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

(5)

APR 16 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM:

SUBJECT: Metalaxyl. Ciba-Geigy Response to the Reregistration Standard: Product Chemistry Data (MRID No. 41912901), Storage Interval Data (MRID No. 41912902), and Corn Fodder Data (MRID No. 41912903).
CBRS No. 8166. DP Barcode No. D165608.

FROM: John Abbotts, Chemist
Special Review Section II
Chemistry Branch II - Reregistration Support
Health Effects Division [H7509C]

THRU: Edward Zager, Chief
Chemistry Branch II - Reregistration Support
Health Effects Division [H7509C]

TO: Lois Rossi, Chief
Reregistration Branch
Special Review and Reregistration Division [H7508C]

Attached are reviews of product chemistry data, storage interval data, and data on corn fodder submitted by Ciba-Geigy Corporation in response to the Update to the Metalaxyl Residue Chemistry Chapter dated 3/13/91. This information was reviewed by Acurex Corporation under supervision of CBRS, HED. The data assessment has undergone secondary review in the branch and has been revised to reflect branch policies.

The due date for these reviews was 10/9/91.

Product Chemistry data requirements remain outstanding. The submitted data fulfill requirements for information on storage intervals; storage stability studies must be submitted and evaluated. The requirement to explain residues on untreated corn fodder samples is fulfilled.

If you need additional input please advise.

Attachment 1: Review of Metalaxyl Product Chemistry Data
Attachment 2: Confidential Appendix for Metalaxyl Product Chemistry Data
Attachment 3: Review of Metalaxyl Residue Chemistry Data
Attachment 4: Metalaxyl Residue Chemistry Summary Through 4/14/92

cc:(with Attachments 1,2,3,4):Abbotts, Reg. Std. File, SF,
PIB/FOD (C.Furlow), Acurex
cc (without Attachment 2):Circ
cc (without any Attachments):RF
RDI:MSMetzger:4/10/92
H7509C:CBII-RS:JAbbotts:CM-2:Rm803B:305-6230:4/14/92

METALAXYL
(Chemical Code 113501)
(CBRS No. 8166; DP Barcode D165608)

TASK 3

Registrant's Response to Residue Chemistry Data Requirements

November 8, 1991

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:

Acurex Corporation
Environmental Systems Division
4915 Prospectus Drive
P.O. Box 13109
Research Triangle Park, NC 27709

3

METALAXYL

(Chemical Code 113501)

(CBRS No. 8166; DP Barcode D165608)

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

Task 3

BACKGROUND

The Metalaxyl Guidance Document dated 9/88 required data on numerous residue chemistry topics. The data CIBA-GEIGY Corporation submitted in response to these requirements (1990; MRID 41449001) were reviewed by the Agency in CBRS No. 7193 (R. Perfetti, 1/91) and in the 3/91 Metalaxyl Reregistration Standard Update. In CBRS No. 7193 the Agency noted deficiencies in the reporting of sample storage intervals. One of the deficiencies cited in the 3/91 update was a need for an explanation of high apparent residues in or on untreated corn fodder samples (1990; MRID 41689701).

To resolve these deficiencies, CIBA-GEIGY Corp. submitted additional information regarding the storage intervals of samples reported in the Guidance Document to support tolerances (1991; MRID 41912902) and explanations for the observed high apparent residues (1991; MRID 41912903). This information is reviewed in this report.

The nature of the residues in plants is adequately understood. The residues of concern are metalaxyl and its metabolites containing the 2,6-dimethylamine moiety and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester. CIBA-GEIGY analytical method AG-395, a modification of Method I in PAM, Vol. II (Pesticide Reg. Sec. 180.408) adequately recovers these residues from plant tissues and has undergone successful Agency validation.

The nature of the residue in animals is not adequately understood. Metalaxyl and regulated metabolites were successfully recovered from beef liver in an Agency validation trial of Method II in PAM, Vol. II, Pesticide Reg. Sec. 180.408.

CONCLUSIONS

1. The available data on sample storage intervals fulfill the requirement for such data on samples from previously submitted studies that were used to support tolerances. When required storage stability data are received, the Agency will determine the validity of residue data for samples with these storage intervals. It should be noted that residue data requirements are still outstanding on some crops and the requested residue data must include information on sample storage.

2. Although the registrant has not successfully traced the source of the apparent detectable residues in or on untreated corn fodder samples, they have addressed several possibilities and have ruled out field and laboratory contamination. Apparent residues at the observed levels are well below the proposed tolerance of 1 ppm for residues in or on cereal grain forage and fodder. This deficiency in the Reregistration Standard Update is resolved.

RECOMMENDATIONS

The registrant should be reminded that complete information on sample storage conditions and intervals must accompany all requested residue data, and that adequate storage stability data must be available to validate residue data used to support established tolerances.

DETAILED CONSIDERATIONS

Storage Stability Data

CIBA-GEIGY Corp. (1991; MRID 41912902) submitted additional storage information for samples reported in previous residue studies. Tables 1 and 2 summarize data that were left out of the submission (1990; MRID 41449001) reviewed in CBRS No. 7193 (1/91).

Table 1. Storage intervals of residue samples reported in MRID 00128102 (Ciba-Geigy Report No. 82078).

Crop or Species	Substrate	Storage Interval Range, Days
Squash	Mature Squash	82
Lettuce	45 Days Lettuce	91
	Mature Lettuce	84
Cabbage	45 Day Cabbage	91
	Mature Cabbage	45
Peppers	Mature Peppers	31
Tomatoes	Mature Tomatoes	42
Grain Sorghum	Stalks 60-Day	65
	Stalks Mature	24
	Grain Mature	24
Peas	Mature Stalks	48
	Mature Pods	48
	Mature Peas	48

Table 1. (continued)

Crop or Species	Substrate	Storage Interval Range, Days
Beets	60-Day Leaves	86
	Mature Leaves	79
	Mature Beets	79
Sunflower	Stalks 60-Day	65
	Stalks	57
	Seed	57
Sunflower	Stalks 60-Day	65
	Stalks	57
	Seed	57
Cucumbers	Cucumbers	61

Table 2. Storage intervals of residue samples reported in MRID 00098428 (Ciba-Geigy Report No. 82014).

Crop or Species	Substrate	Storage Interval Range, Days
Green Onions	Whole Plant	30-160
Onions	Bulbs	45-189
Cantaloupe	Fruit	57-89
	Whole Fruit	57-62
Watermelon	Fruit	72-124
Cucumbers	Fruit	107-117
	Whole Fruit	45-136

For other crops identified in CBRS No. 7193 as deficient in storage information, the registrant provided alternate MRID numbers to demonstrate that these samples were covered by the previous submission. This information is summarized in Table 3.

6

Table 3. Actual MRID citations from crops shown as deficient in CBRS No. 7193 (review of MRID 41449001); information provided in MRID 41912902.

Deficiencies cited in CBRS No. 7193	Actual MRID No.	Ciba-Geigy Report No.	Storage interval (days)
potatoes (MRID 00071616)	00071615	81010	5-116
poultry, eggs (MRID 00071673)	00071615	81010	34-55
lettuce (MRID 00097511)	00114377	82060	47-466
liver and kidney (dairy cattle and goats) (MRID 00100753)	00114376	82061	4-366

These data fulfill the requirement for storage information on samples from previously submitted studies that were used to support tolerances. It should be noted that residue data requirements are still outstanding on some crops and the requested residue data must include information on sample storage. Following receipt and review of all residue data, the Agency will determine whether or not the available storage stability data are adequate to cover the ranges of storage conditions and intervals of samples used to support tolerances.

Magnitude of the Residue in Plants

The Metalaxyl Reregistration Standard Update dated 3/91 raised questions concerning the high apparent residues found in untreated samples of corn fodder (1990; MRID 41689701). Residues were <0.05-0.36 ppm in or on treated fodder from one GA location and <0.05-0.22 ppm in or on the corresponding control samples.

In response to the Agency's request for an explanation of apparent residues, CIBA-GEIGY Corp. submitted a report (1991; MRID 41912903) addressing this issue. The registrants state that apparent residues above the limit of detection have been found in untreated samples of numerous commodities, but that these levels were "significantly lower than the levels found in treated samples and ... lower than the requested or established tolerances." The apparent residues reported in this submission along with the established tolerances for comparison are presented in Table 4. We note that the apparent residues near the tolerance level were reported for untreated peas and beans and wheat grain, although we note also that these levels are consistent in magnitude with those of many of the other commodities in Table 4.

Table 4. Maximum apparent metalaxyl residues found in or on untreated commodities.

Commodity	Maximum apparent residue (ppm)	Established tolerance[a] (ppm)
onions	0.14	3
spinach	0.89	10
broccoli	0.06	2
cauliflower	0.07	2
soybeans	0.07	1
soybean forage	0.26	8
soybean fodder	0.40	8
peas and beans	0.24	0.2
peas and beans fodder	0.23	8
bell peppers	0.12	1
pimento peppers	0.23	1
tomatoes	0.06	1
dried seeds and peel of processed tomatoes	0.42	20
lemons	0.09	1
avocados	0.08	4
green hops	0.14	0.5
dry hops	0.52	2 (feed), 20 (food)
peanut fodder	2.15	20
peanut shells	0.07	2
wheat straw	0.32	2
wheat grain	0.18	0.2
wheat shorts	0.10	1
wheat red dog	0.23	1
wheat flour	0.07	1

[a]Tolerances listed in 40 CFR §180.408(a); food/feed additive tolerances listed in 40 CFR §185.4000(a) and (d) and 40 CFR §186.4000.

The registrant's explanation of these apparent residues cited four potential sources: (i) spray drift during application; (ii) cross contamination during the trial and/or sampling; (iii) natural plant products; and/or (iv) volatility of the applied chemical influenced by weather and/or soil conditions. Spray drift was ruled out in the case of corn fodder because seed treatment

was tested and thus no metalaxyl was applied in the field. Similarly, cross contamination in the field would not be expected. Contamination from laboratory reagents was unlikely because no apparent residues were observed in reagent blanks. The registrant concluded that the apparent residue could have resulted from some unknown natural plant product converted to a moiety with similar GLC properties to metalaxyl and its metabolites.

Although the registrant has not successfully traced the source of the apparent detectable residues in or on untreated corn fodder samples, they have addressed several possibilities and have ruled out field and laboratory contamination. Apparent residues at the observed levels are well below the proposed tolerance of 1 ppm for residues in or on cereal grain forage and fodder.

MASTER RECORD IDENTIFICATION NUMBERS:

MRID documents containing data which have been previously reviewed by the Agency are designated in shaded print in the following bibliographic listing of references used. A summary of the subject memoranda and their associated MRID documents is presented below.

References (used)

00071615 Ciba-Geigy Corporation (1980) [Study of Metalaxyl (Ridomil 25) Residue tolerances in cottonseed, soybeans, wheat, and certain vegetable crops]: AG-A 5457 I. (Complilation; unpublished study, including AG-A 5725, 5456-I, 5545 I, II...) received April 15, 1981 under 100-607; CDL-070019-A).

00071616 Ciba-Geigy Corproation (1981) [Study of various compounds for residue tolerances in potatoes]: AG-A 4601. (Compilation; unpublished study, including AG-A 4614, 4615, 4903..., received April 15, 1981 under 100-607; CDL:070020-A).

00071673 Seim, V.W.; Thomas, W.A. (1980) Biological report for CGA-48988: Residue test in laying hens: Report No. Biol-80009. (Unpublished study received April 15, 1981 under 100-607; submitted by Ciba-Geigy Corp. Greensboro, NC CDL-070021-B).

00097511 Ciba-Geigy Corporation (1981) Residues of Ridomil (R) in Lettuce. (Compilation; unpublished study received April 1, 1982 under 100-EX-71; CDL:070732-A)

00098428 Kahrs, R.A. (1982) Metalaxyl--Melons, Cucumbers, Squash, Green Onions, Bulb Onions, Potatoes--Supportive Data Requested by EPA: Report No. ABR-82014. (Unpublished study received Apr 7, 1982 under 1F2500; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:070765-A)

00100753 Ciba-Geigy Corp. (1982) Residues of Metalaxyl in Cattle and Goats. (Compilation; unpublished study received May 11, 1982 under 1F2500; CDL:070836-A)

00114376 Ciba-Geigy Corp. (1982) Metalaxyl--Rotational Wheat: Report # ABR- 82061. (Compilation; unpublished study received Sep 23, 1982 under 100-607; CDL:071104-A)

00114377 Ciba-Geigy Corp. (1982) Metalaxyl--Lettuce: Report # ABR-82060. (Compilation; unpublished study received Sep 23, 1982 under 100- 607; CDL:071106-A)

00128102 Ciba-Geigy Corp. (1982) Metalaxyl (Apron 2E) Seed Treatments. (Compilation; unpublished study received Feb 3, 1983 under 100-626; CDL:071388-A).

41449001 Ross, J. (1990) Metalaxyl Sample Storage Interval Summary: Lab Project Nos. ABR-90016; 409925. Unpublished study prepared by Ciba-Geigy Corp., Residue Chemistry Dept. 265 p.

41689701 Ross, J. (1990) Metalaxyl-Magnitude of Residues in Field Corn Forage Silage-stage Forage, Fodder, and Grain Following Seed Treatment with Apron 25W: Lab Project Number: ABR 90075. Unpublished study prepared by Residue Chemical Department, Agriculture Div. Ciba-Geigy Corp. 187 p.

41912902 Ross, J. (1990) Metalaxyl: Sample Storage Interval Summary Amendment 1: Lab Project Number: ABR-90016. Unpublished study prepared by Ciba-Geigy Corporation. 29 p.

41912903 Ross, J. (1991) Metalaxyl: Response to EPA Review of Metalaxyl on Corn: Lab Project Number: ABR-91035. Unpublished study prepared by Ciba-Geigy Corporation. 13 p.

Agency Memoranda

CBRS No(s): 7193
Subject: Metalaxyl Sample Storage Data.
From: R. Perfetti
To: L. Rossi
Dated: 1/91
MRID(s): 41689701.

11

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR THE CIBA-GEIGY METALAXYL MANUFACTURING-USE PRODUCTS.[1]

Data Requirements	Test Substance[2]	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)? Yes	No	Bibliographic Citation[3]
40 CFR §158.155-190 Product Chemistry					
Product Composition					
61-1. Product Identity and Disclosure of Ingredients	MP	R	X[4]		41912901 41055201 41055202
61-2. Beginning Materials and Production Process	MP	R		X	41912901 41055201 41055202
61-3. Formation of Impurities	MP	R		X	41912901 41055201 41055202
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis of Product Samples	MP	CR		X	41055201 41055202
62-2. Certification of Ingredient Limits	MP	R	X[4]		41912901 41055201 41055202
62-3. Analytical Methods to Verify Certified Limits	MP	R		X	41912901 41055201 41055202
Physical and Chemical Characteristics					
63-2. Color	MP	R		X	

(Continued, footnotes follow)

TABLE B. (Continued)

Data Requirements	Test Substance[2]	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)? Yes	No	Bibliographic Citation[3]
63-3. Physical State	MP	R		X	
63-4. Odor	MP	R		X	
63-7. Density, Bulk Density, or Specific Gravity	MP	R		X	
63-12. pH	MP	CR		X	
63-14. Oxidizing or Reducing Action	MP	CR		X	
63-15. Flammability	MP	CR		X	
63-16. Explodability	MP	R		X	
63-17. Storage Stability	MP	R		X	
63-18. Viscosity	MP	CR		X	
63-19. Miscibility	MP	CR		X	
63-20. Corrosion Characteristics	MP	R		X	
Other Requirements					
64-1. Submittal of Samples	MP	CR		X[5]	

(Continued, footnotes follow)

TABLE B. (Continued)

[1]Data requirements pertain to the Ciba-Geigy 90% technical Metalaxyl (EPA Reg. No. 100-601). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for Ciba-Geigy Technical Grade of the Active Ingredient."

[2]Test Substance: MP = manufacturing use product.

[3]These references were submitted in response to the Metalaxyl Guidance Document (September, 1988). Underlining indicates documents that have been reviewed for this single action review.

[4]Ciba-Geigy has responded to the requirements of 40 CFR §158.155 and 158.175 regarding the nominal concentration and certified limits, respectively, for the technical metalaxyl (EPA Reg. No. 100-601). The data submitted do not fully satisfy the requirements. Nominal concentrations for each of the listed impurities, including nitrosamines must be provided. Upper certified limit for nitrosamine, a toxicologically significant impurity must be provided as well. A revised Confidential Statement of Formula listing nominal concentrations for each of the listed impurities, including nitrosamine and an upper certified limit for this toxicologically significant impurity must be submitted on EPA Form 8570-4 (Rev. 2-85). Nitrosamine analysis in metalaxyl at zero month and six months after production are currently in progress, due in May, 1992. Additional data are required.

[5]If samples are needed, the Agency will request them.

METALAXYL (CBRS No. 8166; DP Barcode D165608)

(Chemical Code 113501)

REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

TASK 3

(Final Report)

CONFIDENTIAL APPENDIX

Appendix: 5 Page(s)

Confidential Appendix to the Scientific Review of the Registrants Response to Product Chemistry Data Requirements Report for the pesticide metalaxyl by the Chemistry Branch II/Reregistration Section [Confidential FIFRA Trade Secret/CBI].

Page _____ is not included in this copy.

Pages 16 through 20 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

__X__ Description of the product manufacturing process.

__X__ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Internal deliberative information.

_____ Attorney-client privilege.

_____ Claimed Confidential by submitter upon submission to the Agency.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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TASK 3

Registrant's Response to Residue Chemistry Data Requirements

November 8, 1991

Contract No. 68-DO-0142

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Arlington, VA 22202

Submitted by:

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Environmental Systems Division
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(continued)

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soybean forage	0.26	8
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peas and beans	0.24	0.2
peas and beans fodder	0.23	8
bell peppers	0.12	1
pimento peppers	0.23	1
tomatoes	0.06	1
dried seeds and peel of processed tomatoes	0.42	20
lemons	0.09	1
avocados	0.08	4
green hops	0.14	0.5
dry hops	0.52	2 (feed), 20 (food)
peanut fodder	2.15	20
peanut shells	0.07	2
wheat straw	0.32	2
wheat grain	0.18	0.2
wheat shorts	0.10	1
wheat red dog	0.23	1
wheat flour	0.07	1

[a]Tolerances listed in 40 CFR §180.408(a); food/feed additive tolerances listed in 40 CFR §185.4000(a) and (d) and 40 CFR §186.4000.

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00071615 Ciba-Geigy Corporation (1980) [Study of Metalaxyl (Ridomil 25) Residue tolerances in cottonseed, soybeans, wheat, and certain vegetable crops]: AG-A 5457 I. (Complilation; unpublished study, including AG-A 5725, 5456-I, 5545 I, II...) received April 15, 1981 under 100-607; CDL-070019-A).

00071616 Ciba-Geigy Corproation (1981) [Study of various compounds for residue tolerances in potatoes]: AG-A 4601. (Compilation; unpublished study, including AG-A 4614, 4615, 4903..., received April 15, 1981 under 100-607; CDL:070020-A).

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Agency Memoranda

CBRS No(s): 7193
Subject: Metalaxyl Sample Storage Data.
From: R. Perfetti
To: L. Rossi
Dated: 1/91
MRID(s): 41689701.