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HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Ciba-Geigy Corp.: Response to the Metalaxyl
Reregistration Standard: Residue and Processing
Data (MRID # 42233501, CBRS # 9596, Barcode No. D175852.)

FROM: R. B. Perfetti, Ph.D., Chemist *R. B. Perfetti*
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THRU: E. Zager, Chief *E. Zager*
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TO: W. Burnam, Acting Chief
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and

L. Rossi, Chief
Reregistration Branch
Special Review and Reregistration Division (H7508C)

Attached is a review of metalaxyl pineapple residue and processing data submitted by Ciba-Geigy in response to the Metalaxyl Reregistration Standard. This information was reviewed by Acurex Corporation under supervision of CBRS, HED.

This document has undergone secondary review in CBRS and has been revised to reflect the Branch policies.

Please see our conclusions in the attachment regarding the adequacy of the information provided by the Registrant.

A Residue Chemistry Data Summary Table is also included at the end of this review.



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If you need additional input please advise.

Attachment 1 : Review of Metalaxyl Residue and Processing Data.

cc: With Attachment 1: R. B. Perfetti, Metalaxyl Reregistration Standard File, Metalaxyl Subject File, J. Burrell/C. Furlow (PIB/FOD), Acurex, Circ. (7).

cc: Without Attachment: RF.

METALAXYL
(Chemical Code 113501)
(CBRS No. 9596; DP Barcode D175852)

TASK 3

**Registrant's Response
to Residue Chemistry Data
Requirements**

May 26, 1992

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:

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METALAXYL

(Chemical Code 113501)

(CBRS No. 9596; DP Barcode D175852)

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY REQUIREMENTS

Task 3

BACKGROUND

The Metalaxyl Guidance Document dated 9/88, and the Metalaxyl Reregistration Standard Update dated 3/91, required processing data for pineapple juice and bran. In response, Ciba-Geigy Corp. (1992; MRID 42233501) submitted data depicting the magnitude of metalaxyl residues of concern in or on the forage, fruit, and processed commodities of pineapples harvested following applications of the 2 lb/gal EC formulation at 1x the labeled rate and at exaggerated rates. These data are reviewed here for their adequacy in fulfilling the outstanding requirements.

The nature of the residues in plants is adequately understood. The residues of concern are those expressed in the current tolerances as the combined residues of metalaxyl [N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxy methyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester [40 CFR §180.408(a)-(c), §185.4000(a)-(d), and §186.4000(a)-(d)]. Adequate enforcement methodology exists as Methods I and II in PAM, Vol. II (methods AG-348 and AG-349).

Codex MRLs of 0.05 ppm have been proposed (Step 6) for residues of metalaxyl per se in or on pineapples. This MRL differs from the U.S. tolerance with respect to residue level and the compound(s) regulated. Compatibility of this MRL with the corresponding U.S. tolerance would not be possible without a major revision in the U.S. tolerance definition.

CONCLUSIONS/RECOMMENDATIONS

1. Adequate residue analytical methodology (GLC/NPD method AG-395) was used to collect data from pineapple forage, fruit, and processed fractions. No additional data are required.
2. No storage stability data were reported in the current submission. Requirements remain outstanding for data depicting the stability of metalaxyl residues of concern in or on pineapple fruit and forage stored under similar conditions and for similar intervals as residue samples for which data have been submitted. Because storage intervals for processed samples were relatively brief (< 3 months), storage stability data will not be required for pineapple processed fractions, unless the required

stability data for pineapples indicates that residues decline in the first 3 months of frozen storage.

3. The available data on pineapples are insufficient to determine the potential for concentration of residues during processing. The data indicate that metalaxyl residues concentrated in dried pineapple bran processed from pineapples with residues below the validated detection limit. The raw data needed to determine the actual residues in or on bran were not provided. Therefore, a concentration factor could not be calculated. The registrant must submit full-sized copies of the chromatograms for the pineapple fruit and dried bran samples from the 7x treatment, along with raw data showing estimates for residues below the validated detection limit.

DETAILED CONSIDERATIONS

Residue Analytical Methods

Ciba-Geigy Corp. (1992; MRID 42233501) submitted residue data collected from pineapple commodities (forage, fruit, and processed fractions) using the GLC/NPD method AG-395, a modification of the registrant's method AG-348, which is a modification of Method I in PAM, Vol. II. Method AG-395 was reviewed in the Residue Chemistry Chapter of the Metalaxyl FRSTR dated 6/87; it has undergone Agency method validation and radiolabeled sample validation, and is adequate for data collection. Using this method, residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline (DMA) moiety, and N-(2-hydroxy methyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, are detected as DMA, and residues found in treated samples are expressed as metalaxyl equivalents.

Residues are extracted in methanol:water (80:20, v/v) after which the solvent is evaporated. The extract is refluxed with methanesulfonic acid and then made basic, converting the residues of concern to DMA. The DMA residues are steam distilled and cleaned up on a Sep-Pak cartridge. The DMA residues are analyzed using GC with a nitrogen/phosphorus detector in the nitrogen mode. The detection limit is 0.05 ppm.

Concurrently with the residue samples analyzed for the current submission, untreated samples of pineapple commodities were fortified with metalaxyl and analyzed using method AG-395. Recovery data are presented in Table 1 under "Magnitude of the Residue in Plants." Residue levels reported for treated samples were corrected for method recoveries < 100%. Apparent residues were < 0.05 ppm (nondetectable) in or on control samples of all commodities.

- Storage Stability

Ciba-Geigy Corp. did not report storage stability data for pineapples in the current submission (1992; MRID 42233501). Treated RAC samples (unwashed fruit and forage) were stored at approximately -20 °C for 171-173 days from time of harvest until analysis, or

for 150 days from time of harvest until processing began. Samples of fruit segments, canned segments, canned juice, wet bran, and dried bran were stored at approximately -20 °C for maximum intervals of 48, 60, 87, 53, and 60 days, respectively, from time of processing until analysis.

The registrant cited previously submitted storage stability data (MRID 40534802) to support the current residue data. A search of PDMS conducted on 5/15/92 identified MRID 40534802 as a duplicate of MRID 00071678 (1980), cited in the 6/87 FRSTR as containing storage stability data only for potatoes and tobacco. Requirements remain outstanding for data depicting the stability of metalaxyl residues of concern in or on pineapple fruit and forage stored under similar conditions and for similar intervals as residue samples for which data have been submitted. Because storage intervals for processed samples were relatively brief (< 3 months), storage stability data will not be required for pineapple processed fractions, unless the required stability data for pineapples indicates that residues decline in the first 3 months of frozen storage.

Magnitude of the Residue in Plants

Pineapple processing. Tolerances of 0.1 ppm have been established for the combined residues of metalaxyl [N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxy methyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester in or on pineapples, pineapple fodder, and pineapple forage [40 CFR §180.408(a)]. No food or feed additive tolerances have been established for pineapple processed commodities.

A REFS search dated 5/20/92 shows one product registered for use on pineapples, the 2 lb/gal EC formulation (EPA Reg. No. 100-607). This product is registered for use on pineapples as a seed piece dip applied to the crowns before planting at a rate of 0.5-1 lb ai/A in 75-100 gal/A. A feeding restriction is in effect for plant material harvested within 1 year of planting. These application instructions were obtained from the product label.

Ciba-Geigy Corp. (1992; MRID 42233501) submitted data from three tests conducted in HI depicting the combined metalaxyl and associated metabolite residues in or on the forage, unwashed fruit, fruit segments, canned segments, canned juice, wet bran, and dried bran processed from pineapples harvested 573 days after seed piece dip application of the 2 lb/gal EC formulation at planting at 1 lb ai/A (1x), or 45 days after an additional application of the 2 lb/gal EC formulation applied as a broadcast spray at 2 or 6 lb ai/A [total 3x (1x + 2x) or 7x (1x + 6x)]. The registrant indicated that broadcast application was performed only to obtain measurable residues, and that they do not wish to support a postemergence use on pineapples. Pineapples were harvested at maturity, and were processed using laboratory procedures to simulate industrial practice. Treated samples and untreated controls were shipped and stored frozen (approximately -20 °C) before and after processing. Samples were analyzed using method AG-395; residues found were expressed as metalaxyl equivalents, and are summarized in Table 1.

Residues were detected at 0.11 ppm in or on the dried bran sample from 7x treatment; these data therefore indicate that metalaxyl residues concentrated in dried pineapple bran. However, a concentration factor could not be determined because although a chromatogram was provided for the 7x dried bran sample, no chromatogram was provided for the 7x fruit sample. In cases such as this, when RAC samples with no detectable residues yield processed samples with detectable residue, the Agency may estimate residue levels from chromatograms where the response is below the validated limit of detection but indicative of a measurable residue. Additional data are required.

Table 1. Residues of metalaxyl equivalents found in or on pineapple commodities (corrected for method recoveries < 100%).

Processed Fraction	Residues Found (ppm) Following 1x, 3x, and 7x Treatments			Concurrent Method Recovery	
	1x	3x	7x	Fortification Level (ppm)	%
Forage	<0.05-0.06	0.08-0.09	0.15-0.17	0.2	102
				2	79
Unwashed fruit	<0.05	<0.05	<0.05	0.05	73
Fruit segments	<0.05	<0.05	<0.05	0.05	79
				0.2	72
Canned segments	<0.05	<0.05	<0.05	0.1	65
Canned juice	<0.05	<0.05	<0.05	0.1	125
Wet bran	<0.05	<0.05	<0.05	0.2	70
Dried bran	<0.05	<0.05	0.11	0.2	64

References

Citations for the MRID documents referenced in this review are presented below. Submissions reviewed in this document are indicated by shaded type.

00071678/40534802 Ross, J.A. (1980) Stability of Residues of Metalaxyl and Its Metabolites under Freezer Storage Conditions: Report No. ABR-80028. (Unpublished study received April 15, 1981 under 100-607; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:070021-G).

42233501 Budy, L. (1992) Metalaxyl: Magnitude of the Residue in Processed Food/Feed Commodities of Pineapples Following Seed Piece Dip with Ridomil 2E: Lab Project Number: ABR-91086. Unpublished study prepared by Ciba-Geigy Corp. 110 p.



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