plants were 4-8 inches in height, and all applications were made using ground equipment. Duplicate control and treated samples of fresh mint hay were harvested from each site at 29-30 days after the second treatment (DAT). Samples were stored frozen from collection to analysis for up to 62 days, an interval which is supported by available storage stability data.

Residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on mint were determined using a GC/ECD method (Method AG-454B). This method is an updated version of the current tolerance enforcement method and was adequately validated in conjunction with the analysis of field trial samples. The validated method LOQ is 0.05 ppm, and an LOD was not reported.

Following applications of propiconazole (EC) at maximum rates of 0.224-0.227 lb ai/A/season, total propiconazole residues in/on mint hay range from 0.06-2.7 ppm (averaged 1.15 ppm).

The number of trials and geographic representation of the trials are adequate and support the use of propiconazole (EC) on mint as up to two foliar applications at 0.112 lb ai/A/application for a total of 0.224 lb ai/A/season. The data also support a minimum RTI of 14 days and a PHI of 30 days.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the mint field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited a number of minor deviations from GLP requirements relating to records on maintenance chemicals, SOPs, collection of field trial environmental data, and correction of raw data. However, none of deviations were serious enough to adversely affect the conclusions of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities [40 CFR §180.434], including a 0.3 ppm tolerance on mint with a geographical use restriction to areas west of the Cascade Mountains [40 CFR §180.434(c)].

IR-4 has submitted a petition (PP# 8E4931) supporting an amended use for propiconazole (3.6 lb/gal EC; EPA Reg. No. 100-617; Tilt® Fungicide) and expansion of the current region where propiconazole can be used on mint.

TABLE A.1. Nomenclature of Propiconazole

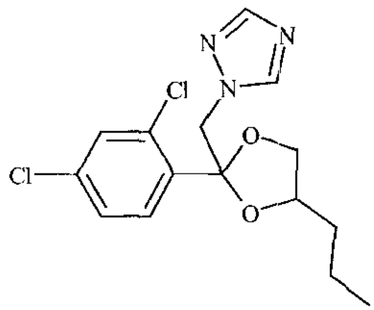
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EP	3.6 lb/gal EC (Tilt Fungicide, EPA Reg. No. 100-617)
Regulated Metabolite	None
Common name	N/A
IUPAC name	N/A
CAS #	N/A

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.		
Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No.:43698701
pH	4.9 @ 25°C (1% aqueous tdispersion)	MRID No.:43698701
Density	1.289 g/cm3 typical @ 20°C	MRID No.: 43698701
Water solubility (20°C)	0.10 g/L at 20°C	MRID No.: 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. n-hexane = 47 g/L	MRID No.: 42030201
Vapor pressure at 25°C	4.2 x 10^{-7} mm Hg @ 25°C	MRID No.: 41720301
Dissociation constant (pK_a)	1.09	MRID No.: 43698701
Octanol/water partition coefficient Log(K_{OW}) (25 °C)	3.72 @ pH 6.6	MRID No.: 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No.: 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Mint was grown and maintained at each test site using typical agricultural practices for the respective geographical region (Table B.1.1). Monthly rainfall and irrigation data were provided for each site, along with detailed temperature data and soil data for four sites. The study author reported that no usual weather conditions were noted that would have an adverse effect on the field trial data. Information was also provided on maintenance chemicals and other pesticides used at each site. Applications in each test were made to field of mint that had been established for 2-5 years. The study use pattern for propiconazole (3.6 lb/gal EC) on mint at the field sites is reported in Table B.1.2.

TABLE B.1.1. Trial Site Conditions.				
Trial Identification (City, State; Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC[2] (meq/g)
Dalton, Wisconsin 1995	Muck	48.2	6..4	NR
Montello, Wisconsin 1995	Muck	12.4	7.4	NR
Jefferson, Oregon 1995	Sandy clay loam	3.7	5.3	NR
Prosser, Washington 1995	Loamy fine sand	0.8	7.3	NR
Prosser, Washington 1995	Silt loam	NR	7.7	NR

[1] These parameters are optional except in cases where their value affects the use pattern for the chemical.
[2] Cation exchange capacity
NR = Not Reported

TABLE B.1.2. Study Use Pattern for Propiconazole on Mint.

Location (City, State; Year) Trial ID	End-use Product	Application Information					Tank Mix/ Adjuvants
		Method; Timing	Volume (gal/A)	Rate (lb ai/A)	RTI [1] (days)	Total Rate (lb ai/A)	
Dalton, Wisconsin 1995 W102	3.6 lb/gal EC	Two broadcast foliar applications at plant heights of 8-12" and 12-20"	26	0.112	--	0.224	None
			25	0.112	13		
Montello, Wisconsin 1995 WI03	3.6 lb/gal EC	Two broadcast foliar applications at plant heights of at 6-8" and 12-14"	26	0.112	---	0.224	None
			25	0.112	13		
Jefferson, Oregon 1995 OR19	3.6 lb/gal EC	Two broadcast foliar applications at plant heights of at 18" and 23"	30	0.114	---	0.226	None
			30	0.112	14		
Prosser, Washington 1995 WA20	3.6 lb/gal EC	Two broadcast foliar applications at plant heights of at 4-5" and 11-14"	28	0.113	---	0.227	None
			27	0.114	14		
Prosser, Washington 1995 WA21	3.6 lb/gal EC	Two broadcast foliar applications at plant heights of at 4-6" and 11-12"	28	0.111	---	0.224	None
			27	0.113	14		

[1] RTI = Retreatment Interval.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones[1]	Mint		
	Submitted	Requested	
		Canada	U.S.
1	---	---	---
2	---	---	---
3	---	---	---
4	---	---	---
5	2	---	2
6	---	---	---
7	---	---	---
8	---	---	---
9	---	---	---
10	---	---	---
11	3	---	3
12	---	---	---
Total	5	NA	5

[1] Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the proposed use is for the U.S. only.
NA = Not applicable

B.2. Sample Handling and Preparation

Duplicate control and treated samples of mint (≥ 4 lb/sample) were harvested from each test site at commercial maturity, 29-30 days following the second application. All samples were placed into freezers within 2 hours of collection and stored at <-6°C until shipment by freezer truck to the analytical laboratory (EPL Bioanalytical Services, Harristown, IL). All samples were held frozen at <-7 °C at the analytical laboratory prior to preparation and extraction for analysis. The frozen samples were stored frozen until homogenization and ground using a commercial processor before analysis.

B.3. Analytical Methodology

Mint samples were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-454B), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, residues are extracted and base hydrolyzed by refluxing for 1 hour with NH_4OH/MeOH (20:80, v/v) and filtered. Residues are concentrated and oxidized to 2,4-DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, sodium meta-bisulfite is added to deactivate the $KMnO_4$, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using diazomethane. Residues are then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and analyzed by GC/ECD, using external standards. The validated method LOQ is 0.05 ppm, and an LOD was not reported.

In conjunction with the analysis of field trial samples, the above method was validated using control samples of mint fortified with propiconazole at 0.05-3.56 ppm. Fortification recoveries ranged from 82%-100%, averaged 88 ± 9% (Table C.1).

C. RESULTS AND DISCUSSION

The number and geographic location of the mint field trials are adequate. In field trials conducted in 1995 in Regions 5 and 11, propiconazole (3.6 lb/gal EC) was applied twice to established fields of mint as broadcast foliar applications at 0.111-0.114 lb ai/A/application, with RTIs of 13-14days, for a total of 0.224-0.227 lb ai/A/season. The first application was made when the plants were 4-8 inches in height. All applications were made using ground equipment in volumes of 25-30 gal/A, and no adjuvants were added to the spray mix. Duplicate control and treated samples of mint were harvested from each site at 29-30 DAT.

The GC/ECD method (Method AG-454 B) used to determine propiconazole residues in/on mint was adequately validated in conjunction with the field sample analyses. Untreated samples of mint hay were fortified with propiconazole at 0.05-3.56 ppm and recoveries averaged 88 ± 9% (Table C.1). Apparent residues of propiconazole were <LOQ in/on all but two control samples, which had apparent residues of 0.05 and 0.06 ppm. The validated method LOQ for propiconazole is 0.05 ppm, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided.

Mint samples were stored frozen for up to 62 days prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating the weathered residues of propiconazole and its metabolites are stable for up to 38 months at -20° C in grass forage, straw, and seed (DP

Barcode D210742, 3/15/95, M. Rodriguez). These data will support the storage intervals and conditions for mint hay in the current field trials.

Following application of propiconazole at rates totaling 0.224-0.227 lb ai/A/season, residues were 0.06-2.7 ppm in/on 10 samples of mint hay harvested at a PHI of 29-30 days (Table C.3); average propiconazole residues were calculated to be1.15 ppm (Table C.4).

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data

TABLE C.1. Summary of Method Recoveries of Propiconazole from Mint.

Analyte	Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Propiconazole	Mint	0.05-3.56	5	88, 82, 94, 100, 76	88 ± 9

TABLE C.2 Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1] (days)	Interval of Demonstrated Storage Stability (months) [2]
Mint hay (fresh)	-20	62	38

1 From harvest to extraction for analysis.
2 DP Barcode D210742, 3/15/95, M. Rodriguez.

TABLE C.3. Residue Data from Mint Field Trials with Propiconazole (EC)

Trial ID (City, State; Year)	Zone	Variety	Total Rate (lb ai/A)	PHI (days)	Propiconazole Residues (ppm)[1]
Dalton, Wisconsin 1995 WI02	5	Scotch Spearmint	0.224	29	1.9, 2.7
Montello, Wisconsin 1995 WI03	5	Scotch Spearmint	0.224	30	0.54, 0.06
Jefferson, Oregon 1995 OR19	11	Redefined Murray Peppermint	0.226	30	1.1, 0.63
Prosser, Washington 1995 WA20	11	Scotch Spearmint	0.227	30	1.0, 1.2
Prosser, Washington 1995 WA21	11	Scotch Spearmint	0.224	30	1.3, 1.1

1 Residues of propiconazole and its DCBA containing metabolites determined as DCBA and expressed in parent equivalents. The LOQ for propiconazole residues in/on mint is 0.05 ppm. The LOD was not reported.

TABLE C.4. Summary of Residue Data from Mint Field Trials with Propiconazole (EC).

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)[1]						
			n	Min.	Max.	HAFT [2]	Median (STMdR)[3]	Mean (STMR)[3]	Std. Dev.
Mint Hay	0.224-0.227	29-30	10	0.06	2.7	2.3	1.1	1.15	0.73

1 The LOQ is 0.05 ppm.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

D. CONCLUSION

The mint field trial data are adequate and support the use of propiconazole (EC) on mint as up to two foliar applications at 0.112 lb ai/A/application for a total of 0.224 lb ai/A/season. The data also support a minimum RTI of 14 days and a PHI of 30 days.

E. REFERENCES

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

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 8E4931
DP Barcode(s): D313963
PC Code: 122101

Template Version June 2005

Primary Evaluator Yan Donovan, Chemist Date: 5/31/06
Yan Donovan

Approved by Susan Hummel Date:5/31/06
Susan Hummel

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 4/28/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

43640401 Ross, J.A. (1994) Propiconazole – Magnitude of Residues in Wheat and Raw Agricultural commodities and Processed Fractions of Rotational Grain Sorghum and Alfalfa Following application of Tilt® 3.6 E to Wheat: Lab Project Number: ABR-92089. Unpublished study prepared by Ciba-Geigy Corporation. 885 p.

EXECUTIVE SUMMARY:

Five rotational crop field trials were conducted on alfalfa in 1989 in Regions 1, 5 and 11. At each site, propiconazole (3.6 lb/gal EC) was applied at 0.11 lb ai/A to winter wheat in the spring as a single broadcast foliar application at Feekes Growth Stages 7-9. Two of the test sites also had additional plots with application rates at 0.22, 0.33 and 0.55 lb ai/A. These application rates were reported to correspond to 1x, 2x, 3x, and 5x the maximum labeled application rate for wheat. All applications were made using ground equipment at volumes of 15-23 gal/A. The wheat was grown to maturity and harvested, and a rotational crop of alfalfa was replanted the same year at plant-back intervals (PBIs) of 72-109 days and was grown using standard agricultural practices. A single control and single or duplicate treated samples of forage were cut in the fall at 60-63 days after planting (DAP), and forage and hay samples also collected the following spring at 269-333 DAP. Samples were stored frozen for up to 35 months, an interval supported by available storage stability data.

Residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on alfalfa forage and forage were determined using a GC/ECD method (Method AG-454 B). This method is an updated version of the current tolerance enforcement method and was adequately validated in conjunction with the analysis of field trial samples. The validated method LOQ is 0.05 ppm, and an LOD was not reported.

Following a single application of propiconazole (EC) at 0.11 lb ai/A (1x rate) to a primary crop of winter wheat, total propiconazole residues in rotational alfalfa forage and hay from PBIs of 72-109 days range from <0.05-0.07 ppm in forage (fall and spring) and <0.05-0.08 ppm in hay. Average residues were 0.04 ppm in both alfalfa forage and hay at the 1x rate.

AA

The extended field rotational crop data on alfalfa are adequate, but the number of field trials conducted at the reported 1x rate is limited. A total of 12 alfalfa field trails are required; however, only 5 were conducted at the 1x rate.

(At the reported 2x rate, residues were <0.05-0.07 ppm in forage and hay. At the reported 3x rate, residues were <0.05-0.07 ppm in forage and <0.05-0.09 ppm in hay. At the reported 5x rate, residues were 0.10-0.14 ppm in the initial fall forage and <0.05-0.06 ppm in spring forage and <0.05-0.09 ppm in spring hay.)

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in this study, the field rotational crop data on alfalfa are classified as scientifically acceptable. However, only 5 field trials were conducted at the reported 1x rate, and typically 12 alfalfa field trials are required. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated GLP, quality assurance, and data confidentiality statements were provided. No deviations from regulatory requirements were noted that would impact the study results or their interpretation.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities [40 CFR §180.434].

Syngenta has previously proposed tolerances (PP# 5F4498) for inadvertent residues on sorghum and alfalfa planted in rotation with propiconazole-treated wheat. This petition has been superseded by PP#2F6371, in which tolerances are being requested on a wide variety of crops (DP Barcode D279300, Y. Donovan, 8/18/2005). The current submission includes residue data on forage and hay of alfalfa planted in rotation with propiconazole-treated wheat.

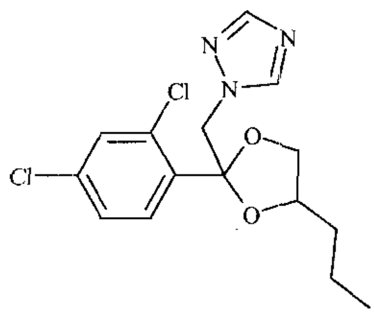
TABLE A.1. Nomenclature of Propiconazole	
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EP	3.6 lb/gal EC (Tilt Fungicide, EPA Reg. No. 100-617)
Regulated Metabolite	None
Common name	N/A
IUPAC name	N/A
CAS #	N/A

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.

Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No.:43698701
pH	4.9 @ 25°C (1% aqueous tdispersion)	MRID No.:43698701
Density	1.289 g/cm3 typical @ 20°C	MRID No.: 43698701
Water solubility (20°C)	0.10 g/L at 20°C	MRID No.: 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. n-hexane = 47 g/L	MRID No.: 42030201
Vapor pressure at 25°C	4.2 x 10^{-7} mm Hg @ 25°C	MRID No.: 41720301
Dissociation constant (pK_a)	1.09	MRID No.: 43698701
Octanol/water partition coefficient Log(K_{OW}) (25 °C)	3.72 @ pH 6.6	MRID No.: 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No.: 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

The primary crop of winter wheat and the rotational crop of alfalfa were grown and maintained at each test site using typical agricultural practices for the respective geographical region (Table B.1.1). Monthly rainfall and irrigation data were provided for each site, along with temperature data. No usual weather conditions were noted that would have an adverse effect on the field trial data. Information was also provided on maintenance chemicals and other pesticides used at each site. Soil types were provided for each site, but no other soil data were provided. However, as the application to wheat was foliar, additional information on soil characteristics are not required.

The study use pattern for propiconazole (3.6 lb/gal EC) on the primary winter wheat crop is reported in Table B.1.2. At each test site, winter wheat was treated once in the spring with a broadcast application of propiconazole (2.6 lb/gal EC) at 0.11 lb ai/A, and two of the sites also had additional plots with application rates at 0.22, 0.33, and 0.55 lb ai/A. The wheat crop was grown to maturity and harvested, and a rotational crop of alfalfa was planted at PBIs of 72-109 days.

TABLE B.1.1. Trial Site Conditions.

Trial Identification (County, State, Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC (meq/g) [2]
Champaign, IL, 1989	Silty Clay Loam	NR	NR	NR
Bannock, ID, 1989	Silty Clay Loam	NR	NR	NR
York, NE, 1989	Silt Loam	NR	NR	NR
Fayette, OH, 1989	Loam	NR	NR	NR
Kent, MD, 1989	Loam	NR	NR	NR

[1] These parameters are optional except in cases where their value affects the use pattern for the chemical.
[2] Cation exchange capacity.
NR = Not Reported.

TABLE B.1.2. Study Use Pattern on Primary Crop of Winter Wheat.						
Location (County, State) Year, Trial ID	End-use Product	Application Information [1]				Rotational Crop
		Method; Timing	Vol. (GPA)	Rate (lb ai/A)	PBI [2] (days)	
Champaign, IL, 1989 04-FR-003-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 7-8	15	0.110 0.220 0.330 0.550	72	Alfalfa
Bannock, ID, 1989 0W-FR-607-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	15	0.110	106	Alfalfa
York, NE, 1989 MW-FR-602-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	20	0.110 0.220 0.330 0.550	77	Alfalfa
Fayette, OH, 1989 NE-FR-201-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	20	0.110	73	Alfalfa
Kent, MD, 1989 NE-FE-302-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 9	23	0.110	109	Alfalfa

1 All applications were made using ground equipment.
2 PBI= plant-back interval.

TABLE B.1.3. Trial Numbers and Geographical Locations.		
NAFTA Growing Zones[1]	Rotational Alfalfa	
	Submitted	Requested
1	1	1
2	--	1
3	--	--
4	--	--
5	3	6
6	--	--
7	--	1
8	--	--
9	--	1
10	--	1
11	1	1
12	--	--
Total	5	12

1 Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the proposed use is for the US only.

B.2. Sample Handling and Preparation

Single control and single or duplicate treated samples of alfalfa forage and hay were harvested from each test at the appropriate stage of maturity. Forage samples were collected the first fall after planting at 60-63 DAP, and forage and hay samples were collected the following spring at 269-333 DAP. Samples were placed in frozen storage at the test sites and later shipped on dry ice to Ciba-Geigy (Greensboro, NC), where samples were stored at -20EC and prepared for analysis. Samples were later shipped frozen the analytical laboratories (EN-CAS Analytical Laboratories, Winston-Salem, NC or EPL-BioAnalytical Services, Harristown, IL), where samples were stored frozen prior to analysis.

B.3. Analytical Methodology

Samples of alfalfa forage and hay were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-454 B), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, residues are extracted and base hydrolyzed by refluxing for 1 hour with NH_4OH/MeOH (20:80, v/v) and filtered. Residues are concentrated and oxidized to 2,4-DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, sodium meta-bisulfite is added to deactivate the $KMnO_4$, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using diazomethane. Residues are then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and analyzed by GC/ECD, using external standards. The validated method LOQ is 0.05 ppm for residues in/on wheat forage, and an LOD was not reported.

In conjunction with the analysis of field trial samples, the above method was validated using control samples of alfalfa forage and hay fortified with propiconazole at 0.05-0.50 ppm.

C. RESULTS AND DISCUSSION

In a total of 5 alfalfa field rotational crop trials conducted in 1989, propiconazole (3.6 lb/gal EC) was applied to winter wheat in the spring as a single broadcast foliar application at Feekes Growth Stages 7-9. Propiconazole was applied at each test site at 0.11 lb ai/A, and two sites also had additional plots with application rates at 0.22, 0.33 and 0.55 lb ai/A. These application rates were reported to correspond to 1x, 2x, 3x, and 5x the maximum labeled application rate for wheat. All applications were made using ground equipment at volumes of 15-23 gal/A. The wheat was grown to maturity and harvested, and a rotational crop of alfalfa was replanted the same year at PBIs of 72-109 days and grown using standard agricultural practices. A single control and single or duplicate treated samples of forage first cut in the fall at 60-63 DAP, and forage and hay samples also collected the following spring at 269-333 DAP.

The GC/ECD method (Method AG-454 B) used to determine propiconazole residues in/on alfalfa forage and hay was adequately validated in conjunction with the field sample analyses. Control samples were fortified with propiconazole at 0.05-0.50 ppm and recoveries averaged 85 $\pm$ 16 % for forage and 86 $\pm$ 21 % for hay (Table C.1). Apparent residues of propiconazole were <LOQ in/on all control samples, with the exception of one control sample from a 1x rate with a residue of 0.05 ppm. The validated method LOQ for propiconazole is 0.05 ppm, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided.

Samples were stored frozen for a maximum of 35 months (Table C.2). Adequate storage stability data are available indicating the weathered residues of propiconazole and its metabolites are stable for up to 38 months at -20° C in grass forage, straw, and seed (DP Barcode D210742, 3/15/95, M. Rodriguez). These data will support the storage intervals and conditions for the current alfalfa field trials.

Following a single application of propiconazole (EC) at 0.11 lb ai/A (1x rate) to a primary crop of winter wheat in 5 tests, total propiconazole residues in rotational alfalfa forage and hay from PBIs of 72-109 days were <0.05-0.07 ppm in forage (fall and spring) and <0.05-0.08 ppm in hay (Table C.3). Average residues were 0.04 ppm in both alfalfa forage and hay at the 1x rate (Table C.4). For the 0.22 lb ai/A rate (2x), residues were <0.05-0.07 ppm in forage and hay. For the 0.33 lb ai/A rate (3x), residues were <0.05-0.07 ppm in forage and <0.05-0.09 ppm in hay. For the 0.55 lb ai/A rate (5x), residues were 0.10-0.14 ppm in the initial fall forage and <0.05-0.06 ppm in spring forage and <0.05-0.09 ppm in spring hay.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

TABLE C.1. Summary of Storage Conditions

Matrix	Storage Temp. (°C)	Actual Storage Duration (months) [1]	Limit of Demonstrated Storage Stability (days) [2]
Forage	-20	26-35	38
Hay			

[1] From harvest to extraction for analysis.
[2] DP Barcode D210742, 3/15/95, M. Rodriguez.

TABLE C.2. Summary of Method Recoveries of propiconazole from Rotational Alfalfa Samples.

Matrix	Spike level (mg/kg)	Sample size (n)	Recoveries (%)	Mean ∀ std dev
Forage	0.05-0.50	12	90, 63, 72, 74, 89, 113, 93, 85, 75, 69, 112, 87	85 ± 16
Hay	0.05-0.50	11	120, 116, 85, 91, 76, 112, 74, 71, 59, 73, 65	86 ± 21

TABLE C.3. Residues in Rotational Alfalfa Forage and Hay Following a Primary Wheat Crop Treated with Propiconazole (EC).

Location (County, State, Year)	EPA Region	Crop/ Variety	Total Rate (lb ai/A)	PBI [1] (days)	Harvest Interval		Alfalfa Commodity	Propiconazole Residues (ppm) [4]
					DAT [2]	DAP [3]		
Champaign, IL, 1989 04-FR-003-89	5	Peak	0.110	72	135	63	Forage	0.06, 0.07
					405	333	Forage	0.07, <0.05
					405	333	Hay	<0.05, <0.05
			0.220	72	135	63	Forage	0.07
					405	333	Forage	0.06
					405	333	Hay	<0.05
			0.330	72	135	63	Forage	0.06
					405	333	Forage	0.07
					405	333	Hay	<0.05
			0.550	72	135	63	Forage	0.14
					405	333	Forage	0.06
					405	333	Hay	<0.05
Bannock, ID, 1989 0W-FR-607-89	11	Cerrex/ Ranger	0.110	106	375	269	Forage	<0.05, <0.05
							Hay	0.05, 0.05
York, NE, 1989 MW-FR-602-89	5	Miller/ Emerald	0.110	77	137	60	Forage	0.05, <0.05
					380	303	Forage	<0.05, <0.05
					380	303	Hay	0.08, <0.05
			0.220	77	137	60	Forage	<0.05
					380	303	Forage	<0.05
					380	303	Hay	0.06, 0.07
			0.330	77	137	60	Forage	<0.05
					380	303	Forage	<0.05
					380	303	Hay	0.06, 0.09
			0.550	77	137	60	Forage	0.10
					380	303	Forage	<0.05
					380	303	Hay	0.08, 0.09
Fayette, OH, 1989 NE-FR-201-89	5	Madison	0.110	73	134	61	Forage	0.05, <0.05
					373	300	Forage	<0.05, 0.06
					373	300	Hay	<0.05, <0.05
Kent, MD, 1989 NE-FE-302-89	1	Drummer	0.110	109	170	61	Forage	<0.05, 0.05
					381	272	Forage	0.05, <0.05
					381	272	Hay	0.06, 0.06

1 PBI = plant-back interval.
2 DAT = days after treatment; Forage samples were first collected in the fall and the following spring.
3 DAP = days after planting.
4 Residues of propiconazole determined as DCBA and expressed in parent equivalents. The LOQ for propiconazole residues in/on alfalfa is 0.05 ppm. The LOD was not reported.

TABLE C.4. Summary of Residue Data in Rotational Alfalfa

Commodity	Total Rate (lb ai/A)	PBI (days)	Residue Levels (ppm) [1]						
			n	Min.	Max.	HAFT[2]	Median (STMdR[3])	Mean (STMR[3])	Std. Dev.
Fall Forage	0.110	72-109	8	<0.05	0.07	0.07	0.05	0.04	0.02
Spring Forage			10	<0.05	0.07	0.05	0.03	0.04	0.02
Spring Hay			10	<0.05	0.08	0.06	0.04	0.04	0.02
Fall Forage	0.220	72-77	2	<0.05	0.07	0.07	0.05	0.05	0.03
Spring Forage			2	<0.05	0.06	0.06	0.04	0.04	0.02
Spring Hay			3	<0.05	0.07	0.07	0.06	0.05	0.02
Fall Forage	0.330	72-77	2	<0.05	0.06	0.06	0.04	0.04	0.02
Spring Forage			2	<0.05	0.07	0.07	0.05	0.05	0.03
Spring Hay			3	<0.05	0.09	0.08	0.06	0.06	0.03
Fall Forage	0.550	72-77	2	0.10	0.14	0.14	0.12	0.12	0.03
Spring Forage			2	<0.05	0.06	0.06	0.04	0.04	0.02
Spring Hay			3	<0.05	0.09	0.09	0.08	0.07	0.04

1 The LOQ for propiconazole residues in/on alfalfa is 0.05 ppm. The LOD was not reported..
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue. For calculation of the median, mean and standard deviation, 2 the LOQ was used for residues reported at <LOQ.

D. CONCLUSION

The extended field rotational crop data on alfalfa are adequate, but the number of field trials conducted at the reported 1x rate is limited. A total of 12 alfalfa field trails are required; however, only 5 were conducted at the 1x rate.

E. REFERENCES

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

DP Barcode: D279300
Subject: Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From: Y. Donovan
To: S. Lewis/J. Guerry
Dated: 8/18/05
MRID: None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 5F4498 (superseded by PP#2F6371)
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, HED Yan Donovan	Date: 5/31/06
Approved by	Susan Hummel, Branch Senior Scientist Susan Hummel	Date: 5/31/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 4/28/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

43640401 Ross, J.A. (1994) Propiconazole – Magnitude of Residues in Wheat and Raw Agricultural commodities and Processed Fractions of Rotational Grain Alfalfa and Alfalfa Following application of Tilt® 3.6 E to Wheat: Lab Project Number: ABR-92089. Unpublished study prepared by Ciba-Geigy Corporation. 885 p.

EXECUTIVE SUMMARY:

In 15 field trials conducted throughout the U.S. in 1989 and 1990, propiconazole (3.6 lb/gal EC) was applied to winter wheat in the spring as a single broadcast foliar application around emergence of the flag leaf (Feekes Growth Stages 7-9). Propiconazole was applied at each test site at 0.11 lb ai/A, but selected sites also had additional plots with application rates at 0.22 lb ai/A (9 tests), 0.33 lb ai/A (5 tests), and 0.55 lb ai/A (5 tests). These application rates were reported to correspond to 1x, 2x, 3x, and 5x the maximum labeled application rate. All applications were made using ground equipment at volumes of 4-25 gal/A. Single control and treated samples of wheat forage were harvested from each site on the day of application (0 DAT). Samples were stored frozen from collection to analysis for up to 36 months, an interval which are supported by available storage stability data.

Residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on wheat forage were determined using a GC/ECD method (Method AG-454 B). This method is an updated version of the current tolerance enforcement method and was adequately validated in conjunction with the analysis of field trial samples. For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and cleaned-up using an acidic alumina cartridge. Methylated DBCA is determined by GC/ECD, using external standards, and residues are expressed in parent equivalents. The validated method LOQ is 0.05 ppm, and an LOD was not reported.

Following a single application of propiconazole (EC) at 0.11 lb ai/A (1x rate), total propiconazole residues were 1.5-6.9 ppm in/on 15 samples of wheat forage harvested at 0 DAT. The number of trials and the geographic representation of the trials are adequate. Following a

BB

single broadcast application to winter wheat at 0.11 lb ai/A, total propiconazole residues were 1.5-6.9 ppm in/on forage at 0 DAT.

A previously submitted and reviewed study on wheat concluded that at the same application rate (0.11 lb ai/A), residues on wheat forage ranged from from <0.05 ppm (nondetectable) to 2.0 ppm in/on wheat forage at 30 days PHI (D271790).

In the exaggerated rate field trials, residues in/on forage at 0 DAT were 3.9-14 ppm in/on 9 samples from the 2x rate, 12-19 ppm in/on 5 samples from the 3x rate, and 14-43 ppm in/on 5 samples from the 5x rate. Average residues in/on forage were 4.33 ppm for the 1x rate, 8.20 ppm for the 2x rate, 15.2 ppm for the 3x rate, and 26.2 ppm for the 5x application rate. Residue decline data were not collected

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the wheat field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited no deviations from GLP compliance.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities, including tolerances of 0.1 and 1.5 ppm on wheat grain and straw [40 CFR §180.434(a)].

Syngenta has previously proposed tolerances (PP# 5F4498) for inadvertent residues on sorghum and alfalfa planted in rotation with propiconazole-treated wheat. This petition has been superseded by PP#2F6371, in which tolerances are being requested on a wide variety of crops including wheat and sorghum (DP Barcode D279300, Y. Donovan, 8/18/2005). The current submission includes residue data on forage from a primary crop of wheat, along with residue data on rotational crops of sorghum and alfalfa that are presented in separate DERs (43640401.der2 and 43640401.der3).

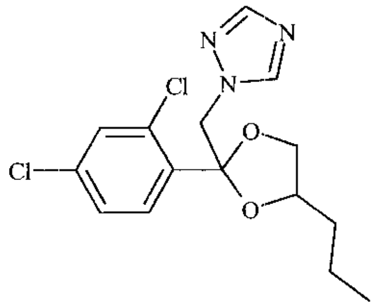
TABLE A.1. Nomenclature of Propiconazole	
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EP	3.6 lb/gal EC (Tilt Fungicide, EPA Reg. No. 100-617)
Regulated Metabolite	None
Common name	N/A
IUPAC name	N/A
CAS #	N/A

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.

Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No.:43698701
pH	4.9 @ 25°C (1% aqueous tdispersion)	MRID No.:43698701
Density	1.289 g/cm3 typical @ 20°C	MRID No.: 43698701
Water solubility (20°C)	0.10 g/L at 20°C	MRID No.: 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. n-hexane = 47 g/L	MRID No.: 42030201
Vapor pressure at 25°C	4.2 x 10^{-7} mm Hg @ 25°C	MRID No.: 41720301
Dissociation constant (pK_a)	1.09	MRID No.: 43698701
Octanol/water partition coefficient Log(K_{OW}) (25 °C)	3.72 @ pH 6.6	MRID No.: 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No.: 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Wheat was grown and maintained at each test site using typical agricultural practices for the respective geographical region (Table B.1.1). Monthly rainfall and irrigation data were provided for each site, along with temperature data. No usual weather conditions were noted that would have an adverse effect on the field trial data. Information was also provided on maintenance chemicals and other pesticides used at each site. Soil types were provided for each site, but no other soil data were provided. However, as the application to wheat was foliar, additional information on soil characteristics are not required. The study use pattern for propiconazole (3.6 lb/gal EC) on the primary winter wheat crop is reported in Table B.1.2.

TABLE B.1.1. Trial Site Conditions.

Trial Identification (County, State; Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC[2] (meq/g)
Fresno, CA, 1989	Sandy Loam	NR	NR	NR
Washington, MS, 1989	Silty Clay Loam	NR	NR	NR
Indian River, FL, 1989	Sand	NR	NR	NR
AR, 1989	Silty Clay Loam	NR	NR	NR
TX, 1989	Silty Clay	NR	NR	NR
Carter, OK, 1989	Loam	NR	NR	NR
Mitchell, GA, 1989	Sandy Clay Loam	NR	NR	NR
Madison, LA, 1989	Clay	NR	NR	NR
Shelby, MO, 1990	Silty Clay Loam	NR	NR	NR
Pawnee, KS, 1989	Silt Loam	NR	NR	NR
Champaign, IL, 1989	Silty Clay Loam	NR	NR	NR
Bannock, ID, 1989	Silty Clay Loam	NR	NR	NR
York, NE, 1989	Silt Loam	NR	NR	NR
Fayette, OH, 1989	Loam	NR	NR	NR
Kent, MD, 1989	Loam	NR	NR	NR

[1] These parameters are optional except in cases where their value affects the use pattern for the chemical.

[2] Cation exchange capacity. NR = Not Reported.

TABLE B.1.2. Study Use Pattern on Wheat.

Location (County, State: Year) Trial ID	End-use Product	Application Information [1]			Tank Mix/ Adjuvants
		Method; Timing	Volume (GPA)	Rate (lb ai/A)	
Fresno, CA, 1989 02-RF-004-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	25	0.11 0.22	None
Washington, MS 1989 03 FR-003-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	15	0.11 0.22 0.33 0.55	None
Indian River, FL 1989 07-FR-002-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	15	0.11	None
Crittenden, AR, 1989 05-FR-102-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	15	0.11	None
Burleson, TX, 1989 0S-FR-203-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	15	0.11 0.33 0.55	None
Carter, OK, 1989 0S-FR-501-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	4	0.11 0.22	None
Micthell, GA, 1989 0S-FR-834-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	15	0.11 0.22	None
Madison, LA, 1989 0S-FR-901-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8-9	25	0.11 0.22	None
Shelby, MO, 1990 MW-FR-202-90	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	20	0.11 0.22	None
Pawnee, KS 1989 MW-FR-301-90	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	15	0.11 0.22	None
Champaign, IL, 1989 04-FR-003-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 7-8	15	0.11 0.22 0.33 0.55	None
Bannock, ID, 1989 0W-FR-607-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	15	0.11	None
York, NE, 1989 MW-FR-602-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	20	0.11 0.22 0.33 0.55	None
Fayette, OH, 1989 NE-FR-201-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	20	0.11 0.33 0.55	None
Kent, MD, 1989 NE-FE-302-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 9	23	0.11	None

[1] All applications were made using ground equipment.

TABLE B.1.3.	Trial Numbers and Geographical Locations.		
NAFTA Growing Zones[1]	Wheat Forage		
	Submitted	Requested	
		Canada	U.S.
1	1	---	--
2	1	---	1
3	1	---	--
4	3	---	1
5	4	---	5
6	2	---	1
7	--	---	5
8	1	---	6
9	--	---	--
10	1	---	--
11	1	---	1
12	--	---	--
Total	15	NA	20

[1] Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the use is for only in the U.S.
NA = Not applicable

B.2. Sample Handling and Preparation

Single control and treated samples of wheat forage (≥ 5lb/sample) were harvested from each test on the day of application (0 DAT) at Feekes Growth Stages 7-9. Samples frozen shortly after harvest and Adequate storage stability data are available indicating the weathered residues of propiconazole and its metabolites are stable for up to 38 months at -20° C in grass forage, straw, and seed (DP Barcode D210742, 3/15/95, M. Rodriguez). These data will support the storage intervals and conditions for mint hay in the current field trials.

B.3. Analytical Methodology

Forage samples were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-454B), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2.4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, residues are extracted and base hydrolyzed by refluxing for 1 hour with NH_4OH/MeOH (20:80, v/v) and filtered. Residues are concentrated and oxidized to 2,4-DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, sodium meta-bisulfite is added to deactivate the $KMnO_4$, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using diazomethane. Residues are then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and analyzed by GC/ECD, using external standards. The validated method LOQ is 0.05 ppm for residues in/on wheat forage, and an LOD was not reported.

In conjunction with the analysis of field trial samples, the above method was validated using control samples of wheat forage fortified with propiconazole at 1.0-30 ppm.

C. RESULTS AND DISCUSSION

In 15 field trials conducted throughout the U.S. in 1989-1990, propiconazole (3.6 lb/gal EC) was applied to winter wheat in the spring as a single broadcast foliar application around emergence of the flag leaf (Feekes Growth Stages 7-9). Propiconazole was applied at each test site at 0.11 lb ai/A, but selected sites also had additional plots with application rates at 0.22 lb ai/A (9 tests), 0.33 lb ai/A (5 tests), and 0.55 lb ai/A (5 tests). The application rates were reported to correspond to 1x, 2x, 3x, and 5x the maximum labeled application rate. All applications were made using ground equipment at volumes of 4-25 gal/A. Single control and treated samples of wheat forage were harvested from each site on the day of application (0 DAT).

The GC/ECD method (Method AG-454 B) used to determine propiconazole residues in/on wheat forage was adequately validated in conjunction with the analysis of field trial samples. The recovery of propiconazole averaged 78 ± 12% from control samples of wheat forage fortified with propiconazole at 1.0-30.0 ppm (Table C.1). Apparent residues of propiconazole were <LOQ in/on all but two control samples, which had apparent residues of 0.06 ppm and 0.66 ppm. The validated method LOQ for propiconazole is 0.05 ppm, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided.

Forage samples were stored frozen for up to 36 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating the weathered residues of propiconazole and its metabolites are stable for up to 38 months at -20° C in grass forage (DP Barcode D210742, 3/15/95, M. Rodriguez). These data will support the storage intervals and conditions for the current field trials.

Following an application of propiconazole (EC) at 0.11 lb ai/A (1x rate), total propiconazole residues were 1.5-6.9 ppm in/on 15 samples of wheat forage harvested at 0 DAT (Table C.3). In the exaggerated rate field trials, residues at 0 DAT were 3.9-14 ppm in/on 9 samples from the 2x application, 12-19 ppm in/on 5 samples from the 3x application, and 14-43 ppm in/on 5 samples from the 5x application. Average residues were 4.33 ppm for the 1x rate, 8.20 ppm for the 2x rate, 15.2 ppm for the 3x rate, and 26.2 ppm for the 5x application rate (Table C.4). No residue decline data were collected.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data

TABLE C.1. Summary of Method Recoveries of Propiconazole from Wheat Forage.

Analyte	Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ± std dev (%)
Propiconazole	Wheat	1.0, 2.0	4	78, 81, 73, 71	78 ± 12

TABLE C.1. Summary of Method Recoveries of Propiconazole from Wheat Forage.

Analyte	Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ± std dev (%)
	forage	5.0	4	87, 116, 84, 67,	
		10, 15	5	70, 65, 76, 77, 79	
		25, 30	2	69, 77	

TABLE C.2 Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1] (months)	Interval of Demonstrated Storage Stability (days)[2]
Wheat forage	-20	11-36	38

1 From harvest to extraction for analysis.
2 DP Barcode D210742, 3/15/95, M. Rodriguez.

TABLE C.3. Residue Data on Wheat Forage from Field Trials with Propiconazole (EC).

Trial ID (County, State, Year)	Zone	Wheat Type/ Variety	Total Rate (lb ai/A)	PHI (days)	Commodity	Total Propiconazole Residues (ppm)[1]
Fresno, CA, 1989 02-RF-004-89	10	Winter/ Proband 775	0.11	0	Forage	3.9
			0.22	0	Forage	7.6
Washington, MS, 1989 03 FR-003-89	4	Winter/ Florida 302	0.11	0	Forage	2.1
			0.22	0	Forage	3.9
			0.33	0	Forage	12
			0.44	0	Forage	14
Indian River, FL, 1989 07-FR-002-89	3	Winter/ Florida 301	0.11	0	Forage	6.9
Crittenden, AR, 1989 05-FR-102-89	4	Winter/ Caldwell	0.11	0	Forage	2.5
Burleson, TX, 1989 0S-FR-203-89	6	Winter/ MIT	0.11	0	Forage	5.6
			0.33	0	Forage	19
			0.55	0	Forage	31
Carter, OK, 1989 0S-FR-501-89	6	Winter/ TAM W101	0.11	0	Forage	2.4
			0.22	0	Forage	8.2
Mitchell, GA, 1989 OS-FR-834-89	2	Winter/ Florida 302	0.11	0	Forage	5.7
			0.22	0	Forage	9.8
Madison, LA, 1989 OS-FR-901-89	4	Winter/ Florida 302	0.11	0	Forage	6.7
			0.22	0	Forage	7.9
Shelby, MO, 1990 MW-FR-202-90	5	Winter/ Caldwell	0.11	0	Forage	2.4
			0.22	0	Forage	4.6
Pawnee, KS, 1990 MW-FR-301-90	8	Winter/ Abilene	0.11	0	Forage	6.0
			0.22	0	Forage	14
Champaign, IL, 1989 04-FR-003-89	5	Winter/ Noble Bear	0.11	0	Forage	3.7
			0.22	0	Forage	3.9
			0.33	0	Forage	12
			0.55	0	Forage	22
Bannock, ID, 1989 0W-FR-607-89	11	Winter/ Stephens	0.11	0	Forage	1.5
York, NE, 1989 MW-FR-602-89	5	Winter/ Siouxland	0.11	0	Forage	6.5
			0.22	0	Forage	14
			0.33	0	Forage	19
			0.55	0	Forage	43

TABLE C.3. Residue Data on Wheat Forage from Field Trials with Propiconazole (EC).

Trial ID (County, State; Year)	Zone	Wheat Type/ Variety	Total Rate (lb ai/A)	PHI (days)	Commodity	Total Propiconazole Residues (ppm)[1]
Fayette, OH, 1989 NE-FR-201-89	5	Winter/ Cardinal	0.11	0	Forage	4.6
			0.33	0	Forage	14
			0.55	0	Forage	21
Kent, MD, 1989 NE-FE-302-89	1	Winter/ Tyler	0.11	0	Forage	4.4

1 Total propiconazole residues were determined as DCBA and expressed in parent equivalents. The LOQ for propiconazole residues in/on wheat is 0.05 ppm. The LOD was not reported.

TABLE C.4. Summary of Residue Data from Wheat Field Trials with Propiconazole (EC).

Commodity	Total Applic. Rate (lb ai/A)	EP	PHI (days)	Residue Levels (ppm)[1]						
				n	Min.	Max.	HAFT[2]	Median (STMdR)[3]	Mean (STMR)[4]	Std. Dev.
Forage	0.110	3.6 lb/gal EC	0	15	1.5	6.9	6.9	4.40	4.33	1.84
	0.220		0	9	3.9	14.0	14.0	7.9	8.2	3.9
	0.330		0	5	12.0	19.0	19.0	14.0	15.2	3.6
	0.550		0	5	14.0	43.0	43.0	22.0	26.2	11.2

1 The LOQ is 0.05 ppm.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

D. CONCLUSION

The wheat field trial data are adequate. Following a single broadcast application to winter wheat at 0.11 lb ai/A, total propiconazole residues were 1.5-6.9 ppm in/on forage at 0 DAT.

E. REFERENCES

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

DP Barcode: D279300
Subject: Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From: Y. Donovan
To: S. Lewis/J. Guerry
Dated: 8/18/05
MRID: None

DP Barcode: D271790
Subject: Propiconazole (122101): Magnitude of Residues in/on wheat for The Registration of Stratego™ use on wheat.
From: Y. Donovan
To: S. Lewis/J. Guerry
Dated: 02/02/05
MRID: 44757208

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 5F4498 (superseded by PP#2F6371)
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator Yan Donovan, Chemist
Yan Donovan Date:5/31/06

Approved by Susan Hummel, Branch Senior Scientist
Susan Hummel Date:5/31/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 4/28/2006). The DER was reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

43640401 Ross, J.A. (1994) Propiconazole – Magnitude of Residues in Wheat and Raw Agricultural commodities and Processed Fractions of Rotational Grain Sorghum and Alfalfa Following application of Tilt® 3.6 E to Wheat: Lab Project Number: ABR-92089. Unpublished study prepared by Ciba-Geigy Corporation. 885 p.

EXECUTIVE SUMMARY:

In a total of 10 sorghum field rotational crop trials conducted in 1989 and 1990, propiconazole (3.6 lb/gal EC) was applied to winter wheat in the spring as a single broadcast foliar application at approximately Feekes Growth Stage 8. Propiconazole was applied at each test site at 0.11 lb ai/A, and selected sites also had additional plots with application rates at 0.22 lb ai/A (7 tests), 0.33 lb ai/A (1 test), and 0.55 lb ai/A (1 test). These application rates reportedly correspond to 1x, 2x, 3x, and 5x the maximum labeled application rate for wheat. All applications were made using ground equipment at volumes of 4-25 gal/A. The wheat was grown to maturity and harvested, and a rotational crop of sorghum was replanted the same year at plant-back intervals (PBIs) of 60-67 days at 8 sites, 75 days at one site, and 100 days at one site. The sorghum was grown using standard agricultural practices, and a single control and single or duplicate treated samples of sorghum forage and hay were collected at 59-76 days after planting (DAP), silage-stage forage was collected at 75-156 DAP, and fodder and grain were collected at 103-173 DAP. Samples were stored frozen for up to 40 months, an interval supported by available storage stability data.

Residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on sorghum commodities were determined using a GC/ECD method (Method AG-454 B). This method is an updated version of the current tolerance enforcement method and was adequately validated in conjunction with the analysis of field trial samples. The validated method LOQ is 0.05 ppm, and an LOD was not reported.

Following an application of propiconazole (EC) at 0.11 lb ai/A (1x rate) in 10 tests, total propiconazole residues in rotational sorghum commodities from a ~60-day PBI were <0.05-0.06 ppm in forage, <0.05-0.25 ppm for hay, <0.05-0.08 ppm in silage-stage forage, and <0.05-0.18 ppm in fodder. Residues in grain were <0.05 ppm with the exception of the two samples from the FL site, which had residues at 0.06 and 0.17 ppm. Average residues from the 1x rate were 0.03 ppm in forage and grain and 0.05 ppm in hay and fodder.

The extended field rotational crop data on sorghum are adequate and indicate that tolerances on rotational sorghum with a PBI around 60 DAT will be covered by current temporary tolerances for sorghum grain and stover.

Following an application of propiconazole at 0.22 lb ai/A in 7 tests (2x rate), residues in rotational sorghum were <0.05-0.11 ppm in forage, <0.05-0.14 ppm in hay, <0.05 ppm in silage stage forage, <0.05-0.06 ppm in fodder, and <0.05 ppm in grain. In the two tests conducted at 0.33 and 0.55 lb ai/A (3x and 5x), residues were <0.05 ppm all forage, hay, fodder and grain samples, with the exception of one grain sample (0.06 ppm) from the 5x test. On average, residue levels are the highest at PBI of 60-67 days, lower at 75 days, lowest at 100 days.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in this study, the field rotational crop data on sorghum are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated GLP, quality assurance, and data confidentiality statements were provided. No deviations from regulatory requirements were noted that would impact the study results or their interpretation.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities, including time-limited tolerances of 0.2 and 1.5 ppm on sorghum grain and stover [40 CFR §180.434(b)].

Syngenta has previously proposed tolerances (PP# 5F4498) for inadvertent residues on sorghum and alfalfa planted in rotation with propiconazole-treated wheat. This petition has been superseded by PP#2F6371, in which tolerances are being requested on a wide variety of crops including wheat and sorghum (DP Barcode D279300, Y. Donovan, 8/18/2005). The current submission includes residue data on forage, hay, grain and fodder of sorghum planted in rotation with propiconazole-treated wheat.

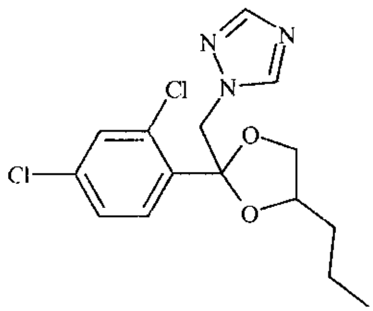
TABLE A.1. Nomenclature of Propiconazole	
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EP	3.6 lb/gal EC (Tilt Fungicide, EPA Reg. No. 100-617)
Regulated Metabolite	None
Common name	N/A
IUPAC name	N/A
CAS #	N/A

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.

Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No.:43698701
pH	4.9 @ 25°C (1% aqueous tdispersion)	MRID No.:43698701
Density	1.289 g/cm3 typical @ 20°C	MRID No.: 43698701
Water solubility (20°C)	0.10 g/L at 20°C	MRID No.: 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. n-hexane = 47 g/L	MRID No.: 42030201
Vapor pressure at 25°C	4.2×10^{-7} mm Hg @ 25°C	MRID No.: 41720301
Dissociation constant (pK_a)	1.09	MRID No.: 43698701
Octanol/water partition coefficient Log(K_{OW}) (25 °C)	3.72 @ pH 6.6	MRID No.: 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No.: 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

The primary crop of winter wheat and the rotational crop of sorghum were grown and maintained at each test site using typical agricultural practices for the respective geographical region (Table B.1.1). Monthly rainfall and irrigation data were provided for each site, along with temperature data. No usual weather conditions were noted that would have an adverse effect on the field trial data. Information was also provided on maintenance chemicals and other pesticides used at each site. Soil types were provided for each site, but no other soil data were provided. However, as the application to wheat was foliar, additional information on soil characteristics are not required.

The study use pattern for propiconazole (3.6 lb/gal EC) on the primary winter wheat crop is reported in Table B.1.2. At each test site, winter wheat was treated once in the spring with a broadcast application of propiconazole (2.6 lb/gal EC) at 0.11 lb ai/A, and selected sites also had additional plots with application rates at 0.22 lb ai/A (7 tests), 0.33 lb ai/A (1 test), and 0.55 lb ai/A (1 test). These rates were reported to correspond to 1x, 2x, 3x and 5x the maximum use rate on wheat. The wheat crop was grown to maturity and harvested, and a rotational crop of sorghum was planted at PBIs of 60-64 days at 8 sites and at PBIs of 75 and 100 days at the other two sites.

TABLE B.1.1. Trial Site Conditions.

Trial Identification (County, State; Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC[2] (meq/g)
Fresno, CA, 1989	Sandy Loam	NR	NR	NR
Washington, MS, 1989	Silty Clay Loam	NR	NR	NR
Indian River, FL, 1989	Sand	NR	NR	NR
Crittenden, AR, 1989	Silty Clay Loam	NR	NR	NR
Burleson, TX, 1989	Silty Clay	NR	NR	NR
Carter, OK, 1989	Loam	NR	NR	NR
Mitchell, GA, 1989	Sandy Clay Loam	NR	NR	NR
Madison, LA, 1989	Clay	NR	NR	NR
Shelby, MO, 1990	Silty Clay Loam	NR	NR	NR
Pawnee, KS, 1989	Silt Loam	NR	NR	NR

[1] These parameters are optional except in cases where their value affects the use pattern for the chemical.
[2] Cation exchange capacity. NR = Not Reported.

TABLE B.1.2. Study Use Pattern on Primary Crop of Winter Wheat.

Location (County, State) Year, Trial ID	End-use Product	Application Information				Rotational Crop
		Method; Timing, Rotational Crop	Vol. (GPA) [1]	Application Rate (lb ai/A)	PBI [2] (days)	
Fresno, CA, 1989 02-RF-004-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	25	0.11 0.22	100	Sorghum
Washington, MS, 1989 03 FR-003-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	15	0.11 0.22	61	Sorghum
Indian River, FL 1989 07-FR-002-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	15	0.11	60	Sorghum
Crittenden, AR, 1989 05-FR-102-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	15	0.11	60	Sorghum
Burleson, TX, 1989 0S-FR-203-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	15	0.11 0.33 0.55	67	Sorghum
Carter, OK, 1989 0S-FR-501-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	4	0.11 0.22	64	Sorghum
Micthell, GA, 1989 0S-FR-834-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	15	0.11 0.22	75	Sorghum
Madison, LA, 1989 0S-FR-901-89	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8-9	25	0.11 0.22	61	Sorghum
Shelby, MO, 1990 MW-FR-202-90	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	20	0.11 0.22	60	Sorghum
Pawnee, KS 1989 MW-FR-301-90	3.6 lb/gal EC	Broadcast foliar application at Feekes Growth Stage 8	15	0.11 0.22	62	Sorghum

[1] All applications were made using ground equipment.
[2] Plant-back Interval.

TABLE B.1.3.1 Trial Numbers and Geographical Locations		
NAFTA Growing Zones[1]	Rotational Sorghum	
	Submitted	Requested
1	--	--
2	1	1
3	1	--
4	3	1
5	1	4
6	2	2
7	--	1
8	1	3
9	--	--
10	1	--
11	--	--
12	--	--
Total	10	12

[1] Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the proposed use is for the US only.

B.2. Sample Handling and Preparation

Single control and single or duplicate treated samples of sorghum forage, hay, silage, fodder and grain were harvested from each test at the appropriate stage of maturity. Forage and hay were collected 59-76 DAP, silage-stage forage was collected 75-156 DAP, and fodder and grain were collected 103-173 DAP. After collection, samples were placed in frozen storage at the test sites and later shipped on dry ice to Ciba-Geigy (Greensboro, NC), where samples were stored at -20EC and prepared for analysis. Samples were later shipped frozen the analytical laboratories (EN-CAS Analytical Laboratories, Winston-Salem, NC or EPL-BioAnalytical Services, Harristown, IL), where samples were stored frozen prior to analysis.

B.3. Analytical Methodology

Samples of sorghum forage, hay, grain and fodder were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-454B), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, residues are extracted and base hydrolyzed by refluxing for 1 hour with NH_4OH/MeOH (20:80, v/v) and filtered. Residues are concentrated and oxidized to 2,4-DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, sodium meta-bisulfite is added to deactivate the $KMnO_4$, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using diazomethane. Residues are then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and analyzed by GC/ECD, using external standards. The validated method LOQ is 0.05 ppm for residues in/on wheat forage, and an LOD was not reported.

In conjunction with the analysis of field trial samples, the above method was validated using control samples fortified with propiconazole at 0.05-0.20 ppm for grain, 0.05-5.0 ppm for forage, 0.05-2.0 ppm for hay, and 0.05-1.0 ppm for fodder.

C. RESULTS AND DISCUSSION

The numbers of the sorghum field rotational crop trials are adequate, and the geographic locations follow common locations for the primary crop of winter wheat. In a total of 10 sorghum field rotational crop trials conducted in 1989 and 1990, propiconazole (3.6 lb/gal EC) was applied to winter wheat in the spring as a single broadcast foliar application at approximately Feekes Growth Stage 8. Propiconazole was applied at each test site at 0.11 lb ai/A, and selected sites also had additional plots with application rates at 0.22 lb ai/A (7 tests), 0.33 lb ai/A (1 test), and 0.55 lb ai/A (1 test). The application rates were reported to correspond to 1x, 2x, 3x, and 5x the maximum labeled application rate for wheat. All applications were made using ground equipment at volumes of 4-25 gal/A. The wheat was grown to maturity and harvested, and a rotational crop of sorghum was replanted the same year at PBIs of 60-67 days at 8 sites, 75 days at one site, and 100 days at the final site. The sorghum was grown using standard agricultural practices, and a single control and single or duplicate treated samples of sorghum forage and hay were collected 59-76 DAP, silage was collected 75-156 DAP and fodder and grain were collected 103-173 DAP.

The GC/ECD method (Method AG-454 B) used to determine propiconazole residues in/on sorghum forage, hay silage, fodder and grain was adequately validated in conjunction with the field sample analyses. Recoveries of propiconazole from each sorghum commodity averaged 81-91% with standard deviations of 10-19% (Table C.1). Apparent residues of propiconazole were <LOQ in/on control samples, with the exception of sorghum forage, hay and fodder samples from the FL trial, which had apparent residues of 0.05-0.10 ppm. The validated method LOQ for propiconazole in each commodity is 0.05 ppm, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided.

Samples were stored frozen for a maximum of 40 months (Table C.2). Adequate storage stability data are available indicating the weathered residues of propiconazole and its metabolites are stable for up to 38 months at -20° C in grass forage, straw, and seed (DP Barcode D210742, 3/15/95, M. Rodriguez). These data will support the storage intervals and conditions for the current sorghum field trials.

Following a single application of propiconazole (EC) at 0.11 lb ai/A (1x rate) to a primary crop of winter wheat in 10 tests, total propiconazole residues in rotational sorghum commodities from a ~60-day PBI were <0.05-0.06 ppm in forage, <0.05-0.25 ppm for hay, <0.05-0.08 ppm in silage-stage forage, and <0.05-0.18 ppm in fodder (Table C.3). Residue in mature sorghum grain were <0.05 ppm with the exception of the two samples from the FL site, which had residues at

0.06 and 0.17 ppm. Average residues from the 0.11 lb ai/A application were 0.03 ppm in forage and grain and 0.05 ppm in hay and fodder (Table C.4). Following an application of propiconazole to wheat at 0.22 lb ai/A in 7 tests (2x rate), residues in rotational sorghum were <0.05-0.11 ppm in forage, <0.05-0.14 ppm in hay, <0.05 ppm in silage stage forage, <0.05-0.06 ppm in fodder, and <0.05 ppm in grain. In the two tests conducted at 0.33 and 0.55 lb ai/A (3x and 5x), residues were <0.05 ppm all forage, hay, fodder and grain samples, with the exception of one grain sample (0.06 ppm) from the 5x test.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

TABLE C.1. Summary of Storage Conditions

Matrix	Storage Temp. (°C)	Actual Storage Duration (months) [1]	Limit of Demonstrated Storage Stability (days) [2]
Forage	-20	22-40	38
Hay			
Forage (silage stage)			
Fodder			
Grain			

1 From harvest to extraction for analysis.
2 DP Barcode D210742, 3/15/95, M. Rodriguez.

TABLE C.2. Summary of Method Recoveries of Propiconazole from Rotational Sorghum Commodities.

Matrix	Spike level (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std dev
Forage	0.05-5.0	10	74, 85, 88, 104, 102, 87, 89, 83, 90, 71	87 ± 10
Hay	0.05-2.0	11	95, 89, 113, 99, 64, 111, 62, 89, 94, 107, 81	91 ± 17
Forage (silage)	0.05-2.0	10	90, 84, 96, 86, 68, 88, 98, 73, 74, 87	84 ± 10
Fodder	0.05-1.0	11	87, 92, 108, 88, 72, 81, 85, 82, 87, 74, 108	88 ± 12
Grain	0.05-0.20	12	81, 79, 70, 59, 86, 55, 72, 83, 89, 83, 90, 130	81 ± 19

TABLE C.3. Residues in Rotational Sorghum Commodities Following a Primary Wheat Crop Treated with Propiconazole (EC).

Location (County, State, Year)	EPA Region	Crop/ Variety	Total Rate (lb ai/A)	PBI [1] (days)	Harvest Intervals DAT [2]	DAP [3]	Sorghum Commodity	Propiconazole Residues (ppm) [4]
Fresno, CA, 1989 02-RF-004-899	10	Funks/G-522DR	0.110	100	161	61	Forage	<0.05, 0.06
					161	61	Hay	0.10, 0.07
					256	156	Silage	<0.05, <0.05
					273	173	Fodder	<0.05, <0.05
					273	173	Grain	<0.05, <0.05
			0.220	100	161	61	Forage	0.11
					161	61	Hay	0.10
					256	156	Silage	<0.05
					273	173	Fodder	0.05
					273	173	Grain	<0.05
Washington, MS. 1989 03 FR-003-89	4	Funks/G-522DR	0.110	61	122	61	Forage	<0.05, <0.05
					122	61	Hay	<0.05,<0.05
					159	98	Silage	<0.05, <0.05
					186	125	Fodder	<0.05. <0.05
					186	125	Grain	<0.05, <0.05
			0.220	61	122	61	Forage	<0.05
					122	61	Hay	0.09
					159	98	Silage	<0.05
					186	125	Fodder	<0.05
					186	125	Grain	<0.05
Indian River, FL, 1989 07-FR-002-89	3	Sugar Drip	0.110	60	136	76	Forage	0.06, <0.05
					136	76	Hay	0.25, 0.13
					157	97	Silage	0.07, 0.08
					179	119	Fodder	0.13, 0.14
					179	119	Grain	0.17, 0.06
Crittenden, AR, 1989 05-FR-102-89	4	Asgro/Topaz	0.110	60	122	62	Forage	<0.05, <0.05
					125	65	Hay	<0.05, <0.05
					154	94	Silage	<0.05, <0.05
					190	130	Fodder	<0.05, <0.05
					190	130	Grain	<0.05, <0.05

TABLE C.3. Residues in Rotational Sorghum Commodities Following a Primary Wheat Crop Treated with Propiconazole (EC).

Location (County, State, Year)	EPA Region	Crop/ Variety	Total Rate (lb ai/A)	PBI [1] (days)	Harvest Intervals DAT [2]	DAP [3]	Sorghum Commodity	Propiconazole Residues (ppm) [4]
Burleson, TX, 1989 0S-FR-203-89	6	Funks/G-522DR	0.110	67	126	59	Forage	<0.05, <0.05
					126	59	Hay	<0.05, <0.05
					148	81	Silage	<0.05, <0.05
					177	110	Fodder	<0.05, 0.06
					177	110	Grain	<0.05, <0.05
			0.330	67	126	59	Forage	<0.05
					126	59	Hay	<0.05
					148	81	Silage	<0.05
					177	110	Fodder	<0.05
					177	110	Grain	<0.05
			0.550	67	126	59	Forage	<0.05
					126	59	Hay	<0.05
					148	81	Silage	<0.05
					177	110	Fodder	<0.05
					177	110	Grain	0.06
Carter, OK, 1989 0S-FR-501-89	6	Funks/G-522 A	0.110	64	124	60	Forage	<0.05, <0.05
					124	60	Hay	<0.05, <0.05
					139	75	Silage	<0.05, <0.05
					192	128	Fodder	0.18, <0.05
					192	128	Grain	<0.05, <0.05
			0.220	64	124	60	Forage	<0.05
					124	60	Hay	0.06
					139	75	Silage	<0.05
					192	128	Fodder	<0.05
					192	128	Grain	<0.05
Micthell, GA, 1989 oS-FR-834-89	2	Funks/G-522DR	0.110	75	135	60	Forage	<0.05,<0.05
					135	60	Hay	<0.05, <0.05
					161	86	Silage	<0.05, <0.05
					178	103	Fodder	<0.05, <0.05
					178	103	Grain	<0.05, <0.05
			0.220	75	135	60	Forage	<0.05
					135	60	Hay	0.14
					161	86	Silage	<0.05
					178	103	Fodder	<0.05
					178	103	Grain	<0.05
Madison, LA, 1989 oS-FR-901-89	4	Topaz	0.110	61	121	60	Forage	<0.05,<0.05
					121	60	Hay	<0.05, <0.05
					145	84	Silage	<0.05, <0.05
					187	126	Fodder	<0.05, <0.05
					187	126	Grain	<0.05, <0.05
			0.220	61	121	60	Forage	<0.05
					121	60	Hay	<0.05
					145	84	Silage	<0.05
					187	126	Fodder	<0.05
					187	126	Grain	<0.05

TABLE C.3. Residues in Rotational Sorghum Commodities Following a Primary Wheat Crop Treated with Propiconazole (EC).

Location (County, State, Year)	EPA Region	Crop/ Variety	Total Rate (lb ai/A)	PBI [1] (days)	Harvest Intervals DAT [2]	DAP [3]	Sorghum Commodity	Propiconazole Residues (ppm) [4]
Shelby, MO, 1990 MW-FR-202-90	5	Garst 5511	0.110	60	120	60	Forage	<0.05,<0.05
					123	63	Hay	<0.05, <0.05
					165	105	Silage	<0.05, <0.05
					185	125	Fodder	<0.05, <0.05
					185	125	Grain	<0.05, <0.05
			0.220	60	120	60	Forage	<0.05
					123	63	Hay	0.08
					165	105	Silage	<0.05
					185	125	Fodder	0.06
					185	125	Grain	<0.05
Pawnee, KS, 1990 MW-FR-301-90	8	Funks G-251	0.110	62	122	60	Forage	<0.05,<0.05
					122	60	Hay	<0.05, 0.15
					144	82	Silage	<0.05, <0.05
					172	110	Fodder	<0.05, <0.05
					172	110	Grain	<0.05, <0.05
			0.220	62	122	60	Forage	<0.05
					122	60	Hay	<0.05
					144	82	Silage	<0.05
					172	110	Fodder	<0.05
					172	110	Grain	<0.05

1 PBI = plant-back interval.
2 DAT= days after treatment.
3 DAP = days after planting.
4 Combined residues of propiconazole and its DCBA containing metabolites, converted to DCBA and expressed in parent equivalents. The LOQ for propiconazole residues in/on sorghum commodities is 0.05 ppm. The LOD was not reported.

TABLE C.4. Summary of Residue Data in Rotational Sorghum

Commodity	Total Rate (lb ai/A)	PBI (days)[4]	Residue Levels (ppm) [1] n	Min.	Max.	HAFT[2]	Median (STMdR[3])	Mean (STMR[3])	Std. Dev.
Forage	0.110	~60	20	<0.05	0.06	0.04	0.03	0.03	0.01
Hay			20	<0.05	0.25	0.19	0.03	0.05	0.06
Silage			20	<0.05	0.08	0.08	0.03	0.03	0.02
Fodder			20	<0.05	0.18	0.14	0.03	0.05	0.05
Grain			20	<0.05	0.17	0.12	0.03	0.03	0.03
Forage	0.220	~60	7	<0.05	0.11	0.11	0.03	0.04	0.03
Hay			7	<0.05	0.14	0.14	0.08	0.07	0.04
Silage			7	<0.05	<0.05	0.03	0.03	0.03	0.00
Fodder			7	<0.05	0.06	0.06	0.03	0.03	0.01
Grain			7	<0.05	<0.05	0.03	0.03	0.03	0.00

1 The LOQ for propiconazole residues in/on sorghum is 0.05 ppm. The LOD was not reported..
2 HAFT - Highest Average Field Trial.
3 STMdR - Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue. For calculation of the median, mean and standard deviation, ½ the LOQ was used for residues reported at <LOQ.
4 Most test sites had PBIs of ~60 days, with one site at 75 and one at 100 days.

D. CONCLUSION

The extended field rotational crop data on sorghum are adequate and indicate that tolerances on rotational sorghum with a PBI around 60 DAT will be covered by current temporary tolerances for sorghum grain and stover.

E. REFERENCES

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

DP Barcode:	D279300
Subject:	Propiconazole (122101): Reregistration Eligibility Decision (RED) Document: Residue Chemistry Considerations.
From:	Y. Donovan
To:	S. Lewis/J. Guerry
Dated:	8/18/05
MRID:	None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 5F4498 (superseded by PP#2F6371)
DP Barcode(s): D315274
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED Yan Donovan	Date: 06/30/06
Approved by	Susan Hummel, Senior Scientist, RRB4/HED Susan Hummel	Date: 06/30/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 6/23/2006). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

43655612 Selman, F. (1995) Propiconazole--Magnitude of the Residues in or on Field and Sweet Corn Following Applications of Tilt and Tilt 45WP: Lab Project Number: ABR/95008. Unpublished study prepared by Ciba Plant Protection. 205 p.

EXECUTIVE SUMMARY:

In two field corn and two sweet corn field trials conducted during 1994 in Regions 1, 3 and 5, propiconazole was applied to corn in side-by-side tests comparing use of the 45% WP and 3.6 lb/gal EC formulations. In each test, propiconazole (EC or WP) was applied four times to field or sweet corn prior to silking, during vegetative development, as broadcast foliar applications at 0.11 lb ai/A/application, at retreatment intervals (RTIs) of 5-9 days, for a total of 0.44 lb ai/A/season. An adjuvant was not added to the spray mix, and all applications were made using ground equipment at 8-35 gal/A. In the field corn tests, single control and duplicate treated samples of forage were collected at 30-31 days after the last treatment (DAT) and again at 56 or 63 DAT, and grain and stover were collected at maturity, 93 or 118 DAT. In the sweet corn tests, single control and duplicate treated samples of forage were collected at 14 DAT, and samples of mature forage and ears (kernels plus cobs with husks removed, K+CWHR) were collected at 25 or 35 DAT. Samples were stored frozen from collection to analysis for up to 7 months, an interval supported by available storage stability data.

Residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on corn commodities were determined using a GC/ECD method (Method AG-454B). This method is an updated version of the current tolerance enforcement method and was adequately validated in conjunction with the analysis of field trial samples. For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and cleaned-up using an acidic alumina cartridge. Methylated DBCA is determined by GC/ECD using external standards, and residues are expressed in parent equivalents. The method LOQ is 0.05 ppm, and an LOD was not reported.

Following up to four early-season foliar applications of propiconazole prior to silking, combined residues in/on field corn treated with an EC formulation averaged 0.60 ± 0.67 ppm for forage at ~30 DAT, 0.28 ± 0.31 ppm for silage-stage forage, and 0.98 ± 1.11 ppm for mature stover. For the WP formulation, combined residues in/on field corn averaged 0.74 ± 0.81 ppm for forage at ~30 DAT, 0.41 ± 0.44 ppm for silage-stage forage, and 1.20 ± 1.34 ppm for mature stover. Combined residues were <LOQ in/on all samples of mature field corn grain, regardless of the formulation used.

Following four foliar applications prior to silking, combined residues in/on sweet corn treated with the EC formulation averaged 0.23 ± 0.15 ppm for forage at 14 DAT and 0.45 ± 0.48 ppm for mature forage. For the WP formulation, residues averaged 0.22 ± 0.10 ppm for forage at 14 DAT and 0.43 ± 0.43 ppm for mature forage. Combined residues were <LOQ in/on all samples of sweet corn ears (K+CWHR) for both formulations.

Although only a limited number of side-by-side tests were conducted, combined propiconazole residues in/on field and sweet corn commodities were similar between the EC and WP formulations following early-season applications.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the corn field trial residue data are classified as scientifically acceptable for the purpose for which they were intended. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited several minor deviations from GLP requirements relating to collection of soil and weather data and characterization of the spray mix. However, none of deviations were serious enough to adversely affect the conclusions of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-DCBA (expressed as parent) in/on a variety of plant and animal commodities, including time-limited tolerances of 0.1 ppm on sweet corn (K+CWHR) and field corn grain and 12 ppm on field corn forage and stover [40 CFR §180.434(a)].

In conjunction with PP#2F6371, Syngenta is proposing new tolerances of residues in/on corn commodities. The current submission includes residue data on field and sweet corn comparing residues levels resulting from use of EC and WP formulations in side-by-side tests.

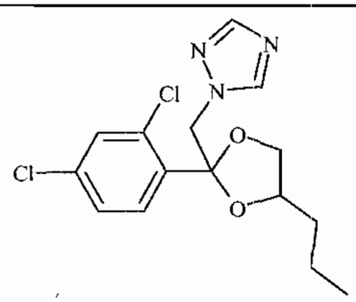
TABLE A.1. Nomenclature of Propiconazole	
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EP	3.6 lb/gal EC (Tilt 3.6E Fungicide, EPA Reg. No. 100-617) 45% WP (Tilt 45W Fungicide, EPA Reg. No. 100-780)

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.		
Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No. 43698701
pH	4.9 at 25°C (1% aqueous dispersion)	MRID No. 43698701
Density	1.289 g/cm^3 at 20°C	MRID No. 43698701
Water solubility	0.10 g/L at 20°C	MRID No. 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. hexane = 47 g/L	MRID No. 42030201
Vapor pressure	4.2 x 10^{-7} mm Hg at 25°C	MRID No. 41720301
Dissociation constant (pK_a)	1.09	MRID No. 43698701
Octanol/water partition coefficient $Log(K_{OW})$	3.72 at pH 6.6 and 25°C	MRID No. 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No. 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Field and sweet corn were grown and maintained at the test sites using typical agricultural practices for the respective geographical regions (Table B.1.1). Monthly rainfall and irrigation data were provided for each site, along with detailed temperature data. No usual weather conditions were noted that would have an adverse effect on the field trial data. Information was also provided on maintenance chemicals and other pesticides used.

In a total of four field trails, two each for field and sweet corn, propiconazole was applied to two plots of corn in side-by-side tests comparing the 3.6 lb/gal EC and 45% WP formulations (Table B.1.2).

TABLE B.1.1. Trial Site Conditions.				
Trial Identification (County, State; Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC[2] (meq/g)
Hamilton, IN 1994	Loam	NR	NR	NR
Champaign, IL 1994	Silty clay loam	NR	NR	NR
Columbia, NY	Sandy loam	NR	NR	NR
Indian River, FL 1994	Sand	NR	NR	NR

[1] These parameters are optional except in cases where their value affects the use pattern for the chemical.
[2] Cation exchange capacity
NR = Not Reported

TABLE B.1.2. Study Use Pattern on Field and Sweet Corn.

Location (County, State; Year) Trial ID	End-use Products	Application Information [1]					Tank Mix/ Adjuvants
		Method; Timing	Volume (GPA)	Single Rate (lb ai/A)	RTI [2] (days)	Total Rate (lb ai/A)	
Field Corn							
Hamilton, IN 1994 NE-FR-105-94	3.6 lb/gal EC 45% WP	Four broadcast foliar applications from V4 stage to V10 stage	17-19	0.11	7, 7, 7	0.44	none
Champaign, IL 1994 04-FR-003-94	3.6 lb/gal EC 45% WP	Four broadcast foliar applications during vegetative development	30	0.11	7, 7, 7	0.44	none
Sweet Corn							
Columbia, NY 1994 05-FR-002-94	3.6 lb/gal EC 45% WP	Four broadcast foliar applications from whorl stage through tassel emergence	35	0.11	7, 7, 7	0.44	none
Indian River, FL 1994 07-FR-050-94	3.6 lb/gal EC 45% WP	Four broadcast foliar applications from stage 3 through stage 7	8	0.11	9, 5, 7	0.44	none

1 All applications were made using ground equipment.
2 RTI = Retreatment Interval.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones[1]	Submitted		Requested	
	Field Corn	Sweet Corn	Field Corn	Sweet Corn
1	---	1	1	2
2	---	---	1	1
3	---	1	---	1
4	---	---	---	---
5	2	---	17	5
6	---	---	1	---
7	---	---	---	---
8	---	---	---	---
9	---	---	---	---
10	---	---	---	1
11	---	---	---	1
12	---	---	---	1
Total	2	2	20	12

1 Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the use is for the US only.

B.2. Sample Handling and Preparation

Single control and duplicate treated samples (≥2 lb/sample) of each commodity were collected from all field and sweet corn tests. Forage was collected at 30-31 DAT from field corn tests and at 14 DAT from sweet corn tests, and silage-stage forage was also collected from the field corn tests at 56 or 63 DAT. Samples of mature forage and ears (K+CWHR) were collected from sweet corn at 25 or 35 DAT, and samples of grain and stover were collected from the field corn tests at maturity, 93 or 118 DAT. All samples were placed into freezers after harvest and shipped by freezer truck to Ciba-Geigy (Greensboro, NC), where samples were stored at -20°C.

Samples were later shipped on dry ice by overnight courier to the analytical laboratory (EPL Bioanalytical Services, Harristown, IL), where samples were also stored frozen.

B.3. Analytical Methodology

Samples of field and sweet corn matrices were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-454 B), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, residues were extracted by refluxing for 1 hour in NH_4OH/MeOH (20:80, v/v), and filtered. Residues were concentrated and oxidized to 2,4-DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract was diluted with water, the $KMnO_4$ was deactivated by the addition of sodium meta-bisulfite, and the extract was acidified by the addition of 6N HCl. Residues of DCBA were then partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using diazomethane. Residues were then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and analyzed by GC/ECD, using external standards. The method LOQ is 0.05 ppm, and an LOD was not reported.

In conjunction with the analysis of field trial samples, the above method was validated using control samples of fortified with propiconazole at 0.5-12 ppm for forage, 0.5 and 1.0 ppm for silage and stover, 0.5 ppm for ears, and 0.05 ppm for grain.

C. RESULTS AND DISCUSSION

In two field corn and two sweet corn field trials conducted in 1994, propiconazole was applied to corn in side-by-side tests to compare use of the 45% WP or 3.6 lb/gal EC formulations. In each test, propiconazole (EC or WP) was applied four times to field or sweet corn prior to silking, during vegetative development, as broadcast foliar applications at 0.11 lb ai/A/application, with RTIs of 5-9 days, for a total of 0.44 lb ai/A/season. An adjuvant was not added to the spray mix, and all applications were made using ground equipment at 8-35 gal/A. In the field corn tests, single control and duplicate treated samples of forage were collected at 30-31 DAT and again at 56 or 63 DAT, and grain and stover were collected at maturity, 93 or 118 DAT. In the sweet corn tests, single control and duplicate treated samples of forage were collected at 14 DAT, and samples of mature forage and ears (K+CWHR) were collected at 25 or 35 DAT.

The GC/ECD method (Method AG-454B) used to determine total propiconazole residues in/on corn matrices was adequately validated in conjunction with the analysis of field samples. Recovery of propiconazole averaged 80-89% from forages, 78% from stover, 108% from grain, and 96% from K+CWHR (Table C.1). Apparent residues of propiconazole were <LOQ in/on all

control samples. The method LOQ for propiconazole is 0.05 ppm, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided. Although the study author reported residue values corrected for concurrent recoveries of <100%, uncorrected residues values were used and reported in this review.

Corn forage, stover, grain, and K+CWHR samples were stored frozen for up to 7 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating that weather residues of propiconazole are stable at -20°C for up to 38 months in grass forage, seeds and straw (DP Barcode D279300, Y. Donovan, 8/18/05). As these matrices are similar to the tested corn matrices, these storage stability data will support the storage intervals and conditions for the current corn field trials.

Combined residues in/on field corn forage harvested at ~30 DAT were <0.05-1.26 ppm for the EC formulation and <0.05-1.66 ppm for the WP formulation (Table C.3), and combined residues in/on silage-stage forage from 56-63 DAT were <0.05-0.64 ppm for the EC and <0.05-0.92 ppm for the WP. Mature stover (93-118 DAT) had combined residues of <0.05-2.15 ppm for the EC and <0.05-2.51 ppm for the WP. Residues were <LOQ on all samples of grain, regardless of the formulation used. For the EC formulation, residues in/on field corn averaged 0.60 ± 0.67 ppm for forage at 30 DAT, 0.28 ± 0.31 ppm for silage-stage forage, and 0.98 ± 1.11 ppm for mature stover (Table C.4). For the WP formulation, residues averaged 0.74 ± 0.81 ppm for forage at ~30 DAT, 0.41 ± 0.44 ppm for silage-stage forage, and 1.20 ± 1.34 ppm for mature stover.

Combined residues in/on sweet corn forage at 14 DAT were 0.10-0.40 ppm for the EC formulation and 0.14-0.36 ppm for the WP formulation, and combined residues in/on mature forage at 25-35 DAT were <0.05-1.05 ppm for the EC and 0.07-0.93 ppm for the WP. Residues were <LOQ on all samples of K+CWHR. For the EC formulation, residues in/on sweet corn averaged 0.23 ± 0.15 ppm for forage at 14 DAT and 0.45 ± 0.48 ppm for mature forage. For the WP formulation, residues averaged 0.22 ± 0.10 ppm for forage at 14 DAT and 0.43 ± 0.43 ppm for mature forage.

Although only a limited number of side-by-side tests were conducted, combined propiconazole residues in/on field and sweet corn commodities were similar between the EC and WP formulations following early-season applications.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data

TABLE C.1. Summary of Method Recoveries of Propiconazole from Field and Sweet Corn.

Analyte	Crop	Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%) [1]
Propiconazole	Field Corn	forage	0.5-12.0	3	93, 76, 98	89
		silage	0.5, 1.0	2	86, 74	80
		fodder	0.5, 1.0	2	82, 73	78
		grain	0.05	2	114, 99	108
	Sweet corn	forage	0.5-12.0	6	81, 71, 84, 86, 85, 74	80 ± 6
		ears	0.5	2	94, 100	96

[1] Standard deviations were only calculated for matrices with over 3 values.

TABLE C.2. Summary of Storage Conditions.

Crop	Matrix	Storage Temperature (°C)	Actual Storage Duration[1] (months)	Interval of Demonstrated Storage Stability (months)[2]
Field corn	Forage	-20	3.0-4.5	36
	Fodder		2.0	
	Grain		2.0	
Sweet corn	Forage		3.0-7.0	
	Ears (K+CWHR)		3-6.5	

[1] Interval from harvest to extraction for analysis. Extracts were stored for 2-10 days prior to analysis.
[2] DP Barcode D279300, Y. Donovan, 8/18/05.

TABLE C.3. Residue Data from Field and Sweet Corn Field Trials with Propiconazole EC and WP.

Trial ID (County, State, Year)	Zone	Corn Type/ Variety	Total Rate (lb ai/A)	Commodity	PHI (days)	End-use Product	Combined Residues (ppm) [1]
Hamilton, IN 1994 NE-FR-105-94	5	Field corn/ Pioneer 3394	0.44	forage	31	3.6 lb/gal EC	1.09, 1.26
						45% WP	1.18, 1.66
				forage (silage stage)	56	3.6 lb/gal EC	0.64, 0.44
						45% WP	0.63, 0.92
				fodder (stover)	93	3.6 lb/gal EC	2.15, 1.71
						45% WP	2.19, 2.51
				grain	93	3.6 lb/gal EC	<0.05, <0.05
						45% WP	<0.05, <0.05
Champaign, IL 1994 04-FR-003-94	5	Field corn/ 1112X CIBA	0.44	forage	30	3.6 lb/gal EC	<0.05, <0.05
						45% WP	<0.05, 0.09
				forage (silage stage)	63	3.6 lb/gal EC	<0.05, <0.05
						45% WP	0.06, <0.05
				fodder (stover)	118	3.6 lb/gal EC	<0.05, <0.05
						45% WP	<0.05, 0.06
				grain	118	3.6 lb/gal EC	<0.05, <0.05
						45% WP	<0.05, <0.05
Columbia, NY 1994 05-FR-002-94	1	Sweet corn/ Silver Queen	0.44	forage	14	3.6 lb/gal EC	0.11, 0.10
						45% WP	0.14, 0.20
				forage	35	3.6 lb/gal EC	0.62, 1.05
						45% WP	0.64, 0.93
				ears (K+CWHR)	35	3.6 lb/gal EC	<0.05, <0.05
						45% WP	<0.05, <0.05
Indian River, FL 1994 07-FR-050-94	3	Sweet corn/ Golden Queen	0.44	forage	14	3.6 lb/gal EC	0.30, 0.40
						45% WP	0.36, 0.18
				forage	25	3.6 lb/gal EC	<0.05, 0.09
						45% WP	0.08, 0.07
				ears (K+CWHR)	25	3.6 lb/gal EC	<0.05, <0.05
						45% WP	<0.05, <0.05

[1] Total propiconazole residues were determined as DCBA and expressed in parent equivalents. Reported values were obtained from the raw data and are not corrected procedural recoveries. The LOQ for propiconazole residues in/on corn commodities is 0.05 ppm. The LOD was not reported.

TABLE C.4. Summary of Residue Data from Field and Sweet Corn Field Trials with Propiconazole (EC or WP).

Crop	Commodity	Total Rate (lb ai/A)	End-use Product	PHI (days)	Total Residue Levels (ppm)[1]						
					n	Min.	Max.	HAFT[2]	Median (STMdR)[3]	Mean (STMR)[3]	Std. Dev.
Field Corn	Forage	0.440	3.6 lb/gal EC	30-31	4	<0.05	1.26	1.18	0.56	0.60	0.67
			45% WP		4	<0.05	1.66	1.42	0.64	0.74	0.81
	Silage	0.440	3.6 lb/gal EC	56-63	4	<0.05	0.64	0.54	0.23	0.28	0.31
			45% WP		4	<0.05	0.92	0.78	0.35	0.41	0.44
	Fodder	0.440	3.6 lb/gal EC	93-118	4	<0.05	2.15	1.93	0.87	0.98	1.11
			45% WP		4	<0.05	2.51	2.35	1.13	1.20	1.34
	Grain	0.440	3.6 lb/gal EC	93-118	4	<0.05	<0.05	<0.05	0.025	0.025	0.00
			45% WP		4	<0.05	<0.05	<0.05	0.025	0.025	0.00
Sweet corn	Forage	0.440	3.6 lb/gal EC	14	4	0.10	0.40	0.35	0.21	0.23	0.15
			45% WP		4	0.14	0.36	0.27	0.19	0.22	0.10
	Forage	0.440	3.6 lb/gal EC	25-35	4	<0.05	1.05	0.84	0.36	0.45	0.48
			45% WP		4	0.07	0.93	0.79	0.36	0.43	0.43
	Ears (K+CWHR)	0.440	3.6 lb/gal EC	25-35	4	<0.05	<0.05	<0.05	0.025	0.025	0.00
			45% WP		4	<0.05	<0.05	<0.05	0.025	0.025	0.00

1 The LOQ is 0.05 ppm. Values are not corrected for procedural recoveries. For calculation of the median, mean, and standard deviation, ½LOQ (0.025 ppm) was used for samples with residues <LOQ.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

D. CONCLUSION

The field and sweet corn field trial data are adequate for the purpose for which the trials were intended. The data indicate that propiconazole residues in/on field and sweet corn commodities are similar following early season applications of the WP and EC formulations.

E. REFERENCES

DP Barcode: D279300
Subject: Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Residue Chemistry Considerations.
From: Y. Donovan
To: S. Lewis/J. Guerry
Dated: 8/18/05
MRID: None

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 2F6371
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

Primary Evaluator	Yan Donovan, Chemist, RRB4/HED Yan Donovan	Date: 5/31/06
Approved by	Susan Hummel, Chemist, RRB4/HED Susan Hummel	Date:5/31/06

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B, Durham, NC 27713; submitted 4/26/2006). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

43655613. Selman, F.B. (1995) Propiconazole-Magnitude of the Residues in or on Celery Following Applications of Tilt and Tilt 45 WP. Lab Project Numbers: ABR-95009. Unpublished study prepared by Ciba-Geigy Corporation. 146 p.

EXECUTIVE SUMMARY:

A side-by-side field trial study on celery was conducted in Region 3 during 1994 comparing propiconazole formulatios of 45% WP and 3.6 lb/gal EC. Each formulation was applied four times to celery as broadcast foliar applications during crop development at 0.11 lb ai/A/application, at retreatment intervals (RTIs) of 7 days, for a total of 0.44 lb ai/A/season. A single control and duplicate treated samples of whole immature plants were harvested from each plot at 0 days after the final application (DAT), and single control and duplicate treated samples of mature untrimmed stalks (RAC) were harvested from each plot at 14 DAT. Subsamples of trimmed stalks and trimmings were also collected at 14 DAT. Samples were stored frozen from collection to analysis for up to 9.5 months, an interval supported by available storage stability data.

Residues of propiconazole and its 2,4-dichlorobenzoic acid (DCBA) containing metabolites in/on celery were determined using a GC/ECD method (Method AG-454B). This method is an updated version of the current tolerance enforcement method and was adequately validated in conjunction with the analysis of field trial samples. For this method, residues are extracted and converted to 2,4-DCBA by base hydrolysis and oxidization. Residues of DCBA are then partitioned into diethyl ether:hexane, concentrated, methylated, and cleaned-up using an acidic alumina cartridge. Methylated DBCA is determined by GC/ECD, using external standards, and residues are expressed in parent equivalents. The validated method LOQ is 0.05 ppm, and an LOD was not reported.

Immediately following the final application (0 DAT), residues in/on whole immature plants were 1.5-2.1 ppm for the EC formulation and 1.3-1.5 ppm for the WP formulation. At maturity (14-DAT), residues in/on untrimmed stalks were 0.27-0.42 ppm for the EC formulation and 0.43-0.51 ppm for the WP formulation, with most of the residues being associated with the upper

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leaves. Residues in/on trimmed stalks at 14 DAT were ≤0.05 ppm for the EC and 0.05-0.07 ppm for the WP, and residues in/on trimmings were 0.41-0.45 ppm for the EC and 0.49-0.83 ppm for the WP. Average residues in/on untrimmed stalks, trimmed stalks, and trimmings were 0.35, 0.04, and 0.43 ppm, respectively, for the EC formulation, and 0.47, 0.06, and 0.66 ppm, respectively, for the WP formulation. Although the data are limited, residues in/on celery from the EC and WP formulations were similar in this trial.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the celery field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D238458.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study author cited several minor deviations from GLP requirements relating to collection of soil and weather data and characterization of the spray mix. However, none of deviations were serious enough to adversely affect the conclusions of the study.

A. BACKGROUND INFORMATION

Propiconazole is a triazole-type fungicide that provides broad spectrum disease control through inhibition of sterol biosynthesis in fungi. It is registered to Syngenta Crop Protection for the control of fungal diseases on a variety of crops. Tolerances for propiconazole are currently established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent) in/on a variety of plant and animal commodities [40 CFR §180.434], including at 5.0 ppm tolerance for residues in/on celery.

IR-4 is currently supporting a petition (PP#6E4788) to expand the use of propiconazole (EC and WP) from celery to the leaf petioles crop subgroup 4-B. The current submission is a side-by-side field trial on celery comparing residues resulting from EC and WP formulations.

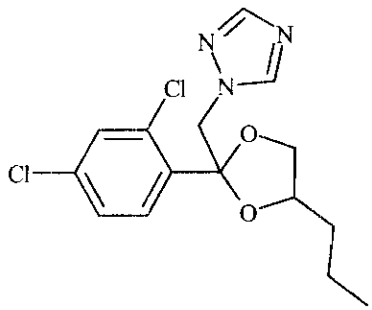
TABLE A.1. Nomenclature of Propiconazole	
Compound	
Common name	Propiconazole
Company experimental names	CGA-64250
IUPAC name	1-[2-(2,4_dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS #	60207-90-1
End-use products/EP	3.6 lb/gal EC (Tilt Fungicide, EPA Reg. No. 100-617)
Regulated Metabolite	None
Common name	N/A
IUPAC name	N/A
CAS #	N/A

TABLE A.2. Physicochemical Properties of Technical Grade Propiconazole.		
Parameter	Value	Reference
Boiling point	120°C at 1.9 Pa, >250°C at 101.325 kPa	MRID No.:43698701
pH	4.9 @ 25°C (1% aqueous tdispersion)	MRID No.:43698701
Density	1.289 g/cm3 typical @ 20°C	MRID No.: 43698701
Water solubility (20°C)	0.10 g/L at 20°C	MRID No.: 41720301
Solvent solubility (temperature not specified)	Completely miscible in ethanol, acetone, toluene and n-octanol. n-hexane = 47 g/L	MRID No.: 42030201
Vapor pressure at 25°C	4.2×10^{-7} mm Hg @ 25°C	MRID No.: 41720301
Dissociation constant (pK_a)	1.09	MRID No.: 43698701
Octanol/water partition coefficient Log(K_{OW}) (25 °C)	3.72 @ pH 6.6	MRID No.: 43698701
UV/visible absorption spectrum (8max, nm)	Not available	MRID No.: 40583703

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Celery was grown and maintained at the test site using typical agricultural practices for the geographical region (Table B.1.1). Monthly rainfall and irrigation data were provided for the site, along with detailed temperature data. No usual weather conditions were noted that would have an adverse effect on the field trial data. Information was also provided on maintenance chemicals and other pesticides used. Propiconazole was applied to two plots of celery in side-by-side tests comparing the 3.6 lb/gal EC and 45% WP formulations (Table B.1.2).

TABLE B.1.1. Trial Site Conditions.				
Trial Identification (City, State; Year)	Soil characteristics [1]			
	Type	%OM	pH	CEC[2] (meq/g)
Florida 1994	Sandy Loam	NR	NR	NR

[1] These parameters are optional except in cases where their value affects the use pattern for the chemical.
[2] Cation exchange capacity
NR = Not Reported

TABLE B.1.2. Study Use Pattern on Celery.							
Location (County, State; Year) Trial ID	End-use Product	Application Information					Tank Mix/ Adjuvants
		Method; Timing	Volume (GPA)	Rate (lb ai/A)	RTI [1] (days)	Total Rate (lb ai/A)	
Palm Beach, Florida, 1994 FL-FR-451-94	3.6 lb/gal EC	Four broadcast foliar applications during crop development	45	0.110	7	0.440	none
	45% WP			0.110		0.440	

[1] RTI = Retreatment Interval.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones[1]	Celery		
	Submitted	Requested	
		Canada	U.S.
1	---	---	---
2	---	---	---
3	1	---	2
4	---	---	---
5	---	---	1
6	---	---	---
7	---	---	---
8	---	---	---
9	---	---	---
10	---	---	5
11	---	---	---
12	---	---	---
Total	**1**	**NA**	**8**

[1] Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the proposed use is for the US only.
NA = Not applicable.

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of immature whole plants were collected from each plot at 0 DAT, and single control and duplicated treated samples of mature untrimmed celery stalks (≥ 5 lb/sample) were harvested from each plot at 14 DAT. Subsamples of trimmed stalks and trimmings were also collected at the 14-DAT interval. All samples were placed into freezers after harvest and shipped by freezer truck to Ciba-Geigy (Greensboro, NC), where samples were stored at -20°C. Samples were later shipped on dry ice by overnight courier to the analytical laboratory (EPL Bioanalytical Services, Harristown, IL), where samples were also stored frozen.

B.3. Analytical Methodology

Celery samples were analyzed for residues of propiconazole and its DCBA-containing metabolites using a GC/ECD method (Method AG-454 B), which is an updated version of the current tolerance enforcement method for propiconazole residues in plant commodities. The method converts all residues to 2,4-DCBA through base hydrolysis and oxidation, and residues are then determined as methylated 2,4-DCBA and expressed in parent equivalents.

For this method, propiconazole residues are extracted by refluxing for 1 hour in NH_4OH/MeOH (20:80, v/v), and filtered. Residues are concentrated and oxidized to 2,4-DCBA by refluxing with $KMnO_4$ in 1N NaOH for 75 minutes. After reflux, the extract is diluted with water, the $KMnO_4$ is deactivated by the addition of sodium meta-bisulfite, and the extract is acidified by the addition of 6N HCl. Residues of DCBA are partitioned into diethyl ether:hexane (10:90, v/v), evaporated to dryness, and methylated using diazomethane. Residues are then cleaned-up using an acidic alumina Sep-Pak eluted with diethyl ether:hexane (10:90, v/v), and analyzed by GC/ECD, using external standards. The validated method LOQ is 0.05 ppm, and an LOD was not reported.

In conjunction with the analysis of field trial samples, the above method was validated using control samples of celery fortified with propiconazole at 0.05-5.0 ppm. Concurrent recoveries ranged from 81% to 89%, with average and standard deviation of 83% ± 4.

C. RESULTS AND DISCUSSION

In a single field trial conducted in 1994, propiconazole was applied to celery in side-by-side tests to compare use of the 45% WP or 3.6 lb/gal EC formulations. In each test, propiconazole (EC or WP) was applied four times to celery during crop development as broadcast foliar applications at 0.11 lb ai/A/application, with RTIs of 7 days, for a total of 0.44 lb ai/A/season. An adjuvant was not added to the spray mix, and all applications were made using ground equipment at 45 gal/A. Single control and duplicate treated samples of whole immature plants were collected from each plot at 0 DAT, and single control and duplicate treated samples of untrimmed celery stalks (RAC) were harvested from each plot at 14 DAT. Subsamples of trimmed stalks and trimmings were also collected at 14 DAT.

The GC/ECD method (Method AG-454 B) used to determine total propiconazole residues in/on celery was adequately validated in conjunction with the field sample analyses. Untreated samples of celery were fortified with propiconazole at 0.05-5.0 ppm and recoveries averaged 83 ± 4 % (Table C.1). Apparent residues of propiconazole were <LOQ in/on all control samples. The validated method LOQ for propiconazole is 0.05 ppm, and the LOD was not reported. Adequate sample calculations and example chromatograms were provided.

Celery samples were stored frozen for up to 9.5 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating that propiconazole is stable for up to 36 months in frozen celery (DP Barcode 240856, T. Morton, 2/23/05). These data will support the frozen storage intervals in this trial.

Immediately following the final application (0 DAT), residues in/on whole immature plants were 1.5-2.1 ppm for the EC formulation and 1.3-1.5 ppm for the WP formulation (Table C.3). Average residues in/on immature plants for the EC and WP were 1.8 and 1.4 ppm, respectively (Table C.4). At maturity (14-DAT), residues in/on untrimmed stalks (RAC) were 0.27-0.42 ppm for the EC formulation and 0.43-0.51 ppm for the WP formulation, with most of the residues being associated with the upper leaves. Residues in/on trimmed stalks at 14 DAT were ≤0.05 ppm for the EC and 0.05-0.07 ppm for the WP, and residues in/on trimmings were 0.41-0.45 ppm for the EC and 0.49-0.83 ppm for the WP. Average residues in/on untrimmed stalks, trimmed stalks, and trimmings were 0.35, 0.04, and 0.43 ppm, respectively, for the EC formulation, and 0.47, 0.06, and 0.66 ppm, respectively, for the WP formulation. Although the data are limited, residues in/on celery from the EC and WP formulations were similar in this trial.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data

TABLE C.1. Summary of Method Recoveries of Propiconazole from Celery.					
Analyte	Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Propiconazole	Celery	0.05-5.0	5	83, 82, 81, 80, 89	83 ± 4

TABLE C.2 Summary of Storage Conditions.			
Matrix	Storage Temperature (°C)	Actual Storage Duration[1] (months)	Interval of Demonstrated Storage Stability (months)[2]
Celery RAC	-20	9-9.5	36

[1] From harvest to extraction for analysis.
[2] DP Barcode 240856, T. Morton, 2/23/05.

TABLE C.3. Residue Data from Celery Field Trials with Propiconazole EC and WP.							
Trial ID (County, State; Year)	Zone	Variety	Total Rate (lb ai/A)	End-use Product	PHI (days)	Commodity	Propiconazole Residues (ppm)[1]
Palm Beach, Florida, 1994 FL-FR-451-94	3	June Belle	0.440	3.6 lb/gal EC	0	Whole Plant	1.5, 2.1
					14	Untrimmed Stalks (RAC)	0.27, 0.42
						Trimmings	0.41, 0.45
						Trimmed Stalks	0.05, <0.05
				45% WP	0	Whole Plant	1.5, 1.3
					14	Untrimmed Stalks (RAC)	0.51, 0.43
						Trimmings	0.49, 0.83
						Trimmed Stalks	0.05, 0.07

[1] Total propiconazole residues determined as DCBA and expressed in parent equivalents. The LOQ for propiconazole residues in/on celery is 0.05 ppm. The LOD was not reported.

TABLE C.4. Summary of Residue Data from Celery Field Trials with Propiconazole (EC or WP).										
Commodity	Total Applic. Rate (lb ai/A)	End-use Product	PHI (days)	Total Residue Levels (ppm)[1]						
				n	Min.	Max.	HAFT[2]	Median (STMdR)[3]	Mean (STMR)[3]	Std. Dev.
Immature Whole Plant	0.440	3.6 lb/gal EC	0	2	1.5	2.1	1.8	1.8	1.8	0.42
		45% WP	0	2	1.3	1.5	1.4	1.4	1.4	0.14
Untrimmed Stalks (RAC)	0.440	3.6 lb/gal EC	14	2	0.27	0.42	0.35	0.35	0.35	0.11
		45% WP	14	2	0.43	0.51	0.47	0.47	0.47	0.06
Trimmings	0.440	3.6 lb/gal EC	14	2	0.41	0.45	0.43	0.43	0.43	0.03
		45% WP	14	2	0.49	0.83	0.66	0.66	0.66	0.24
Trimmed Stalks	0.440	3.6 lb/gal EC	14	2	<0.05	0.05	0.04	0.04	0.04	0.02
		45% WP	14	2	0.05	0.07	0.06	0.06	0.06	0.01

[1] The LOQ is 0.05 ppm. For calculation of the median, mean, and standard deviation, ½LOQ was used for samples with residues <LOQ
[2] HAFT = Highest Average Field Trial.
[3] STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

D. CONCLUSION

The celery field trial data are adequate, but limited. The data indicate that propiconazole residues in/on celery are similar for the WP and EC formulations.

E. REFERENCES

DP Barcode:	240856
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).
From:	T. Morton
To:	P. Dobak/S. Lewis
Dated:	2/23/05
MRID(s):	44411201, 44411202, 44411203, 44411204, 44411205, 44411206, 44411207, 44411208

F. DOCUMENT TRACKING

RDI: Yan Donovan, RRB4/HED
Petition Number(s): 6E4788
DP Barcode(s): D238458
PC Code: 122101

Template Version June 2005

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R132010

Chemical: Diazinon

PC Code:
057801

HED File Code: 11000 Chemistry Reviews
Memo Date: 12/9/1987
File ID: 00000000
Accession #: 000-00-0108

HED Records Reference Center
8/24/2006