

US EPA ARCHIVE DOCUMENT

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(11)

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



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 10, 2005

MEMORANDUM:

SUBJECT: Propiconazole (PC Code 122101): Petition PP#5F04424: Magnitude of the Residue in/on Soybean Aspirated Grain Fractions (GLN 860.1500). DP Barcode # D246884. Case 3125. MRID # 44549101.

FROM: Thurston G. Morton, Chemist
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Thurston G. Morton

THROUGH: Susan V. Hummel, Branch Senior Scientist
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TO: Patrick Dobak/Susan Lewis
Reregistration Branch I
Special Review & Reregistration Division (7508C)

EXECUTIVE SUMMARY:

Syngenta (formerly Novartis) has submitted additional data concerning the magnitude of the residue in/on soybean aspirated grain fractions to support a petition (PP#5F04424, DP Barcodes D210266 and D210295, 3/5/97, M. Rodriguez) for the establishment of permanent 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 in/on dry beans and soybeans. All submitted studies (cited above) were reviewed by Dynamac Corporation under contract to EPA. The attached Dynamac review was modified to reflect current Agency policies. Based on these studies and previously reviewed studies, HED makes the following conclusions:

- The submitted soybean aspirated grain field trial data are adequate for the purpose of this petition. The results of the soybean field trials indicate that residues of propiconazole may concentrate in soybean aspirated grain fractions, therefore exceeding the proposed tolerance of 0.5 ppm in/on soybean seed treated with foliar applications of the 3.6 EC formulation for 0.33 lb ai/A (1x the maximum proposed seasonal application rate). The concentration factors for soybean aspirated grain fractions were 1x and 7.5x for the two field trials and an average concentration factor of 4.3x.

MAY 17 2005

- Because aspirated grain fractions used in commercial feed production typically consist of more than one grain, Guidance requires that tolerances for aspirated grain fractions be established based on the use of the pesticide on corn, wheat, sorghum, and soybeans (refer to OPPTS 860.1500). Previously submitted data concerning aspirated grain fractions of wheat (T. Morton, D240856, 2/23/05) indicate that residues of propiconazole concentrated at 8.3x; the maximum expected propiconazole residues in wheat aspirated grain fractions would be 0.66 ppm based on the HAFT (0.08 ppm) in/on wheat grain. The maximum expected propiconazole residues in soybean aspirated grain fractions would be 2.0 ppm based on the HAFT (0.47 ppm) in/on soybean seed. No data are available for corn aspirated grain fractions. The Agency can not assess an appropriate tolerance for residues of propiconazole in/on aspirated grain fractions until additional data concerning residues in corn aspirated grain fractions are submitted. This deficiency will be resolved during the reregistration eligibility decision process.

cc : Chem F. Chron F. Morton

RDI:Team: 1/14/05; SVH:3/10/05

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

PROPICONAZOLE
PC Code No. 122101; Case No. 3125
(DP Barcode D246884)

PP#5F04424: Evaluation Of Additional Residue Chemistry Data
To Support A Permanent Tolerance For Use Of
Propiconazole On Soybeans

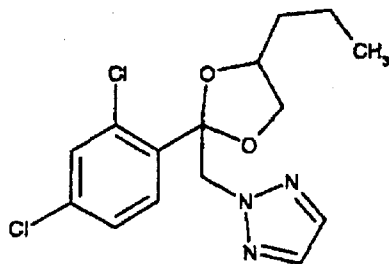
February 10, 2005

Contract No. 68-W-99-053

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

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

PROPICONAZOLE



PC CODE 122101; CASE 3125; DP BARCODE D246884

PP#5F04424: EVALUATION OF ADDITIONAL RESIDUE CHEMISTRY DATA TO
SUPPORT A PERMANENT TOLERANCE FOR USE OF PROPICONAZOLE ON SOYBEAN

INTRODUCTION

Syngenta (formerly Novartis) submitted a petition (PP#5F04424) for the establishment of permanent 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 in/on dry beans and soybeans, and amendments of registrations of end-use labels for Tilt® Fungicide (EPA Reg. No. 100-617) and Tilt Gel® Fungicide (EPA Reg. No. 100-737) for inclusion of bean and soybean uses (PP#5F04424, DP Barcodes D210266 and D210295, 3/5/97, M. Rodriguez). Syngenta has submitted additional data concerning the magnitude of the residue in/on soybean aspirated grain fractions to support the petition.

Propiconazole is a systemic broad spectrum fungicide used for control of disease in a variety of field and orchard crops. Propiconazole is a List C chemical undergoing reregistration.

Tolerances are currently established for residues of propiconazole (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole) and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in/on various plant and animal commodities [40 CFR §180.434]. The established permanent tolerances for plant and animal commodities [40 CFR §180.434(a)] range from 0.05 ppm (milk) to 60 ppm (grass seed screenings). Tolerances with regional registration are also established for wild rice at 0.5 ppm and mint at 0.3 ppm [40 CFR §180.434(c)]. Time limited tolerances which expire 12/31/98 are established for almond nutmeats and hulls, dry beans, forage and hay, cranberries, grain sorghum, and sorghum stover ranging 0.1-8.0 ppm [40 CFR §180.434(b)].

Under petition PP#8F3674, tolerances were proposed for propiconazole in/on celery, corn, pineapple, and the legume vegetable crop group. As of 12/14/88, the Agency recommended against the legume vegetable crop group tolerance due to several deficiencies (CB No. 4279, C. Deyrup). The petitioner pursued the celery, corn, and pineapple tolerances, but withdrew the legume vegetable crop group tolerance petition. Under the current petition (PP# 5F04424), the petitioner requested that the legume data submitted under PP#8F3674, be considered in support of dry beans and soybeans. In addition, a Section 18 for the use of propiconazole formulated as Tilt Fungicide in/on beans was recommended (SLN ND950093, DP Barcode D214846, 5/10/95, W. Cutchin).

Conclusions presented herein are comprehensive for the topics required to support the petition for residues of propiconazole in/on dry beans and soybeans. A single volume of residue chemistry data pertinent to aspirated grain fractions was evaluated for this document.

CONCLUSIONS

OPPTS 830 Series GLNs: Product Properties

1. Additional data are required for GLN 830.6313 (stability) concerning the stability of the technical grade of the active ingredient (TGAI) upon exposure to metal ions. However, this deficiency will be resolved under the reregistration process. All other product chemistry data requirements have been previously reviewed and deemed adequate.

OPPTS GLN 860.1200: Proposed Uses

2. Preharvest intervals (PHIs) and grazing/feeding restrictions on soybean fodder (straw) and bean hay and forage should be removed from the labels because these commodities are not significant food/feed commodities for which tolerances are needed. Therefore, a revised Section B and revised proposed labels for Tilt Fungicide and Tilt Gel Fungicide, are required. In addition, the Section F should be revised to remove proposed tolerances for these commodities, and to express the proposed tolerances for dry beans and soybeans as "beans, dry" and "soybeans, seed," respectively.

OPPTS GLN 860.1300: Nature of the Residue in Plants and Animals

3. The quantitative nature of the residue in plants and animals is adequately understood. The residues of concern is propiconazole *per se*.

OPPTS GLN 860.1340: Residue Analytical Method

- 4a. For enforcement purpose, residue method AG-354 is available for the determination of propiconazole *per se* in/on plant commodities using gas chromatography and flame ionization detection. The reported LOQ is 0.05 ppm. The petitioner may submit an

independent laboratory validations of this method if this is what the registrant wish to use as an enforcement method, but it is not a requirement since Multiresidue Methods Section 302 (Luke Method; Protocol D) picks up parent propiconazole.

- 4b. Analytical GC/ECD method AG-626 was used for determination of the total residues of propiconazole in soybean seeds and aspirated grain fractions; the reported limit of quantitation was <0.05 ppm. Concurrent method recoveries demonstrated that the method is adequate for quantitation of propiconazole residues; recoveries ranged 72-119% in soybean seed (n=4) and 76-116% (n=4) in aspirated grain fractions.

OPPTS GLN 860.1360: Multiresidue Method

5. Propiconazole is completely recovered via FDA Multiresidue Protocol Section 302. However, recoveries of propiconazole metabolites such as CGA-91305, CGA-118244, and the 1,2,4-triazole using Protocol Section 302 are variable.

OPPTS GLN 860.1380: Storage Stability Data

- 6a. Soybean seed samples were shipped to Texas A&M University for the generation of aspirated grain fractions. The generated aspirated grain fractions were shipped on dry ice to Novartis Crop Protection, Inc. (Greensboro, NC). Samples were stored frozen (-20 C) in plastic bags prior to and following residue analysis. Total storage intervals were 123-166 days (-4-6 months).
- 6b. Storage stability data were previously submitted demonstrating that residues of propiconazole are stable for up to 6 months in soybean fodder and 4 months in soybean grain (Phase 4 Review dated 6/25/92); and for up to 12 months in/on peaches, bananas, corn meal, wheat grain, peanut hulls, peanut nutmeats, and peanut hay, and 4 months in/on celery and corn oil (DP Barcode D220935, T. Morton, 3/25/99); no additional data are required to support the submitted aspirated grain fraction data.

OPPTS GLN 860.1500: Crop Field Trials

- 7a. In previously reviewed data on 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 2, 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.
- 7b. 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 2, Section F should be revised to

indicate the appropriate 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.

- 7c. The submitted soybean aspirated grain field trial data are adequate for the purpose of this petition. The results of the soybean field trials indicate that residues of propiconazole may concentrate in soybean aspirated grain fractions, therefore exceeding the proposed tolerance of 0.5 ppm in/on soybean seed treated with foliar applications of the 3.6 EC formulation for 0.33 lb ai/A (1x the maximum proposed seasonal application rate). The concentration factors varied between the two field trials (1x and 7.5x); the average concentration factor is 4.3x.
- 7d. Because aspirated grain fractions used in commercial feed production typically consist of more than one grain, Guidance requires that tolerances for aspirated grain fractions be established based on the use of the pesticide on corn, wheat, sorghum, and soybeans (refer to OPPTS 860.1500). Previously submitted data concerning aspirated grain fractions of wheat (T. Morton, D240856, 2/23/05) indicate that residues of propiconazole concentrated at 8.3x; the maximum expected propiconazole residues in wheat aspirated grain fractions would be 0.66 ppm based on the HAFT (0.08 ppm) in/on wheat grain. The maximum expected propiconazole residues in soybean aspirated grain fractions would be 2.0 ppm based on the HAFT (0.47 ppm) in/on soybean seed. No data are available for corn aspirated grain fractions. The Agency can not assess an appropriate tolerance for residues of propiconazole in/on aspirated grain fractions until additional data concerning residues in corn aspirated grain fractions are submitted. This deficiency must be resolved during the reregistration eligibility decision process.

OPPTS GLN 860.1520: Processed Food/Feed

8. It was previously demonstrated that propiconazole residues did not concentrate in soybean processed commodities. Accordingly, no tolerances for soybean processed commodities are required.

OPPTS GLN 860.1480: Meat, Milk, Poultry, Eggs

9. There are no feed items associated with dried beans, with the specific exception of cowpea forage and hay; feed items associated with soybeans include 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 of propiconazole resulting from the proposed use of propiconazole in/on soybeans are not expected to exceed the established tolerances in/on meat, milk, poultry, and eggs. However, pending submission and acceptance of the outstanding aspirated corn grain fraction data, revised tolerances may be required.

Codex Issues

10. There are currently no Codex, Canadian, or Mexican limits for propiconazole in/on beans or soybeans. Harmonization with Codex will be addressed in the Reregistration Eligibility Decision (RED).

RECOMMENDATIONS

The Branch cannot recommend for the establishment of the proposed tolerances for residues of propiconazole in/on bean and soybean commodities owing to the deficiencies outlined under Conclusion 2. Revised labels and Sections B and F should be submitted for review.

DETAILED CONSIDERATIONS

Proposed Use:

Two proposed labels for the 3.6 lb/gal emulsifiable concentrate formulation (EC; EPA Reg. No. 100-617) and 4 fl oz gel water soluble packet formulation (WSP; EPA Reg. No. 100-737) were submitted with the original petition submission (DP Barcodes D210266 and D210295, 3/4/97, M. Rodriguez) for use on beans and soybeans. The maximum registered use on soybeans is 64-75 g ai/A (0.14-0.17 lb ai/A) with a repeat application 14-21 days later for up to a total of 150 g ai/A (0.33 lb ai/A/season). The proposed PHI is 50 days for soybean fodder (straw), and 30 days for soybean hay. The labels prohibit the grazing or harvesting of treated forage within 30 days of treatment. Revised labels (Section B) have not been submitted with the additional residue data reviewed in this document.

OPPTS GLN 860.1500: Crop Field Trials

Soybean Aspirated Grain Fractions

In response to the review (DP Barcodes D210266 and D210295, 3/5/97, M. Rodriguez) of a petition for tolerances for propiconazole residues in soybean and dry bean commodities (PP#5F4424), Syngenta submitted data (citation listed below) depicting the magnitude of propiconazole residues in/on soybean aspirated grain fractions.

44549101 K. Lin (1998) Propiconazole - Magnitude of the Residues in or on Soybean Aspirated Grain Fractions. Novartis Laboratory Project Identification Number 387-97. Unpublished Study submitted by Novartis Crop Protection, Inc. 61 p.

Two soybean field residue trials were conducted during the 1997 growing season in IL and NC. Mature soybean grain samples were harvested 45 or 56 days following the last of two foliar applications of the 3.6 lb/gal EC formulation at 0.17 lb ai/A/application, with a 14 day retreatment interval. The total applied rate was 0.33 lb ai/A (~1x the maximum proposed

seasonal rate, respectively); applications were made using ground equipment (Tractor or CO₂ sprayer) in ~15 gal/A.

Soybean seed samples were shipped to Texas A&M University for the generation of aspirated grain fractions. The generated grain fractions were shipped on dry ice to Novartis Crop Protection, Inc. (Greensboro, NC). Samples were stored frozen (-20 C) in plastic bags prior to and following residue analysis. Total storage intervals were 123-166 days (~4-6 months). Storage stability data were previously submitted demonstrating that residues of propiconazole are stable for up to 6 months in soybean fodder and 4 months in soybean grain (Phase 4 Review dated 6/25/92); and for up to 12 months in/on peaches, bananas, corn meal, wheat grain, peanut hulls, peanut nutmeats, and peanut hay, and 4 months in/on celery and corn oil (DP Barcode D220935, T. Morton, 3/25/99); no additional data are required to support the submitted aspirated grain fraction data.

Samples of soybean seed and aspirated grain fractions were analyzed for residues of propiconazole using Syngenta GC/ECD Method AG-626; method AG-626 has been adequately described under previous reviews. To demonstrate the efficiency of the method to recover residues of propiconazole from soybean, control samples were fortified with propiconazole at 0.013 and 0.033 ppm (seed) or 0.004 and 0.02 ppm (aspirated grain fractions) and analyzed concurrently with the treated samples. Recoveries ranged 72-119% in soybean seed (n=4) and 76-116% in aspirated grain fractions (n=4). Apparent residues of propiconazole were below the analytical method's LOQ (<0.05 ppm) in/on two untreated samples each of soybean seed and aspirated grain fractions. Residues of propiconazole in/on treated soybean seed and aspirated grain fractions treated at 1x are presented in Table 1.

Table 1. Residues of propiconazole in/on soybean aspirated grain fractions harvested 45 or 56 days following the last of two foliar spray applications of a 3.6 EC formulation at 0.33 lb ai/A/application (1x).

Test Location (EPA Region)	PHI ^a (days)	Residues (ppm) ^b		Concentration Factor ^c
		Soybean Seed	Aspirated Grain Fractions	
Champaign, IL (Region 5)	45	0.27, 0.28 (0.28)	0.22, 0.32 (0.27)	1x
Sampson, NC (Region 2)	56	0.19, 0.20 (0.20)	1.4, 1.6 (1.5)	7.5x

^a Preharvest interval.

^b Values represent duplicate samples; averages are reported in parentheses.

^c Concentration factors were calculated using average values.

Study summary: The submitted soybean aspirated grain field trial data are adequate for the purpose of this petition. The results of the soybean field trials indicate that residues of propiconazole may concentrate in soybean aspirated grain fractions, therefore exceeding the proposed tolerance of 0.5 ppm in/on soybean seed treated with foliar applications of the 3.6 EC formulation for 0.33 lb ai/A (1x the maximum proposed seasonal application rate). The concentration factors for soybean aspirated grain fractions were 1x and 7.5x for the two field trials and an average concentration factor of 4.3x.

Because aspirated grain fractions used in commercial feed production typically consist of more than one grain, Guidance requires that tolerances for aspirated grain fractions be established based on the use of the pesticide on corn, wheat, sorghum, and soybeans, as applicable (refer to OPPTS 860.1500). Previously submitted data concerning aspirated grain fractions for wheat (T. Morton, D240856, 2/23/05) indicate that residues of propiconazole concentrated at 8.3x; the maximum expected propiconazole residues in wheat aspirated grain fractions would be 0.66 ppm based on the HAFT (0.08 ppm) in/on wheat grain. The maximum expected propiconazole residues in soybean aspirated grain fractions would be 2.0 ppm based on the HAFT (0.47 ppm) in/on soybean seed. No data are available for corn aspirated grain fractions. The Agency can not assess an appropriate tolerance for residues of propiconazole in/on aspirated grain fractions until additional data concerning residues in corn aspirated grain fractions are submitted. This deficiency must be resolved during the reregistration process.

List of Attachments

- I. International Residue Limit Status Sheet

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ATTACHMENT I

International Residue Limit Status Form

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL: Propiconazole

CODEX NO. N/A

CODEX STATUS:

No Codex Proposal (Step 6 or above)

PROPOSED U.S. TOLERANCES:

Petition No: PP#5F04424

Agency Reviewer: T. Morton

Residue (if Step 8):

Residues Proposed For Inclusion in the Tolerance Expression:

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 in/on beans and soybeans.

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>	<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
		soybeans, seed	0.5 ppm
		soybeans, forage	8.0 ppm
		soybeans, fodder/straw	8.0 ppm
		soybeans, hay	25.0 ppm
		beans, dry	0.5 ppm
		bean, vines/forage	8.0 ppm
		bean, hay	8.0 ppm

CANADIAN LIMITS:

No Canadian limit

Residue:

MEXICAN LIMITS:

No Mexican limit

Residue:

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>	<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
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NOTES:



13544

R108230

Chemical:	Propiconazole
PC Code:	122101
HED File Code	11500 Petition Files Chemistry
Memo Date:	03/10/2005
File ID:	DPD246884
Accession Number:	412-05-0096

HED Records Reference Center
05/18/2005