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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

APR 12 1989

MEMORANDUM

SUBJECT: PP# 9F3706, Amendment (2/24/89)
Tilt^{R} (Propiconazole) in or on Hay, Forage, and Seed Screenings of Grasses Grown-for-Seeds. Revised Section F

DEB No(s): 5058

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THRU: Richard D. Schmitt, Acting Chief
Dietary Exposure Branch
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TO: Susan Lewis, PM 21
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and

Fungicide-Herbicide Support
Toxicology Branch
Health Effects Division (H7509C)

In response to DEB memorandums of February 7 and 15, 1989, Ciba-Geigy has submitted a revised section F requesting establishment of group tolerances for the residues of the fungicide, 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 the parent compound in or on the following agricultural commodities (proposed tolerances in ppm are given in parenthesis):

Section 40 CFR 180.434	
Grass Forage	(0.5)
Grass Hay	(5.0)
Grass Seed Screenings	(10.0)

In addition, revised tolerances of 2.0 ppm (each) have been proposed for liver and kidney.

CONCLUSIONS

1. Ciba-Geigy claims that the proposed tolerance for grass seed screenings is supported by the enforcement data generated by the Food and Drug Administration and by the Oregon Department of Agriculture. However, as expressed in the DEB memorandum of January 23, 1989, monitoring data do not provide the basis for establishing tolerances. The recommended tolerance (with an expiration date) for grass seed screenings was based on the limited field residue data provided. The monitoring data, however, indicate that while the petitioner proceeds to address the deficiencies reflected in the memorandum of February 7, 1989, including submission of additional data generated from field studies, the residues on seed screenings are unlikely to exceed the proposed interim tolerance.

2. The petitioner has proposed revised group tolerances of 0.5, 5.0, and 10.0 ppm for residues of 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 the parent compound in or on forage (regrowth), hay, and seed screenings, respectively, of grasses grown-for-seed. In addition, revised tolerances of 2.0 ppm (each) have been proposed for liver and kidney.

RECOMMENDATIONS:

Toxicological considerations permitting, DEB does not object to establishing the proposed tolerances with appropriate expiration dates. The petitioner must, however, proceed to address the deficiencies raised in the memorandum of February 7, 1989 before permanent tolerances could be established for the subject commodities.

NOTE TO PM:

Although the petitioner has not specified, the revised tolerances for liver and kidney, refer to those of cattle, goat, hog, sheep, and horses.

DETAILED CONSIDERATIONS

Amendment of 1/6/89
In the amendment Ciba Geigy proposed establishment of group tolerances of 0.5 and 5.0 ppm for residues of concern in/on forage and hay, respectively, of grasses grown-for-seed. In addition, an interim tolerance of 10.0 ppm (expiration date 12/31/1990) was proposed for grass seed screenings.

DEB Response to the Amendment of 1/6/89, Memorandum of 2/7/89
Conclusions/Recommendations:
Remaining Deficiencies (Reproduced from the Memorandum) -

2. Since grasses may be harvested for seeds on ranges, the label should be revised such that the rangeland application of the fungicide is prohibited. In addition, either aerial application of the Tilt^{R} should be prohibited or appropriate field residue data in support of the latter application technique should be provided.

3b. Although the previously submitted metabolism data were found to be adequate in conjunction with previous petitions which led to a negligible dietary exposure of livestock to residues of the fungicide and its metabolites, the current use would result in significantly higher dietary burden. The petitioner should, therefore, conduct the requested metabolism study in lactating cows or goats using phenyl labelled ^{14}C-CGA-64250 to determine the nature of metabolites present, and provide an adequate material balance; the metabolism study was initially requested in conjunction with petitions on agricultural commodities, peanut (pp# 8F3654) and corn (pp# 8F3674).

4a. Analytical methodologies provided are adequate for determination of known residues of 1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-1H-1,2,4-triazole and its metabolites in the subject commodities. However, recovery data need to be submitted for grass forage.

4b. For the purpose of establishing permanent tolerances on the subject feeds, DEB can not presently address the adequacy of previously submitted methodology for livestock products, until the result from the study requested in aforementioned conclusion 3b is evaluated. Should the livestock metabolism study lead to the detection of any new metabolite(s) of toxicological concern, additional enforcement method(s) may be required.

5a. Additional residue data reflecting appropriate geographic representation as well as representative grass species should be provided on the subject feeds; refer to the section on Magnitude of the Residues. In addition, storage stability data should be provided on hay.

5b. Although residue data on livestock products have been provided in conjunction with other petitions, until the result from the requested metabolism study, 3b, is evaluated, DEB can not comment on the adequacy of available data.

6a. The petitioner has proposed group tolerances of 0.5 and 5.0 ppm for residues of 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 in or on hay and forage (regrowth), respectively, of grasses grown-for-seeds. In addition, an interim tolerance of 10.0 ppm has been proposed for seed screenings. DEB can not presently comment on the adequacy of the proposed permanent tolerances, until the deficiencies raised in aforementioned conclusion 5a are resolved. TOX considerations permitting, however, DEB would not object to establishing tolerances with expiration dates on the subject feeds.

6b. For the purpose of establishing permanent tolerances on the subject feed items, DEB can not presently address the adequacy of established tolerances on meat, fat, liver, kidney, meat by products, and milk until the issue raised in conclusion 3b is resolved.

As a result of aforementioned conclusions; 2, 3b, 4a, 4b, 5a, 5b, 6a, and 6b; DEB recommends against establishing the proposed permanent tolerances on the subject commodities. TOX considerations permitting, however, DEB would not object to establishing tolerances with the proposed expiration date on the subject feeds, forage, hay, and seed screenings.

TOX's Deference, Memorandum of 2/1/89
TOX requested input from DEB on whether the residues of concern in/on animal commodities would exceed the established tolerances as a result of the proposed interim tolerance for grass seed screenings.

DEB Response to TOX's Deference, Memorandum of 2/15/1989
Comments/Conclusions:
Summary -
As a result of inadequate metabolism studies, considering a worse-case-scenario for the purpose of dietary exposure to all the residues containing the chlorophenyl moiety (characterized and uncharacterized, including potential chlorophenol metabolites), the magnitude of tolerances established for milk (0.05 ppm) and meat/fat (0.1 ppm) are not likely to be exceeded as a result of application of Tilt^{R} to grasses grown-for-seeds. The residues containing the chlorophenyl moiety may, however, exceed the magnitude of the established tolerance (0.2 ppm) for liver and kidney. The residues in/on the aforementioned

commodities may reach 1.5-2.0 ppm.

Since Tilt^{R} has been registered for use on grasses grown-for-seeds, TOX considerations permitting, DEB would not object to establishment of tolerances with expiration dates on the subject feeds (forage, hay and seed screenings) with concomitant revised tolerances of 2.0 ppm (with expiration date) for liver and kidney, while the petitioner proceeds to address the deficiencies raised in the memorandum of 2/7/89.

Petitioner Response, Amendment of 2/24/89
A revised section F has been submitted in which Ciba-Geigy requests establishment of group tolerances of 0.5, 5.0, and 10.0 ppm for residues of 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 the parent compound in or on forage, hay, and seed screenings, respectively, of grasses grown-for-seed. In addition, revised tolerances of 2.0 ppm (each) have been proposed for liver and kidney. Although the petitioner has not specified, the revised tolerances for liver and kidney refer to those of cattle, goat, and hog, sheep, and horses.

It should be noted that, in the present correspondence Ciba Geigy claims that the proposed tolerance for grass seed screenings is supported by the enforcement data generated by the Food and Drug Administration and by the Oregon Department of Agriculture. However, as expressed in the DEB memorandum of January 23, 1989, monitoring data do not provide the basis for establishing tolerances. The recommended tolerance (with an expiration date) for grass seed screenings was based on the limited field residue data provided. The monitoring data, however, indicate that while the petitioner proceeds to address the deficiencies reflected in the memorandum of February 7, 1989, including submission of additional data generated from field studies, the residues on seed screenings are unlikely to exceed the proposed interim tolerance.

cc: Reading File, Circulation, Reviewer (H. Fonouni), pp# 9F3706, ISB/PMSD (E. Eldredge), R. Tomerlin (TAS/SACB).

RDI:Acting Section Head: D. Edwards: 4/3/1989, R. Loranger: 4/11/89.

H7509C: DEB: Reviewer(HF): CM#2,Rm803: 557-7561: typist(hf): 4/3/1989.