



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

DEC 20 1991
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MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: HI-910009. Propiconazole (Tilt®) Special Local Need [24 (c)] Registration for Tilt on Hawaiian Bananas to Control Black Leaf Streak.
(No MRID#) [CBTS#9035] (HED Project# 2-0722)

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THRU: R. W. Cook, Acting Section Head *RWCook*
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TO: Susan Lewis, PM-21
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The State of Hawaii Department of Agriculture has issued to Ciba-Geigy Corp., Agriculture Division a Special Local Need (SLN) [24(c)] registration for application of Tilt® 250 EC to control black leaf streak (aka black sigatoka) on bananas in Hawaii. Tilt® 250 EC is a new end use product that is currently not registered with EPA. However the ingredients are the same as in Tilt® Fungicide (EPA Reg. No. 100-617). The active ingredient in Tilt® is propiconazole (1-((2-(2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl) methyl)-1H-1,2,4-triazole).

Tolerances are established for residues of propiconazole and its metabolites determined as 2, 4-dichlorobenzoic acid and expressed as the parent compound in or on various agricultural commodities including bananas at 0.2 ppm; barley, wheat, rice, rye at 0.1 ppm; eggs at 0.1 ppm; milk at 0.05 ppm; in meat, fat, and meat byproduct (except kidney and liver) of cattle, goats, hogs horses, and sheep at 0.1 ppm (see 40 CFR §180.434).

CONCLUSION

1. The petitioner has an adequate set of directions for use of Tilt® 250 EC on bananas in Hawaii to control black leaf streak. These directions for use for the special local need registration are nearly identical to the established use for a banana import tolerance. The SLN use is not expected to

increase the likelihood of over tolerance propiconazole residues in banana samples.

- 2a. The nature of the residue in plants is adequately understood. The residue of concern is the parent propiconazole and its metabolites determined as 2, 4-dichlorobenzoic acid.
- b. The nature of the residue in animals is adequately understood. However, there are no livestock feed items involved in this SLN registration. Thus, the animal metabolism need not be discussed further, and there is no need for livestock feeding studies from Tilt® use on bananas
3. Adequate residue analytical methods were used to gather the residue data. Modified and improved residue analytical method successfully passed on EPA petition method validation (PMV) and are suitable to enforce the propiconazole tolerance on bananas. The method has been forwarded to FDA for publication in PAM-II.
- 4a. Residues of propiconazole and its 2,4-dichlorobenzoic metabolites from use of Tilt® 250 EC on bananas when used as directed by the Hawaiian SLN [24 (c)] registration are not expected to exceed the established 0.2 ppm tolerance.
- b. There are adequate geographically representative banana crop field trial residue data available to support the SLN Hawaiian registration.
- c. The international crop field trial residue data can be translated to support a US tolerance/registration.

RECOMMENDATION

CBTS recommends for the [24(c)] registration for use of Tilt® 250 EC (propiconazole a.i.) on bananas in Hawaii.

PROPOSED USE

In PP# 4F3026 the petitioner proposed a use of Tilt® 250 EC at a rate of 0.4 L/hectare (100 grams a.i.) at 14-28 day intervals, 9 applications per season and no PHI. 100 grams a.i./hectare is approximately 1.4 oz. a.i. per acre. This use is for a banana import tolerance.

For this [24 (c)] registration the Tilt® application is by ground equipment only at a rate of 5.5 fl. oz (approximately 1.4 oz a.i.) per acre. Tilt® 250 EC (containing 25.2% propiconazole by weight) is applied in 10-30 gallons of water at 21-25 day intervals, 8 applications per season, and no PHI. Use of a crop oil such Volck Supreme (EPA Reg. #59639-20) or Volck Superior,

and an emulsifier at 0.6 fl. oz./gallons is also recommended. Tilt® is applied on the Big Island of Hawaii from July to January, and on other Hawaiian islands from October to January.

Restrictions include no application to non-bagged bananas, or application within 100 yards of non-bagged bananas. Also, do not apply Tilt® through any type of irrigation system.

The use is to control black leaf streak or black sigatoka in bananas.

NATURE OF THE RESIDUE

According to PP# 4F3026 (see memorandum by K.H. Arne dated June 20, 1984) the nature of the residue in plants is adequately understood. The residue in plants consists of parent plus free and conjugated metabolites of parent that have been hydroxylated on the alkyl side chain of the dioxolane ring, free and conjugated components containing both the phenyl and triazole rings (CGA-91304, CGA-91305, and CGA-104284), and 1,2,4 triazole-1-alanine. The residues of concern are the parent and its metabolites determined as 2,4-dichlorobenzoic acid.

The nature of the residue in animals is adequately understood. However, since no feed items are involved, animal metabolism will not be further discussed.

RESIDUE ANALYTICAL METHODS

Magnitude of the residue data for propiconazole, parent only were generated using Analytical Method REM 11/81. The method involves homogenizing with methanol, filtration, partitioning with CH_2Cl_2 , cleaning through an Alumina V column, and determination by GC equipped with a nitrogen specific detector. The limit of detection is 0.02 ppm.

The total dichlorobenzyl moiety method is Analytical Method AG-356. This method used a HNO_3 digestion to form 2,4-dichlorobenzoic acid, partition into CH_2Cl_2 , methylation, cleanup on a silica gel column, and determination by GC/MS. This method was deemed suitable to gather valid pesticide residue results in plants tissues (see memorandum in PP# 4F3026 by S. Malak dated 3/20/87). An updated version of this method AG-454A underwent a successful petition method validation (see memorandum by E. Greer of ACB dated 4/27/87). Overall EPA recoveries from fortification at 0.1 ppm and 0.2 ppm in wheat grain and pecan nutmeats ranged from 79 to 107% with method sensitivity at 0.05 ppm for wheat grain and pecan nutmeats. The method AG-454A is suitable to enforce the proposed tolerance, and has been forwarded FDA for publication in PAM-II.

STORAGE STABILITY

Residues of propiconazole from fortified soybean fodder and grain samples stored frozen are stable for at least six months. Field weathered residues of propiconazole in/on peanut hay, shells, and nuts are stable in frozen storage for at least 25 months. Bananas Samples in this petition were stored up to 12 months. There are adequate storage stability data to support the banana crop field trial residue samples submitted with PP# 4F 3026, and the data are translatable to this registration request.

MAGNITUDE OF THE RESIDUE-CROP FIELD TRIALS

No new propiconazole in banana crop field trial residue data were presented in this 24(c) request. No US propiconazole in banana crop field trial residue data have been presented.

In summary crop field trial residue data were presented from Martinique (1), Belize (2), Ivory Coast (4), and Honduras (13) for the crop years 1981, 1982, and 1983. Tilt® was applied at a rate of 100 grams a.i./ hectare (1x), and at 200 grams a.i. (2x) per hectare in 1 to 13 application, with PHIs ranging from 0 to 21 days. Foliar applications were in water or oil and applied at 10 to 42 day intervals. The maximum total residue in banana pulp was 0.18 ppm from 13 application 9 days PHI; and the maximum total residue from the 2x use at 0 day PHI was 0.052 ppm. The maximum total propiconazole residues in pulp from the 1x application (100 grams a.i. and 0 day PHI up to 9 application per season) are 0.046 ppm. While peels are not a food or feed item the present tolerance is for "bananas" at 0.2 ppm. This tolerance includes residue data from peels plus pulp (see 40 CFR §180.1(j)(1)). The maximum propiconazole in banana peels is 0.2 ppm from a 2x application, 13 times. From the proposed use rate 100 grams a.i./hectare or 1.4 oz. a.i. per acre no total propiconazole residues exceed 0.05 ppm in banana peels.

These data are acceptable to CBTS and we will translate all of the international propiconazole on bananas residue data for the import tolerance to support the propiconazole US registration and US tolerance. These data show the proposed 24(c) use should not cause bananas to have residues in excess of the established 0.2 ppm tolerance. A tolerance of 0.1 ppm as suggested by Hawaii Dept. of Agriculture is not necessary with this established tolerance.

MAGNITUDE OF THE RESIDUE-PROCESSED FOOD/FEED

According to Table II attached to the Residue Chemistry Guidelines there are no processed banana commodities, thus no processing studies are required for this use.

MAGNITUDE OF THE RESIDUE-MEAT/POULTRY/EGGS

Since there are no livestock feed items involved with bananas, ruminant and poultry feeding are not necessary for this use.

H-7509C:CBTS:Reviewer(FDG):vg:12/188/91:(CM#2):RM814B:305-5826:
edit:fdg:12/19/91.

cc:R.F., Circu(7), 24(c) File, Reviewer(FDG), PIB/FOD(Furlow).

RDI:SecHd:RWCook:12/19/91:BrSrSci:RALoranger:12/19/91.