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DP#=5F04424

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: *PP5F04424 & ID#000100-00618 CGA-64250 Technical: Propiconazole in/on Dry Beans and Soybeans. Evaluation of Residue Data and Analytical Methodology.*
CBTS #s 14859 & 14860; **DP Barcode #s** D210266 & D210295
Case #s 286012 & 037683
MRID #s 433865-00, 433865-01, & 433865-02

FROM: María Isabel Rodríguez, Chemist
TPT I/CBTS/HED (7509C)
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3/4/1997

THROUGH: Elizabeth Haeberer, Acting Chief
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Elizabeth T. Haeberer

TO: Deborah L. McCall/Steve Robbins
RS/RCAB/HED (7509C)

Ciba Plant Protection/Ciba-Geigy Corporation, in letter from Dr. G.R. Watson - Regulatory Manager - dated September 21, 1994, is proposing tolerances for residues of propiconazole (1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-1H-1,2,4-triazole) and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound equivalent in the following commodities:

soybeans	0.5 ppm
soybean forage	8.0 ppm
soybean fodder/straw	8.0 ppm
soybean hay	25.0 ppm
dry beans	0.5 ppm
dry bean vines/forage	8.0 ppm
dry bean hay	8.0 ppm

Two volumes of residue data, proposed Sections B and F, and two proposed labels were submitted for review. Furthermore, the petitioner is requesting that we reconsider residue data previously submitted to the Agency and reviewed in the Chemistry Branch under PP8F3674. Additionally, the petitioner is

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requesting approval of proposed labeling to allow applications of Tilt Fungicide (EPA Reg No 100-617) and Tilt Gel Fungicide (EPA Reg No 100-737) to the subject crops.

EXECUTIVE SUMMARY OF RESIDUE CHEMISTRY DEFICIENCIES:

The petitioner should submit the following information/data:

- Revised Section F
- Revised labels for both products (Section B)
- Residue data on aspirated grain fractions

BACKGROUND:

Propiconazole is a systemic broad spectrum fungicide. Propiconazole is a List C chemical undergoing reregistration.

Tolerances have been established for propiconazole under 40 CFR §180.434(a) from 0.05 to 60 ppm for plant and animal commodities. These tolerances include fat, meat, and meat-by-products (mbyp)(except kidney and liver) of cattle, goats, hogs, horses, poultry, and sheep at 0.1 ppm; kidney and liver of cattle, goats, hogs, horses, and sheep at 2.0 ppm; kidney and liver of poultry at 0.2 ppm; eggs at 0.1 ppm; milk at 0.05 ppm; grass, hay (straw) at 40 ppm; and grass, seed screenings at 60 ppm. There is a tolerance with regional registration in/on wild rice at 0.5 ppm. There are tolerances limited by an expiration date of 12-31-1998 for corn, peanut, and pineapple commodities.

In PP8F3674, a petition for tolerances was filed for propiconazole in/on celery, corn, pineapple, and the legume vegetable crop group. As of 12-14-1988, the Chemistry Branch (then known as RCB), recommended against the legume vegetable crop group tolerance due to several deficiencies associated with the petition (C. Deyrup, RCB#4279). The petitioner pursued the celery, corn, and pineapple tolerance petitions. However, the legume vegetable crop group tolerance was withdrawn. The petitioner is now requesting that the data originally submitted under PP8F3674 for legumes, be considered at this time for soybeans and dry beans.

CBTS recommended for a Section 18 for the use of propiconazole formulated as Tilt Fungicide in/on beans (ID#95ND00093, W. Cutchin, 5-10-1995, D214846, CBTS #15481). Although not indicated in that review, the data used for the Section 18 Registration were gathered from the present submission.

CONCLUSIONS:

1. Product Chemistry Data Guideline 63-13, the test for stability, is still an outstanding data gap for the technical

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grade active ingredient (TGAI); Additional data are required for stability on metal ions. However, this deficiency will be resolved through the reregistration process. All other Product Chemistry data have been reviewed and deemed acceptable.

2a. Soybean fodder (straw), beans hay, and beans forage are not significant food or feed commodities for which tolerances are needed. Therefore, pre-harvest intervals (PHIs) and grazing/feeding restrictions on these commodities should be removed from the labels (Section B). Accordingly, a revised Section B and revised proposed labels for both products, Tilt Fungicide and Tilt Gel Fungicide, need to be submitted for review. Additionally, Section F should be revised by deleting those commodities from the proposed tolerance expression. Furthermore, Section F should be revised to express tolerances for "dry beans" as "beans, dry" and "soybeans" as "soybeans, seed."

2b. CBTS considers that both labels are identical and may be followed when applying propiconazole in/on soybeans and beans once the tolerances are established under this petition. Both labels reflect the proposed use.

3a. CBTS notes that submission and acceptance of additional celery metabolism studies are required in the reregistration process. For this petition only, the metabolism of propiconazole in/on plants is adequately understood. This decision is based on the facts that propiconazole metabolism in rotational crops is the same as in target crops, and that the method detects residues as a common moiety, 2,4-dichlorobenzoic acid. The residues of concern are propiconazole *per se* and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA) and expressed as parent compound. This deficiency will be resolved during the reregistration process.

3b. The metabolism of propiconazole in/on animals is adequately understood. The residues of concern are propiconazole *per se* and its metabolites determined as 2,4-dichlorobenzoic acid.

4a. Ciba-Geigy Analytical Methods AG-454 and AG-517 are available for determination of propiconazole and its metabolites in plant and animal commodities, respectively. The methods use a single moiety detection in which residues are converted to 2,4-dichlorobenzoic acid methyl ester and reported as propiconazole equivalents. Both methods have been successfully validated by the Agency and have been forwarded to FDA for publication in *PAM II*.

4b. Analytical Method AG-454B was used to analyze the samples for residues of propiconazole and metabolites containing the 2,4-dichlorophenyl moiety. This method is identical to the enforcement method but provides additional explanation in certain

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steps. Final determination is made with capillary GC/ECD. The limit of determination is 0.05 ppm determined as 2,4-dichloro-benzoic acid methyl ester and expressed as propiconazole equivalents. An additional petition method validation (PMV) is not warranted as the petitioner has presented sufficient validation data.

4c. The method has been previously radiovalidated.

4d. Analytical reference standards for propiconazole and 2,4-Odichlorobenzoic acid (DCBA) are available from the U.S. EPA Pesticide and Industrial Chemical Repository in RTP, NC. Pending results of required plant metabolism studies, analytical reference standards for additional relevant metabolites identified may need to be send to the Repository in RTP, NC.

4e. If the pending plant metabolism studies identify additional metabolites, new plant methodology, independent laboratory and Agency validation (ILV and PMV) may have to be required.

4f. Pending results of required plant metabolism studies, CBTS concludes that adequate enforcement methods are available for the proposed tolerances in plant commodities. Adequate enforcement methods are available for detection of possible residues in/on animal commodities. The petitioner has been informed (through the reregistration process) that a substitute methylating agent is needed in order to replace diazomethane. The deficiency will be resolved through the reregistration process. However, in the future, if the petitioner shows that other methylating agents are not as efficient as diazomethane, then CBTS will accept diazomethane.

5. Propiconazole is completely recovered *via* FDA Multiresidue Protocol D. However, recovery of propiconazole metabolites (CGA91305, CGA118244 and the 1,2,4-triazole) *via* this method is variable.

6a. For beans, maximum residues observed were 8.4 ppm for dry bean foliage, 5.5 ppm for bean hay, and 0.15 ppm for beans. The petitioner is proposing tolerances of 8.0 ppm for dry bean foliage (vines), 8.0 ppm for bean hay, and 0.5 ppm for dry beans. Therefore, the data support the proposed tolerances. However, as indicated in Conclusion 2a, Section F should be revised to indicate the appropriate commodities and their proper names. Therefore, a tolerance of 0.5 ppm for beans, dry is appropriate.

6b. For soybeans, maximum residues observed were 6.2 ppm for dry bean foliage, 24 ppm for soybean, hay, and 0.47 ppm for beans. The petitioner is proposing tolerances of 8.0 ppm for soybean forage, 8.0 ppm for soybean fodder, 25 ppm for soybean hay, and 0.5 ppm for soybean beans. However, as indicated in Conclusion 2a, Section F should be revised to indicate the appropriate

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commodities and their proper names. Therefore, the following tolerances are appropriate: soybean, forage at 8.0 ppm, soybean, hay at 25 ppm, and soybeans, seed at 0.5 ppm.

6c. The Agency has determined that tolerances on aspirated grain fractions (previously referred to as "grain dust") should be established based on the use of the pesticide on corn, wheat, sorghum, and soybeans. Therefore, data on soybean aspirated grain fractions are required. The petitioner is referred to the document *Aspirated Grain Fractions (Grain Dust): A Tolerance Perspective* (E. Saito/E. Zager, 6-7-1994), for further information.

6d. Accumulation of residues in soybean processed commodities is not expected to occur as a result of the proposed use of propiconazole in/on soybeans. Accordingly, there is no need for tolerances on these commodities for the use of propiconazole in/on soybeans.

6e. Based on our Field Trials Guidance Document (June 1994), sufficient geographically representative residue data have not been provided by the petitioner for beans and soybeans. However, the residue data were generated prior to the issuance of the document and are consistent in that there is no wide variance. Therefore, the available data will be used to satisfy the geographical/regional requirement of the field trials.

6f. Bean and soybean samples were stored frozen (-20 °C) for up to 41 months until analysis. Residues of propiconazole in peaches, bananas, corn oil, corn meal, wheat grain, celery, peanut hulls, peanut nutmeats, and peanut hay have been shown to be stable for up to 39-41 months. As part of the reregistration process, additional storage stability data on these commodities as well as grass seed will be submitted for review. Therefore, for this petition only, the available data will be translated to cover the storage interval for beans and soybeans.

7a. There are no feedstuffs associated with beans. Therefore, secondary residues of propiconazole in/on meat, milk, poultry, and eggs are not expected to occur as a result of the proposed use in/on beans.

7b. Feedstuff associated with soybeans are seed, forage, hay, aspirated grain fractions, meal, hulls, and silage. Previously calculated worst case diets for beef and dairy cattle and laying hens indicated that residues resulting from the proposed use of propiconazole in/on soybeans are not expected to exceed established tolerances in/on meat, milk, poultry, and eggs. However, pending submission and acceptance of required aspirated grain fractions residue data (Conclusion 6c), revised tolerances may be required.

8. There are no CODEX, Canadian or Mexican limits for propiconazole in/on beans or soybeans. Therefore, compatibility is not an issue at this time. However, it should be noted that the tolerance expression is different for the U.S., CODEX, Mexico, and Canada. Therefore, harmonization with CODEX may be an issue in the future.

9. HED notes that the Food Quality Protection Act (FQPA) of 1996 has amended and strengthened the standard for establishing tolerances under the FFDCA. OPP is still assessing the full impact of this change in the law on the tolerance-setting process and plans to issue guidelines concerning the establishment of tolerances under the amended statute. All tolerance petitions have to meet the requirements of the FFDCA as amended by the FQPA and OPP may require additional data to determine if the terms of the amended statute are met.

RECOMMENDATIONS:

CBTS cannot recommend for the proposed tolerances for residues of propiconazole in/on bean and soybean commodities due to the deficiencies outlined in Conclusions 2a, 6c, and 9.

Revised labels and Sections B and F should be submitted for review. Residue data on aspirated grain fractions should also be submitted for review.

A DRES Analysis may be initiated at this time. The following values should be used: 0.5 ppm for beans, dry, and soybeans, seed at 0.5 ppm. Accumulation of residues in processed commodities is not expected to occur as a result of the proposed use of propiconazole.

DETAILED CONSIDERATIONS:

PRODUCT CHEMISTRY:

Product Chemistry Data Guideline 63-13, the test for stability, is still an outstanding data gap for the technical grade active ingredient (TGAI) (K. Dockter, 1-29-96, CBRS Review #s 14752/15949, D309608/D217383). Acceptable stability data under sunlight and metal containers storage have been submitted. Additional data are required for stability on metal ions. However, this deficiency will be resolved through the reregistration process. All other Product Chemistry data have been reviewed and deemed acceptable.

No additional product chemistry information on propiconazole is required from the petitioner at this time.

PROPOSED USE:

Two proposed labels and a Section B were submitted for review with this petition.

The petitioner is proposing to use propiconazole formulated as Tilt Fungicide (EPA Reg No 100-617) and Tilt Gel Fungicide (EPA Reg No 100-737) in/on soybeans and dry beans. Both products contain 41.8% propiconazole as the active ingredient. Tilt is formulated as an emulsifiable concentrate containing 3.6 lbs ai/gallon. Tilt Gel is formulated as a gel packaged in 4 fl oz packet size water-soluble film placed in a recyclable protective package.

- For soybeans: Apply 64-75 g ai/A (3 packets/2A or 5-6 fl oz/A Tilt Gel or 158-185 g ai/Ha of Tilt or Tilt Gel) and a repeat application 14-21 days later up to a maximum of 150 g ai/A per season (3 packets/A or 12 fl oz/A Tilt Gel or 370 g ai/Ha of Tilt or Tilt Gel). Pre-harvest intervals (PHIs) for soybeans and soybean fodder (straw) is 50 days. PHI for soybean hay is 30 days. Do not graze or harvest forage within 30 days of application.

- For dry beans: Apply 50 g ai/A (1 packet or 4 fl oz/A Tilt Gel or 125 g ai/Ha of Tilt or Tilt Gel) on a 14-day schedule up to a maximum of 150 g ai/A per season (3 packets/A or 12 fl oz/A Tilt Gel or 370 g ai/Ha of Tilt or Tilt Gel). PHI for beans and bean hay is 28 days. Do not graze or feed bean forage within 7 days of application. Some varieties may develop smaller, greener leaves. Do not apply to succulent bean varieties.

Soybean fodder (straw), bean hay, and bean forage are not significant food or feed commodities for which tolerances are needed. Therefore, PHIs and grazing/feeding restrictions on these commodities should be removed from the labels (Section B) (Refer to *Table 1 - Raw Agricultural and Processed Commodities and Feedstuffs Derived From Crops*). Accordingly, a revised Section B and revised proposed labels for both products, Tilt Fungicide and Tilt Gel Fungicide, need to be submitted for review. Additionally, Section F should be revised by deleting those commodities from the proposed tolerance expression. Furthermore, Section F should be revised to express tolerances for "dry beans" as "beans, dry" and "soybeans" as "soybeans, seed."

CBTS considers that both labels are identical and may be used when applying propiconazole in/on soybeans and beans once the tolerances are established under this petition. Both labels reflect the proposed use.

NATURE OF THE RESIDUE:

- Plants and Rotational Crops:

Plant metabolism studies were not submitted for review with this petition.

Previously reviewed plant metabolism studies using triazole-labeled propiconazole have shown that soil residues are absorbed by crops planted in rotation with propiconazole-treated peanuts, wheat, and corn. Additional plant metabolism data have also been submitted for lettuce. Metabolism studies have also been performed in/on grape and rice. (A. Smith, PP4F3007, 5/15/84). According to the Reregistration Document (1994), the petitioner has been requested to submit additional metabolism data using phenyl-^{14}C-propiconazole on all crops for which field trials have been (or will be) done. Currently, a metabolism study in/on celery is being conducted (F. Fort, CBRS Review #13166, D198815, 4-26-1994). Use of propiconazole in/on celery has been previously registered but the metabolism has never been studied.

Rotational crops data have been previously reviewed [Memo from E. Regelman to L. Rossi, 3-23-1987, Review #70298 and Memo from E. Regelman to R. Taylor, 6-20-1986, Review #6261, EAB (Exposure Assessment Branch, now known as EFGWB, Environmental Fate and Ground Water Branch) (In both memos, studies were reviewed by E.B. Conerly)]. Soil samples were analyzed for propiconazole and for total residues containing 2,4-dichlorobenzene moieties using methods AG-354 and AG-356, respectively. Plant samples were analyzed for total residues containing the 1,2,4-triazole moiety using method AG-357 and for total residues containing the 2,4-dichlorobenzene moiety using method AG-407. Data from confined accumulation in rotational crop studies indicated that ^{14}C-propiconazole may accumulate in all plant parts of wheat, corn, carrots, and lettuce planted in soils treated with propiconazole up to 5 months pre-planting. For rotated leaf lettuce at 279 days post-treatment the following results were obtained. For rotated leaf lettuce a total of 0.06 ppm total triazole was obtained and parent propiconazole and the triazole acetic metabolite were not detected. For winter wheat, corn, and sugar beets, the following data were obtained at 261 days after treatment. For rotated corn and wheat, parent propiconazole was not detected. Using mature carrot tops as a surrogate crop for sugar beet tops, 0.09 ppm of triazole residues were obtained; triazole acetic acid was obtained in 0.06 ppm.

Plant uptake and metabolism in rotational crops result in two major metabolites, the alanine and acetic acid triazole conjugates. The petitioner indicated that the metabolism proceeded through the hydroxylation of the n-propyl group on the dioxolane ring to give 4-hydroxy isomers which subsequently form

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sugar conjugates. Further metabolism involves deketalization of the dioxolane ring yielding the alkanol. Subsequent metabolism involves cleavage of the alkyl bridge to form 1,2,4-triazole and the phenol moiety. Low quantities of the phenyl-related radioactivity in crops treated with phenyl ^{14}C-propiconazole strongly support the conclusions that the phenyl moiety is mineralized to $^{14}CO_2$. Triazole is conjugated with serine to form the alanine conjugate, which is further metabolized to the acetic acid conjugate. The metabolism of propiconazole in rotational crops was the same as in target crops. Information in the EFGWB files indicates that additional studies have also been performed with cabbage, sweet potatoes, barley, rye, and sorghum.

CBTS concludes that, pending submission and acceptance of additional metabolism studies as required in the reregistration process, the metabolism of propiconazole in/on plants is understood. This decision is based on the facts that propiconazole metabolism in rotational crops is the same as in target crops, and that the method detects residues as a common moiety, 2,4-dichlorobenzoic acid. The residues of concern, as previously determined (PP#8F3674, 12/14/88), are propiconazole *per se* and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA) and expressed as parent compound. This deficiency will be resolved during the reregistration process.

No additional plant metabolism information on propiconazole in/on soybeans and dry beans is required from the petitioner at this time.

- **Animals:**

Animal metabolism studies were not submitted for review with this petition.

Poultry metabolism studies will be reviewed as part of the reregistration process.

The goat metabolism study used exaggerated (3.2-4.4X) feeding levels. Total residues for fat and muscle were only 0.08 ppm for each sample. A total of 86% of the radioactivity in fat has been identified. In muscle, a total of 50% has been identified. In muscle, 19% of the radioactivity has been characterized; all other residues did not require characterization. A total of 51% (3.83 ppm) of the liver residues have been identified and 15% characterized. For kidney, a total of 32% (2.53 ppm) have been identified and 31% characterized. A total of 70% of the liver residues were detected as 2,4-dichlorobenzoic acid. In milk, a total of 52% (0.22 ppm) were identified and 25% were characterized. A total of 81% of milk residues were detected as 2.4-dichlorobenzoic acid. (F. Fort, 4-26-1994, CBRS Review #13166, D198815).

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The metabolism of propiconazole in/on animals is adequately understood. The residues of concern are propiconazole *per se* and its metabolites determined as 2,4-dichlorobenzoic acid (PP5F4591, L. Kutney, 6-14-96, CBTS #16294, D21966).

No additional animal metabolism information on propiconazole is required from the petitioner at this time.

ANALYTICAL METHODOLOGY:

Analytical Methodology studies were not submitted for review with this petition.

Ciba-Geigy Analytical Methods AG-454 and AG-517 are available for determination of propiconazole and its metabolites in plant and animal commodities, respectively. The methods use a single moiety detection in which residues are converted to 2,4-dichlorobenzoic acid methyl ester and reported as propiconazole equivalents. Both methods have been successfully validated by the Agency and have been forwarded to FDA for publication in *PAM II*.

Analytical Method AG-454B was used to analyze the samples for residues of propiconazole and metabolites containing the 2,4-dichlorophenyl moiety. This method is identical to the enforcement method but provides additional explanation in certain steps. Briefly, in both methods, the samples are refluxed with ammonium hydroxide/methanol. An aliquot is concentrated, refluxed with potassium permanganate/sodium hydroxide and then partitioned with diethyl ether/hexane. The organic phase is evaporated to dryness and derivatized with diazomethane. The derivative is cleaned-up with alumina. Final determination is made with capillary GC/ECD. The limit of determination is 0.05 ppm determined as 2,4-dichlorobenzoic acid methyl ester and expressed as propiconazole equivalents using the conversion factor of 1.79. CBTS concludes that an additional petition method validation (PMV) is not warranted as the petitioner has presented sufficient validation data.

Method recoveries of propiconazole from dry bean foliage, hay, and bean samples, as well as from soybean beans, fodder, forage, and hay samples fortified prior to extraction ranged from 51 to 123% for fortification values of 0.05 to 10.0 ppm. Radiovalidation data have been previously submitted as part of PP8F3674 (C. Deyrup, RCB#4279 [Chemistry Branch then known as Residue Chemistry Branch], 12-14-1988). In these original studies, recoveries ranged from 77 to 133% for fortification values of 0.05 to 2.0 ppm.

Analytical reference standards for propiconazole and 2,4-dichlorobenzoic acid (DCBA) are available from the U.S. EPA Pesticide and Industrial Chemical Repository in RTP, NC. Pending

results of required plant metabolism studies, analytical reference standards for additional relevant metabolites identified may need to be send to the Repository in RTP, NC.

It should be noted that if the pending plant metabolism studies identify additional metabolites, new plant methodology, independent laboratory and Agency validation (ILV and PMV) may have to be required.

Pending results of required plant metabolism studies, CBTS concludes that adequate enforcement methods are available for the proposed tolerances in plant commodities. Adequate enforcement methods are available for detection of possible residues in/on animal commodities. The petitioner has been informed (through the reregistration process) that a substitute methylating agent is needed in order to replace diazomethane. The deficiency will be resolved through the reregistration process. However, in the future, if the petitioner shows that other methylating agents are not as efficient as diazomethane, then CBTS will accept diazomethane.

No additional analytical methodology information on propiconazole is required from the petitioner at this time.

MULTIRESIDUE TESTING:

Multiresidue Testing studies were not submitted for review with this petition.

Propiconazole is completely recovered *via* FDA Multiresidue Protocol D. However, recovery of propiconazole metabolites (CGA91305, CGA118244 and the 1,2,4-triazole) *via* this method is variable [PESTRAK Data Base (11/6/90)].

No additional multiresidue testing information on propiconazole is required from the petitioner at this time.

RESIDUE DATA:

- Field Studies:

The following studies were submitted for review with this petition:

Ross, J.A. July 20, 1994. *Propiconazole - Magnitude of the Residues in or on Dry Beans Following Application(s) of Tilt 3.6E.* Study performed and submitted by Ciba-Geigy Corporation, NC. Lab Project ID ABR-94018. (MRID #433865-01)

Smith, J.W. August 24, 1994. *Magnitude of Residues of Propiconazole (Tilt) in or on Soybean Beans, Fodder, Forage, and Hay Following Application of Tilt 3.6E.* Study performed and submitted by Ciba-Geigy Corporation, NC. Lab Project ID ABR-94013. (MRID #433865-02)

Beans:

The study with MRID #433865-01 reports five field trials conducted with dry beans in Idaho, Colorado, North Dakota, Nebraska, and Michigan. Three foliar applications were performed with propiconazole formulated as Tilt 3.6E. Applications were made at 62.5 (1X) or 125.0 (2X) grams ai per acre each in plots of navy, pinto, or red kidney beans. PHIs were 7 days for dry bean foliage (vines), and 28 days for hay and beans. The samples were stored frozen (-20 °C) for up to 41 months until analysis.

Analytical Method AG-454B was used to analyze the samples for residues of propiconazole and metabolites containing the 2,4-dichlorophenyl moiety. This method is identical to the enforcement method and has already been described in the Analytical Methodology Section of this review. Method recoveries of propiconazole from dry bean foliage, hay, and bean samples fortified prior to extraction ranged from 67 to 123% (Average=89%, n=30).

Residue values were as follows:

Location	Dry Bean Type	Substrate	Treatment Rate *g ai/A*	PHI *days*	Total Residues *ppm*
Idaho	Pinto	Vines	3 x 62.5	7	2.4, 1.8
			3 x 125	7	4.7
		Hay	3 x 62.5	36[1]	1.7, 1.7
			3 x 125	36	1.8
		Beans	3 x 62.5	36[1]	<0.05, <0.05
			3 x 125	36	<0.05
Colorado	Pinto	Vines	3 x 62.5	7	5.3, 3.8
			3 x 125	7	9.9
		Hay	3 x 62.5	28	0.38, 1.4
			3 x 125	28	1.1
		Beans	3 x 62.5	28	0.12, 0.12
			3 x 125	28	0.10

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Location	Dry Bean Type	Substrate	Treatment Rate *g ai/A*	PHI *days*	Total Residues *ppm*
North Dakota	Navy	Vines	3 x 62.5	7	1.2, 1.2
		Hay	3 x 62.5	28	0.17, 0.71
		Beans	3 x 62.5	31	0.09, 0.10
Nebraska	Red Kidney	Vines	3 x 62.5	7	1.5, 1.5
		Hay	3 x 62.5	23	2.9, 2.4
		Beans	3 x 62.5	23	0.06, <0.05
Michigan	Pinto	Vines	3 x 62.5	7	7.5, 4.9
			3 x 125	7	1.9
		Hay	3 x 62.5	28	4.9, 4.8
			3 x 125	28	15
		Beans	3 x 62.5	28	0.13, 0.06
			3 x 125	28	0.10

1 Samples taken at 25 days and allowed to field dry for 11 days.

Maximum residues at the 1X treatment for dry bean foliage collected at a PHI of 7 days, hay at a PHI of 28 days, and beans at a PHI of 28 days were 7.5 ppm, 4.9 ppm, and 0.13 ppm, respectively. These results were corrected for procedural recoveries. Therefore, uncorrected values should be 8.4 ppm for dry bean foliage, 5.5 ppm for bean hay, and 0.15 ppm for beans.

The petitioner is proposing tolerances of 8.0 ppm for dry bean foliage (vines), 8.0 ppm for bean hay, and 0.5 ppm for dry beans. Therefore, the data support the proposed tolerances. However, as indicated in the Proposed Use Section, Section F should be revised to indicate the appropriate commodities and their proper names. Therefore, a tolerance of 0.5 ppm for beans is appropriate.

No additional residue data on beans for propiconazole is required from the petitioner at this time.

Soybeans:

The study with MRID #433865-02 reports fourteen field trials conducted with soybeans in Mississippi, Illinois (2), Texas, Oklahoma, North Carolina, Georgia, Alabama, Louisiana, Iowa, Kansas, Missouri, North Dakota, and Maryland. Soybeans were

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treated foliarly with two ground applications of propiconazole at 75 (1X) or 150 (2X) grams ai per acre each. The first application was made at beginning pod and the second approximately 21 days later, at pod fill. Propiconazole was formulated as Tilt 3.6E. Aerial application was also performed for comparison purposes. Additionally, some applications were made at 3X (225 g ai/acre) the proposed application rate for comparison purposes. The only data reported in this review corresponds to the 1X treatment, unless otherwise indicated. PHIs ranged from 0 to 32 days for soybean forage (lush) and hay (forage allowed to field dry 2-16 days), and from 41 to 99 days for fodder and beans. The samples were stored frozen (-20 °C) for up to 41 months until analysis.

Analytical Method AG-454B was used to analyze the samples for residues of propiconazole and metabolites containing the 2,4-dichlorophenyl moiety. This method is identical to the enforcement method and has already been described in the Analytical Methodology Section of this review. Method recoveries of propiconazole from soybean beans, fodder, forage, and hay samples fortified prior to extraction ranged from 51 to 116% (Average=86%, n=79).

Residue values were as follows.

Location	Substrate	PHI *days*	Total Residues *ppm*
Mississippi	Beans	56	0.37, 0.23
	Forage	0	8.0, 8.3
		7	7.9, 3.1
		14	5.6, 5.9
		21	5.5, 5.5
		30	3.3, 3.1
	Hay	0	31, 30
		7	24, 18
		14	19, 36
		21	1.9, 5.4
		30	2.6, 3.2
	Fodder	56	0.64, 0.76

Location	Substrate	PHI *days*	Total Residues *ppm*
Texas	Beans	52	0.11, 0.13
	Forage	30	2.6, 1.0
	Hay	30	2.2, 2.6
	Fodder	52	1.3, 2.3
Oklahoma	Beans	67	0.10, 0.14
	Forage	30	1.6, 0.87
	Hay	30	0.80, 1.7
	Fodder	67	0.22, 0.34
North Carolina	Beans	59	0.18, 0.34
	Forage	31	1.2, 1.8
	Hay	31	1.7, 1.8
	Fodder	59	0.57, 1.4
Georgia	Beans	60	0.16, 0.19
	Forage	30	3.5, 2.2
	Hay	31	7.7, 4.6
	Fodder	60	0.59, 0.64
Alabama	Beans	73	0.37, 0.31[1] 0.40, 0.32[1]
	Forage	31	2.4, 3.8
	Hay	31	2.8, 3.3
	Fodder	73	0.12, 0.12[1] 0.21, 0.27[1]
Louisiana	Beans	69	0.21
	Forage	30	4.9, 5.4
	Hay	30	3.7, 5.8
	Fodder	69	0.53, 0.79
Iowa	Beans	50	0.25, 0.20
	Forage	31	0.39, 1.9

Location	Substrate	PHI *days*	Total Residues *ppm*
	Hay	31	0.48, 3.0
	Fodder	50	0.75, 0.53
Missouri	Beans	51	0.13, 0.11
	Forage	30	1.2, 0.93
	Hay	30	2.7, 1.6
	Fodder	51	0.56, 1.4
North Dakota	Beans	41	0.31, 0.28
	Forage	21	0.63, 1.1
	Hay	21	1.4, 4.5
	Fodder	41	0.52, 0.51
Kansas	Beans	99	0.12, 0.06
	Forage	31	1.2, 1.6
	Hay	31	3.4, 7.0
	Fodder	99	<0.05, <0.05
Maryland	Beans	79	0.14, 0.19
	Forage	31	4.9, 5.4
	Hay	31	12, 8.8
	Fodder	79	4.6, 6.2
Illinois	Beans	49	0.15
	Forage	0	6.9, 4.9
		7	5.7, 9.2
		14	9.7, 7.6
		21	2.8, 3.8
		30	3.7, 5.4
	Hay	0	35, 37
		7	26, 15, 70
		14	6.8, 23, 50
		21	4.0, 6.5

Location	Substrate	PHI *days*	Total Residues *ppm*
		30	21, 21
	Fodder	49	3.2, 3.2
Illinois	Beans	52	0.8, 0.14
	Forage	32	1.3, 0.33
	Hay	32	2.0, 0.49
	Fodder	52	0.16, 0.16

1. Samples were re-extracted and re-analyzed.

Maximum residues resulting from two foliar applications at the 1X treatment for soybean forage collected at a PHI of 30 days, hay at a PHI of 30 days, fodder at a PHI of 79 days, and beans at a PHI of 73 days were 5.4 ppm, 21 ppm, 6.2 ppm, and 0.40 ppm, respectively. These results were corrected for procedural recoveries. Therefore, uncorrected values for dry bean foliage, hay, and beans should be 6.2 ppm, 24 ppm, 7.2 ppm, and 0.47 ppm, respectively.

Maximum residues resulting from two aerial applications at the 1X treatment for soybean forage collected at a PHI of 30 days, hay at a PHI of 30, fodder at a PHI of 49 days, and beans at a PHI of 49 days were 4.7 ppm, 20 ppm, 6.8 ppm, and 0.22 ppm, respectively. These results were corrected for procedural recoveries. Therefore, uncorrected values for dry bean foliage, hay, and beans should be 5.5 ppm, 23 ppm, 8 ppm, and 0.25 ppm, respectively. The data show no significant differences between aerial and ground applications.

The petitioner is proposing tolerances of 0.5 ppm for soybean beans, 8.0 ppm for soybean forage, 8.0 ppm for soybean fodder, and 25 ppm for soybean hay. However, as indicated in the Proposed Use Section, Section F should be revised to indicate the appropriate commodities and their proper names. Therefore, the following tolerances are appropriate: soybeans, seed at 0.5 ppm, soybean, forage at 8.0 ppm, and soybean, hay at 25 ppm.

The Agency has determined that tolerances on aspirated grain fractions (previously referred to as "grain dust") should be established based on the use of the pesticide on corn, wheat, sorghum, and soybeans. Therefore, data on soybean aspirated grain fractions are required. The petitioner is referred to the document *Aspirated Grain Fractions (Grain Dust): A Tolerance Perspective* (E. Saito/E. Zager, 6-7-1994), for further information.

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Additional Residue Data - Beans & Soybeans (Previously Reviewed):

Previously, in PP8F3674 (C. Deyrup, RCB#4279 [Chemistry Branch then known as Residue Chemistry Branch], 12-14-1988) data for beans and soybeans were reviewed.

Residue data were generated on lima beans, great northern beans, pinto beans, red kidney beans, soybeans, and canning beans (succulent). Residue data (2 trials) reflected analyses of forage. The beans residue data (excluding soybeans) reflect field trials conducted in CA, NE, MN, MI. Residue data on soybeans were submitted from IA, SC, and MS. The pea trial was conducted in WI. The field trials reflect 2-3 treatments at rates of 62.5 g ai/A, 75 g ai/A, and 125 g ai/A. Treatment intervals ranged from 6-31 days. PHIs ranged from 25-105 days. Forage samples were analyzed 7 days after treatment. Analyses were performed using Method AG-454. The data were as follows. The commodities of interest to this review have been highlighted in the table.

Commodity	Treatment Rate (g ai/A)	PHI (days)	ppm Propiconazole[1]
Canning Peas (succulent)	3 x 62.5	28	0.14-0.25
Lima Beans	3 x 62.5	48	<0.05
Dry Beans (except Soybeans)	3 x 62.5	25	0.08-0.14
	3 x 62.5	48-89	<0.05-0.14 (81)
Soybeans	3 x 62.5	64-90	0.15-0.41 (64)
Dry Beans (except Soybeans)	2 x 75	56-89	0.07-0.14 (89)
Soybeans	2 x 75	71-105	0.10-0.43 (86)
Dry Beans (except Soybeans)	3 x 125	48-57	0.07-0.13 (57)
Soybeans	3 x 125	64	0.61-0.74
Pea Pods (succulent)	3 x 62.5	7	0.28-0.31
	3 x 62.5	14	0.18-0.22
Pea Stems (succulent)	3 x 62.5	7	4.08-4.50
	3 x 62.5	14	4.71-4.92

Commodity	Treatment Rate (g ai/A)	PHI (days)	ppm Propiconazole[1]
Lima Bean Pods (succulent)	3 x 62.5	7	0.10
	3 x 62.5	14	<0.05
Lima Bean Stems (succulent)	3 x 62.5	7	2.99
	3 x 62.5	14	0.39
Pea Hay	3 x 62.5	28	3.77-4.74
Bean Hay	3 x 62.5	25-81	0.45-2.93 (25)
	2 x 75	56-89	0.24-0.59 (56)
	3 x 125	48-57	1.36-1.93 (48)
Soybean Hay	3 x 62.5	77-90	0.77-3.92 (90)
	2 x 75	86-105	0.98-2.05 (105)

1 Number in parenthesis is the PHI with highest residues.

At the time of the review, additional data were requested; including additional data for beans and soybeans. These previously reviewed data provide additional information on expected propiconazole residues at different application rates, PHIs, and sites. No additional information has been provided at the proposed PHIs and application rates.

- **Processing Studies**:

Beans:

There are no processed commodities for the raw agricultural commodity (rac) beans. Therefore, no processing studies are required at this time.

Soybeans:

Processing studies were not submitted for review with this petition.

Processed commodities for soybeans include meal, hulls, and oils, refined.

In PP8F3674 (C. Deyrup, 12-14-1988, RCB#4279), the original legume vegetable crop group submittal, the petitioner was requested to submit information indicating if the processing study complied with commercial practices. Although no details

about the procedure were given by the petitioner, it has been indicated that the processing study was conducted by the Food Protein Research and Development Center of the Texas A & M University System, College Station, Texas.

As indicated in PP8F3674, processing data were generated for soybean fractions, among them, soybean beans, meal, hulls, and refined oils. Results were as follows.

Commodity	ppm Propiconazole
Soybean Beans	0.40-0.61
Soybean Meal	0.40-0.75
Soybean Hulls	0.26-0.31
Soybean Refined Oils	<0.05

Therefore, using the highest residues for each commodity, accumulation of residues in soybean processed commodities is not expected to occur as a result of the proposed use of propiconazole in/on soybeans. Accordingly, there is no need for tolerances on these commodities for the use of propiconazole in/on soybeans.

No additional processing residue data on soybeans for propiconazole is required from the petitioner at this time.

- **Geographical/regional Representation of the Residue Data:**

Based on our Field Trials Guidance Document (June 1994), sufficient geographically representative residue data have not been provided by the petitioner for beans and soybeans. However, for both beans and soybeans, the residue data were generated prior to the issuance of the 1994 document and the data are consistent in that there is no wide variance. Therefore, the available data will be used to satisfy the geographical/regional requirement of the field trials.

- **Storage Stability:**

Storage stability studies were not submitted for review with this petition.

As indicated above for both beans and soybeans, the samples were stored frozen (-20 °C) for up to 41 months until analysis. Residues of propiconazole in soybean fodder and grain have been shown to be stable under freezer storage conditions for up to 6 months (PP#8F3654, CBTS Review #12638, M. Flood, 11/8/93). In

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peaches, bananas, corn oil, corn meal, wheat grain, celery, peanut hulls, peanut nutmeats, and peanut hay, storage has been shown for up to 39-41 months. However, as part of the reregistration process, the petitioner has agreed to submit additional storage stability data on these commodities as well as grass seed. (F. Fort, 4-26-1994, CBRS Review #13166, D198815). Therefore, for this petition only, the available data will be translated to cover the storage interval for beans and soybeans.

No additional storage stability information on propiconazole is required from the petitioner at this time.

MEAT, MILK, POULTRY AND EGGS:

Feeding studies were not submitted for review with this petition.

There are no feedstuffs associated with beans. Therefore, secondary residues of propiconazole in/on meat, milk, poultry, and eggs are not expected to occur as a result of the proposed use in/on beans.

Feedstuffs associated with soybeans are seed, forage, hay, aspirated grain fractions, meal, hulls, and silage. Soybeans can be fed up to 30% in the diet of beef and dairy cattle, up to 40% to poultry, and up to 25% to swine.

The petitioner calculated worst case diets for beef and dairy cattle and for laying hens using the proposed tolerances for beans. The Chemistry Branches had previously (D. McNeilly, CBRS Review #10135, D179969, 7-1-1992, and Addendum of 7-21-1992), calculated dietary burdens for propiconazole. These calculations were based on cattle feeding studies reflecting and ingestion of feed dosed at 15, 75, and 150 ppm of propiconazole. For poultry, the feeding study was conducted at 7.5 ppm. Based on these previously calculated diets, residues (proposed tolerances) resulting from the proposed use of propiconazole in/on soybeans are not expected to exceed established tolerances in/on meat, milk, poultry, and eggs.

No degradation of residues have been found after a four year period for residues of propiconazole in animal commodities using Methods AG-359 (validated) and AG-517 (current enforcement method) (F. Fort, CBRS #13166, D198815, 4-26-1995)

Therefore, pending submission and acceptance of required aspirated grain fractions residue data (see Residue Data Section), CBTS anticipates that the existing tolerances for meat, milk, poultry, and eggs are adequate to cover the possible secondary residues resulting from the proposed use of propiconazole in/on dry beans and soybeans.

OTHER CONSIDERATIONS:

- **CODEX Harmonization:**

There are no CODEX, Canadian or Mexican limits for propiconazole in/on beans or soybeans. Therefore, compatibility is not an issue at this time. However, it should be noted that the proposed U.S. definition includes both propiconazole and metabolites determined as 2,4-dichlorobenzoic acid (DCBA), while the CODEX definition is for propiconazole *per se*, the Mexican definition is for the "presumed" parent, and the Canadian definition includes the propiconazole residue defined as parent and metabolites with the 2,4-dichlorophenyl-1-methyl moiety. Due to these differences in definition of the tolerance expression, harmonization with CODEX may be an issue in the future.

- **DRES Analysis:**

A DRES Analysis may be initiated at this time. The following values should be used: 0.5 ppm for beans, dry, and soybeans, seed at 0.5 ppm. Accumulation of residues in processed commodities is not expected to occur as a result of the proposed use of propiconazole.

- **Food Quality Protection Act:**

HED notes that the Food Quality Protection Act (FQPA) of 1996 has amended and strengthened the standard for establishing tolerances under the FFDCA. OPP is still assessing the full impact of this change in the law on the tolerance-setting process and plans to issue guidelines concerning the establishment of tolerances under the amended statute. All tolerance petitions have to meet the requirements of the FFDCA as amended by the FQPA and OPP may require additional data to determine if the terms of the amended statute are met.

Attachments: IRLS Sheet

cc: MIRodríguez, PP#5F04424, KScanlon (7505C/PMT#21), Reading File, & Circulation.

RDI: TPT#1 (1-30-97); FDGriffith for RALoranger (2-28-97); EHaeberer (3-3-97)

MIRodríguez: Draft (1-24-1997), Edited (3-4-1997)
Mail Code 7509C; Tel (703)-305-6710; CM #2, Rm 804-T

I. Rios 10/15/96

Attachment:

Page 1 of 1

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Propiconazole

CODEX NO. _____

CODEX STATUS:

[M] No Codex Proposal Step 6 or Above (on soybean or dry bean)

Residue (if Step 8): _____

propiconazole per se

Crop(s)	Limit (mg/kg)

PROPOSED U.S. TOLERANCES:

Petition No. 5F04424

CBTS [redacted] Reviewer MIRodriguez

Residue: Propiconazole and its metabolites*

Crop(s)	Limit (mg/kg)
Soybeans	0.5 ppm
Soybean forage	8.0
Soybean fodder/straw	8.0
Soybean hay	25.0
Dry beans	0.5
Dry bean vines/forage	8.0
Dry bean hay	8.0

CANADIAN LIMITS:

[M] No Canadian Limit (on soybean or drybean)

Residue: propiconazole and metabolites containing 2,4-dichlorophenyl-(-methyl) substituted moiety

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

[M] No Mexican Limit (on subject commodity)

Residue: _____

Crop(s)	Limit (mg/kg)

NOTES

*Propiconazole (1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-1H-1,2,4-triazole) and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound equivalent.

Form Revised 1989