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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 25, 1999

MEMORANDUM:

SUBJECT: **Propiconazole** (122101): Residue Analytical Method(GLN 860.1340) and Storage Stability Data(GLN 860.1380). **DP Barcode #** D220935. **Case 3125.** CB 16494; **MRID #** 43825401, 43825402

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Thurston G. Morton 3/25/99

THROUGH: Susan V. Hummel, Senior Scientist
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TO: Mark Hartman/Kathy Monk, PM #52
Reregistration Section
Special Review & Reregistration Division [7508W]

EXECUTIVE SUMMARY OF RESIDUE CHEMISTRY DEFICIENCIES:

- The Agency finds this study of a methylating agent to replace diazomethane unacceptable. Since various crop matrices have tolerance values at 0.1 ppm, then the method must have the ability to adequately quantitate propiconazole residues at that level. Acceptable recoveries at the 0.05 and 0.1 ppm levels must be demonstrated for CH_3I/TBAH derivatization of propiconazole. The proposed method for propiconazole residues using CH_3I/TBAH derivatization in various plant and animal commodities gives unacceptable recoveries.

- The registrant did not include any animal tissues in the analytical method study. Method AG-517 is utilized for propiconazole residues in meat, milk and eggs analysis for propiconazole. The registrant must also demonstrate acceptable recoveries of propiconazole by CH_3I/TBAH derivatization in samples of meat, milk, and eggs at 0.05 and 0.1 ppm.

- Results show that total residues of propiconazole are stable in peaches, bananas, corn meal, wheat grain, peanut hay, peanut hulls, and peanut nutmeat for a minimum of 12 months and in celery and corn oil for a minimum of 4 months of freezer storage. The registrant commented that results of samples fortified and stored for up to three years will be reported at a later date.

- Despite the fact that diazomethane is the methylating agent employed in the current propiconazole analytical method we recommend that the current method be employed until a satisfactory methylating agent is found to replace diazomethane.

INTRODUCTION/BACKGROUND:

In response to a Phase 4 DCI dated 9/30/93, the registrant has submitted an analytical method for plant commodities and a storage stability study to support the reregistration of propiconazole.

Tolerances are established for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA), expressed as parent in/on numerous plant and animal commodities in 40 CFR 180.434. Tolerances range from 0.1 ppm - 60 ppm. Propiconazole is a List C chemical. The Agency RED has not been completed.

DISCUSSION:

Residue Analytical Method GLN 860.1340:

HED has previously stated that a substitute methylating agent was needed, to replace diazomethane in Analytical Method AG-517 and AG-454. The registrant has submitted a study titled:

> ***Investigations Into The Methylation Of 2,4-Dichlorobenzoic Acid As A Part of Analytical Methods AG-517 and AG-454B. MRID 438254-01***
> *Author: Kaijun Lin, PhD*
> *Laboratory Project Identification: ABR-94065*
> *Date Completed: October 18, 1995*

Six common derivatization agents were tested in comparison with diazomethane. The average response factors from the calibration standards were checked against the average response factor of diazomethane. All agents except for methyl iodide/tetrabutyl ammonium hydroxide (CH_3I/TBAH) were less than 90% of diazomethane. Only CH_3I/TBAH was used for further analytical testing. The following crop matrices were fortified with propiconazole : corn grain, corn forage, corn meal, peanut hulls, and wheat grain. The crop matrices were fortified at 0.05, 0.1, 0.5, and 2 ppm of propiconazole. Table 1 shows the recoveries of propiconazole in the various crop matrices for both CH_3I/TBAH and diazomethane. The registrant did not include in their summary of the results the recoveries from the 0.05 and 0.1 ppm because of the residue values which occurred in the control samples. Numerous livestock and plant commodities have

tolerances set at 0.1 ppm.

Table 1. Summary of Propiconazole Recoveries in Various Crop Matrices

Derivatized by CH_3I/TBAH

Crop Matrix	Control	0.05 ppm	0.1 ppm	0.5 ppm	2 ppm
Corn Grain	0.098 ppm	35 %	96 %	68 %	57 %
Corn Forage	0.37 ppm	190 %	91 %	50 %	39 %
Corn Grain*	0.061 ppm	84 %	NA	66 %	66 %
Corn Meal	0.195 ppm	171 %	330 %	83 %	67 %
Peanut Hulls	0.056 ppm	200 %	95 %	90 %	79 %
Wheat Grain	0.084 ppm	15 %	<0 %	73 %	103 %

Derivatized by Diazomethane

Crop Matrix	Control	0.05 ppm	0.1 ppm	0.5 ppm	2 ppm
Corn Grain	0.033 ppm	78 %	80 %	47 %	24 %
Corn Forage	0.21 ppm	103 %	<0 %	31 %	35 %
Corn Grain*	0.043 ppm	114 %	38	23 %	17 %
Corn Meal	0.24 ppm	110 %	<0 %	17 %	58 %
Peanut Hulls	0.38 ppm	181 %	99 %	98 %	99 %
Wheat Grain**	0.106 ppm	NA	NA	85 %	88 %

*Samples were under Test Number RI-MV-011-94
**Data were obtained from Storage Stability Study (207-94) and fortification levels were 1 ppm
NA - Data were not available

Storage Stability GLN 860.1380:

The registrant has submitted a study titled:

> ***Stability Of Propiconazole Fortified Into Crops And Processed Fractions Under Freezer Storage Conditions. Interim Report MRID 438254-02***
> *Author: Larry W. Eudy, PhD*
> *Laboratory Project Identification: ABR-95092*
> *Date Completed: October 17, 1995*

A freezer storage stability study was initiated in May, 1994 to determine the stability of propiconazole residues in crop matrices and processed fractions. Samples were fortified with 1 ppm propiconazole and stored under frozen conditions (-20° C). Samples of peaches, bananas, corn meal, wheat grain, peanut hay, peanut hulls, and peanut nutmeat were analyzed at 0-day and at storage intervals of 4-5 months and 12-13 months. Celery and corn oil samples were analyzed at 0-day and 4-5 month intervals. Storage stability recoveries are summarized in Table 2.

Table 2. Summary of storage stability recoveries in various crop matrices and processed fractions fortified with 1.0 ppm propiconazole.

Crop/Storage Interval (days)		Percent Recovery Uncorrected	Percent Recovery Corrected*
Peach	0	66, 75	92, 105
	126	90, 78	134, 114
	385	80, 89	81, 93
Banana	0	61, 58	74, 69
	123	96, 104	97, 106
	385	81, 74	97, 88
Corn Meal	0	90, 91, 89	118, 108, 106
	128	102, 97	119, 112
	377	77, 81	100, 105
Wheat Grain	0	86, 94	87, 96
	123	99, 97	107, 104
	409	71, 69	105, 102
Peanut Hay	0	81, 57	104, 73
	122	91, 81	106, 93
	361	72, 69	106, 101
Peanut Hull	0	91, 76	119, 100
	124	80, 78	110, 107
	364	70, 73	96, 99
Peanut Nutmeat	0	70, 76	87, 95
	126	86, 97	88, 101
	359	63, 65	104, 107
Celery	0	79, 86	99, 109
	125	79, 82	101, 104
Corn Oil	0	66, 65	92, 91
	151	58, 66	88, 102

*Procedural recoveries are corrected for control values.

The submitted storage stability data are adequate. Results show propiconazole residues are stable under frozen conditions in peaches, bananas, corn meal, wheat grain, peanut hay, peanut hulls and peanut nutmeat for a minimum of 12 months. Propiconazole residues are stable under frozen conditions in celery and corn oil for a minimum of 4 months. The registrant stated that results for samples stored for up to three years under frozen conditions will be reported at a later date.

cc : Chem F, Chron F. Morton

RDI:Team: 3/25/99; SVH:3/25/99

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

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HED Records Reference Center
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