EFED Document

2002043

Shaughnessy No. : 122101

Date Out of EFGWB: SEP - 6 1989

To: S. Lewis/Stone, PM 21
Registration Division (H7505C)

From: Emil Regelman, Supervisory Chemist
Environmental Chemistry Review Section #2
Environmental Fate and Ground Water Branch/EFED (H7507C)

Through: Henry Jacoby, Acting Chief
Environmental Fate and Ground Water Branch/EFED (H7507C)

Attached, please find the EFBWB review of . . .

Reg./File # : 100-617

Chemical Name : Propiconazole; 1-[2-(2,4-dichlorophenyl)4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole

Type Product : Fungicide

Product Name : Tilt, Banner

Company Name : Ciba-Geigy Corporation

Purpose : Request to amend federal label to permit double-cropping of treated winter wheat with soybeans

Date Received: 6-1-89 EFGWB # (s): 90613

Action Code : 305 Total Review Time (days): 2.0

Deferrals to:

_____ Ecological Effects Branch, EFED

_____ Science Integration and Policy Staff, EFED

_____ Non-Dietary Exposure Branch, HED

_____ Dietary Exposure Branch, HED

_____ Toxicology Branch I, HED

_____ Toxicology Branch II, HED

1. CHEMICAL: Common name:

Propiconazole.

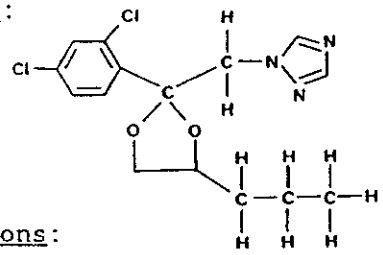
Chemical name:

1-[(2-[2,4-Dichlorophenyl]-4-propyl-1,3-dioxolan-2-yl)-methyl]-1H-1,2,4-triazole.

Trade name(s):

Tilt, Banner, Embolden, CGA-64250, Desmel.

Structure:



Formulations:

3.6 lb/gal EC (Tilt); 1.125 lb/gal EC (Banner).

Physical/Chemical properties:

Empirical formula:		$C_{15}H_{17}O_2N_3Cl_2$.
Molecular weight	:	341.
Physical state	:	Colorless, odorless, viscous liquid.
Solubility	:	110 ppm at 20°C in watel; well miscible with most organic solvents.
Boiling point	:	180°C at 0.1 mm Hg.
Vapor pressure	:	$\leq 3 \times 10^{-6}$ Torr at 20°C.

2. TEST MATERIAL:

Study 1 - Tilt 3.6 EC.

3. STUDY/ACTION TYPE:

Request to amend federal label to permit double-cropping of cereals with soybeans.

4. STUDY IDENTIFICATION:

Cheung, M.W. 1989. Propiconazole in soybean beans, forage, hay, and fodder double-cropped behind winter wheat. Laboratory Project No. ABR-89030. Unpublished study prepared and submitted by Ciba-Geigy Corporation, Greensboro, NC. (41102001)

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5. REVIEWED BY:

A. Reiter
Chemist
EFGWB/EFED/OPP
Review Section #2

Signature: A. Reiter

Date: September 5, 1989

6. APPROVED BY:

Emil Regelman
Supervisory Chemist
EFGWB/EFED/OPP
Review Section #2

Signature: Emil Regelman

Date: SEP - 6 1989

7. CONCLUSIONS:

A. Propiconazole residues (detected as 2,4-dichlorobenzoic acid (DCBA) methyl ester and expressed as propiconazole equivalents) were not detected (<0.05 ppm) in harvest soybeans grown in plots that had been treated at the maximum application rate of 50 g ai/A (1X) or at exaggerated rates of 3X and 5X in all field trials in 8 states. Nominal residues (0.06 to 0.11 ppm) were detected in two replicate samples from a site that had been treated at the 2X exaggerated rate in one of the eight field trials; this was attributed to an apparently higher application rate than intended as suggested by disproportionately relatively higher residue levels on the winter wheat forage for this particular field trial when compared to the other seven trials.

B. In many respects the submitted field study satisfies the requirement for field rotational accumulation of propiconazol on soybeans. Since no residues were detected in soybeans rotated behind wheat treated at the maximum label rate as early as 55 days after application and harvested 172-229 days after planting, a tolerance may not be needed. Since residues were detected in soybean forage, hay and fodder (straw) (0.09, 0.11 and 0.17 ppm, respectively, a restriction on the use of these by-products for animal feed is proposed by the registrant.

C. However, since the confined rotational crop requirement has not been fulfilled (required under §158 for terrestrial food crop registration), then no conclusion relative to the adequacy of the submitted field study can be made at this time.

D. Furthermore, there were no soil analyses performed to confirm the application rates. The registrant can only affirm that propiconazole was applied by citing the residues on the winter wheat forage and uptake in the soybean forage, hay and fodder.

E. Finally, the analytical method employed was the FDA enforcement method. We find this method to be inadequate since a major expected metabolite of propiconazole, 1,2,4-triazole, may not be detected (see comment in Background section below). The registrant states that the

FDA method detects the parent and metabolites containing 2,4-dichlorobenzoic acid.

8. RECOMMENDATIONS:

EFGWB **does not concur** with the request by the registrant for a federal label amendment to allow the rotation of propiconazol treated winter wheat with soybeans.

A) The registrant is reminded that the confined rotational crop requirement has not been fulfilled and is necessary under §158 for terrestrial food crop registration.

B) The registrant must provide a convincing argument that the application rates used in these field studies are valid in the absence of pre- and post-application (day 0) soil residue analyses.

If the above conditions are satisfied, then, at a later date EFGWB may need to make the following deferrals:

A) Considering that there are reported levels of propiconazole in soybean forage, hay, and fodder (straw) and in winter wheat forage, DEB may need to be asked whether the rotational crop restriction statements are adequate:

"To avoid possible illegal residues:
(1) Do not double-crop treated acreage when Tilt is applied to the first crop, unless the second crop appears on this label.
(2) Do not graze or feed forage, fodder, or straw from rotational crops planted in the fall or the spring following treatment."

D) Considering that the submitted field study utilized a tolerance enforcement analytical method which detects propiconazole residues as the 2,4-dichlorobenzoic acid methyl ester and which residues are converted to propiconazole equivalents, Toxicology Branch II may need to comment on the adequacy of this method. Specifically, the question that might need to be resolved is whether the expected 1,2,4-triazole metabolite is of toxicological concern?

9. BACKGROUND:

A. Introduction

Propiconazole is a broad spectrum foliar fungicide with systemic and eradicative properties registered for use on pecan trees (both bearing and nonbearing), wheat, barley, rye, and to grasses grown for seed. It is the only registered fungicide that with a single treatment to wheat can provide full control of all foliar diseases (Letter of M. Newman, Univ. of Tennessee Inst. of Agriculture, to Ciba-Geigy Corp., dated March 3, 1989, submitted with 24C request).

The following environmental fate studies (and results) have been considered fulfilled by EAB:

- o hydrolysis: stable;
- o aqueous photolysis: rapid with sensitizers; $t_{1/2}$ < 1 day;
- o soil photolysis: none over 24 hr period;
- o aerobic soil metabolism: $t_{1/2}$ = 10 wks;
- o mobility, adsorption/desorption: tightly bound to soil;
- o mobility, column leaching: little propensity of both aged and non-aged residues to leach;
- o field dissipation: $t_{1/2}$ < 1 month in sandy loam soils;
- o fish accumulation (BCF 24X in muscle: depuration almost complete in 2 weeks.
- o field rotational crop accumulation: considered fulfilled in EAB Memo of 3/23/87 for 3 standard crop groupings. Two major metabolites were found to be taken up by plants: the alanine and acetic acid triazole conjugates. No rotational crop intervals were established at that time. Tolerances have been established on the crops appearing on the label.

The following studies were required postregistration based upon a letter from the registrant to H. Jacoby dated 4/15/85:

- o aerobic aquatic metabolism
- o anaerobic aquatic metabolism.

The registrant estimated completion by September 1986. They have recently been received by EFGWB. Preliminary review by both Dynamac and EFGWB indicates that neither aquatic study will satisfy the data requirements (see EFGWB #90416).

The following environmental fate requirement has not been satisfied. The registrant was advised that these data are required in EAB memoranda of 6/20/86 and 5/18/87:

- o **confined rotational crop accumulation.**

Furthermore, the registrant was advised in the memo of 6/20/86 that "since 1,2,4-triazole is the major metabolite of propiconazole, it ... and the 2,4-dichlorobenzene moiety should be looked for" in plant uptake studies, "not simply total triazoles or ^{14}C".

The current application proposes to amend the federal label for propiconazole to allow double-cropping of soybeans following its application to wheat. While this proposal was under review, EFGWB has received a copy of DEB Memo #5295 requesting comments on whether soybeans should be subject to a tolerance as a double crop for a similar Section 24C petition from the State of Tennessee.

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B. Directions for use

According to the approved label received by RD on 6/22/88 propiconazole may be applied at 0.11 to 0.22 lb ai/A in 20 gal of water per application to pecans (bearing); 0.11 to 0.15 lb ai/A to pecans (nonbearing) up to four applications per season; one application at 0.11 lb ai/A to wheat, barley, and rye; and, up to two applications at 0.16 to 0.275 lb ai/A on rice.

No tolerances have been established for soybeans. The current label bears a restriction against rotating or double-cropping unless the second crop already appears on the label.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

See attached review.

11. COMPLETION OF ONE-LINER:

The one-liner was updated on 8/1/88.

12. CBI APPENDIX:

None; the registrant has attached a statement of "No Claim of Confidentiality".

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Emil, 10/18

If we received this deferral now (see p. 3) we would conclude that their proposal to restrict feeding of the forage, fodder and straw of the subsequent soybean crop is impractical, and that rotational crop tolerances would be needed for soybean forage, fodder and seed.

Debra Edwards
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