

US EPA ARCHIVE DOCUMENT



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

Reg. Std

JAN 15 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Ciba-Geigy Corp.: Response to the Metalaxyl Reregistration Standard: Storage Stability and Sample Histories and Multiresidue Protocol Data (MRID # 41449001, 41055203 and 40534803, DEB # 7193.

FROM: R. B. Perfetti, Ph.D., Chemist
Reregistration Section
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C) *R B Perfetti*

THRU: W. J. Boodee, Section Head
Reregistration Section
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C) *WJ*

TO: Reto Engler, Ph.D., Chief
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

and

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

Attached is a review of residue chemistry data requirements submitted by Ciba-Geigy Corp. in response to the metalaxyl Reregistration Standard. These studies were reviewed by Acurex Corporation under supervision of CBRS, HED.

This information 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.

If you need additional input please advise.

Attachment 1 : Review of the Metalaxyl Residue Chemistry
Studies.

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

cc: Without Attachment: P. Fenner-Crisp (HED), R. Schmitt and RF.

**METALAXYL
(DEB No. 7193)**

TASK 3

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

January 10, 1991.

Contract No. 68-DO-0142

Submitted for:

U.S. Environmental Protection Agency
Arlington, Virginia, 22204.

Submitted by:

Acurex Corporation
Environmental Systems Division
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METALAXYL (DEB No. 7193)

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

TASK - 3

INTRODUCTION

The Metalaxyl Guidance Document dated 9/88 requires data examining the stability of residues of concern in stored plant and animal commodities and information regarding sample storage intervals. In response to these requirements, Ciba-Geigy (DEB No. 7193) has submitted data pertaining to the storage intervals of commodity samples used to generate data submitted in support of established tolerances (1990; MRID 41449001). These data are reviewed here for their adequacy in fulfilling outstanding residue chemistry data requirements.

DEB No. 7193 also covers two submissions pertaining to residue analytical methods. MRID 41055203 contains data from multiresidue testing and has been forwarded to the Food and Drug Administration for evaluation. MRID 40534803 duplicates data in a previously reviewed submission, MRID 00148440, discussed in the Residue Chemistry Chapter (FRSTR) dated 6/22/87.

CONCLUSIONS

The registrant has reported the intervals and conditions of storage for 134 raw and processed animal and plant commodities from 52 studies submitted in support of established tolerances. When the promised storage stability data are received, the Agency will determine the validity of the residue data generated using these samples. Sample storage information was not provided for studies with potatoes, lettuce, onions, cucumbers, melons, sorghum grain and stalks, sunflower seeds and stalks, beets, beet greens, poultry tissues and eggs, and liver and kidney of dairy cattle and goats.

RECOMMENDATIONS

The Registrant should submit sample storage information for the following samples cited in the Guidance Document as providing data in support of tolerances: potatoes (MRID 00071616), poultry and eggs (MRID 00071673), lettuce (MRID 00097511), onions, cucumbers and melons (MRID 00098428), liver and kidney of dairy cattle and goats (MRID 00100753), and beets and beet greens, sorghum stalks and grain, and sunflower seeds and stalks (MRID 00128102).

DETAILED CONSIDERATIONS

Storage Stability Data

Ciba-Geigy Corp. (1990; MRID 41449001) submitted information concerning the intervals and conditions of storage of commodity samples used to generate residue data on metalaxyl and metabolites submitted by the company in support of established tolerances. These data are summarized in Table 1. The report indicated that the storage intervals reported for all processed commodities were determined beginning with the sampling date of the raw agricultural commodity. It was reported that samples were "frozen as soon as possible in the field (generally the same day), shipped frozen and stored in a freezer at -15 C until extracted for analysis."

The validity of residue data generated using these samples will be determined following review of forthcoming storage stability studies, which the registrant indicates are in progress.

The following MRID numbers indicate references cited in the Guidance Document that are not represented by storage information in this submission.

<u>MRID No.</u>	<u>Commodity</u>
00071616	potatoes
00071673	poultry
00097511	lettuce
00098428	onions
	cucumbers
	melons
00100753	liver and kidney (dairy cattle and goats)
00128102	beets, beet greens
	sorghum stalks, sorghum grain
	sunflower seed, stalks

The registrant needs to submit information pertaining to the storage intervals and conditions for the samples analyzed in these studies.

Table 1. Summary of Sample Storage Intervals for Plant and Animal Commodity Samples from Residue Studies Submitted to EPA

<u>Crop or Species</u>	<u>Substrate</u>	<u>Ciba-Geigy Report No.</u>	<u>MRID No.^a</u>	<u>Storage Intervals Ranges, Days</u>
Apples	Whole Fruit	84037	<u>00141519</u>	165-228
Apples	Whole Fruit	83006	<u>00126315</u>	33-147
	Unwashed Fruit			108
	Washed Fruit			108
	Apple Slices			113
	Cores & Peels			108
	Dried Cores & Peels			115
	Apple Sauce			113
	Wet Pomace			113
	Dried Pomace			115
	Juice			109
Avocado	Fruit	81016	<u>00074488</u>	59-136
Broccoli	Heads	83045	<u>00130773</u>	31-355
Broccoli	Heads	81010	<u>00071615</u>	306-453
Cabbage	Heads	82064	<u>00104387</u>	40-102
Cabbage	Heads	83045	<u>00130773</u>	31-355
Cabbage	Heads	81010	<u>00071615</u>	138-453
Cantaloupes	Fruit	81010	<u>00071615</u>	338-393
Carrots	Tops	88112	40838301	171-360
	Roots			273-443
Cauliflower	Heads	83045	<u>00130773</u>	31-340
Cauliflower	Heads	81010	<u>00071615</u>	280-454

(continued)

^a Underlining indicates those references cited in the Guidance Document dated 9/88 as containing data useful for tolerance assessment.

Table 1. Summary of Sample Storage Intervals for Plant and Animal Commodity Samples from Residue Studies Submitted to EPA

<u>Crop or Species</u>	<u>Substrate</u>	<u>Ciba-Geigy Report No.</u>	<u>MRID No.^a</u>	<u>Storage Intervals Ranges, Days</u>
Citrus	Hamlin Oranges	83073	<u>00133020</u>	130-145
	Lemons			149-163
	Navel Oranges			149-163
	Grapefruit			134-148
Citrus	Oranges	82069	<u>00117969</u>	183-317
	Grapefruit			216-331
	Lemons			188-304
	Unwashed Fruit			271
	Washed Fruit			271
	Pulp			271-272
	Chopped Peels			271
	Dried Peels			271
	Peel Frits			271-272
	Orange Juice			271-278
	Press Liquor			271-278
	Citrus Oil			271-278
	Molasses			271-278
	Corn			Silage-Stage Forage
Fodder		56-76		
Grain		48-76		
Cotton	Cottonseed	81046	<u>00109402</u>	34-276
	Gin Trash			34
	Kernels			171-298
	Meal			171-298
	Hulls			171-298
	Crude Oil			171-298
	Refined Oil			171-298
	Refined Bleached Oil			197-276
	Refined Bleached Hydrogenated Oil			182-276
	Refined Bleached Hydrogenated Deodorized Oil			182-276
	Soapstock			197-299

(continued)

Table 1. Summary of Sample Storage Intervals for Plant and Animal Commodity Samples from Residue Studies Submitted to EPA

<u>Crop or Species</u>	<u>Substrate</u>	<u>Ciba-Geigy Report No.</u>	<u>MRID No.^a</u>	<u>Storage Intervals Ranges, Days</u>
Cotton	Cottonseed	85002	<u>00148440</u>	34
	Gin Trash			34
Cotton	Seed	81010	<u>00071615</u>	57-314
Cucumbers	Fruit	81010	<u>00071615</u>	289-390
Cucurbits	Squash	83042	<u>00130693</u>	106-159
	Cantaloupe			89-157
	Cucumbers			80-241
	Honeydew Melon			92-97
Forages (Rotational)	Fall Forage	88023	40569302	991-1024
	Spring Forage			792-856
	Mature Forage			732-847
	Mature Hay			720-796
	Forage, 1st Cut			761-850
	Hay, 1st Cut			761-850
	Hay			827
Green Beans & Peas	Bean Vines	87085	40569303	245-320
	Bean Pods & Beans			320
	Beans			179-293
	Pea Vines			323-389
	Pea Pods			323-389
	Bean Forage			273-322
	Bean Fodder			179-292
	Dry Beans			245-263
	Pea Forage			321-337
	Pea Fodder			285-300
	Peas			301
Dried Peas	237			

(continued)

Table 1. Summary of Sample Storage Intervals for Plant and Animal Commodity Samples from Residue Studies Submitted to EPA

<u>Crop or Species</u>	<u>Substrate</u>	<u>Ciba-Gelgy Report No.</u>	<u>MRID No.^a</u>	<u>Storage Intervals Ranges, Days</u>
Hops	Dry Cones	81024	<u>00079433</u>	61-86
	Wet Cones			58-86
	Spent Hops			215
	Yeast			215
	Filter Cake			214
	Trub			214
	Beer			214
Lemons	Whole Fruit	85002	<u>00148440</u>	100-304
Lettuce	Heads	82060	<u>00114377</u>	37-466
Lettuce Head	Heads	88079	40775801	84-429
Lettuce	Heads	83044	<u>00130695</u>	58-266
	Forage			58-266
Lettuce	Heads	81010	<u>00071615</u>	165-466
Melons (Honeydew)	Fruit	81010	<u>00071615</u>	289-336
Onions	Green Onions	83043	<u>00130694</u>	65-283
	Bulbs			48-254
Onions (Bulb)	Bulbs	81010	<u>00071615</u>	42-434
Onions (Green)	Plant	81010	<u>00071615</u>	233-451
Oranges	Whole Fruit	85002	<u>00148440</u>	131-274

(continued)

Table 1. Summary of Sample Storage Intervals for Plant and Animal Commodity Samples from Residue Studies Submitted to EPA

<u>Crop or Species</u>	<u>Substrate</u>	<u>Ciba-Geigy Report No.</u>	<u>MRID No.^a</u>	<u>Storage Intervals Ranges, Days</u>
Peanuts	Fodder	83032	<u>00128738</u>	118-165
	Shells			118-165
	Nuts			118-165
	Kernels			159
	Meal			159
	Crude Oil			173
	(Screw-Pressed)			
	Crude Oil			173
	(Solvent Extracted)			
	Refined Oil			174
Refined Bleached	174			
Deodorized Oil				
Soapstock		174		
Peppers	Fruit	85109	<u>00157480</u>	26-317
Pineapple	Fodder	82045	<u>00109472</u>	302-673
	Shells			302-673
	Peeled Fruit			302-673
Pod Vegetables	Pea Forage	83036	<u>00129003</u>	269-277
	Pea Fodder			248-255
	Peas			248-255
	Snap Bean Forage			148-254
	Snap Bean Fodder			124-216
	Snap Bean Beans			124-216
	Pinto Bean Forage			204-231
	Pinto Bean Fodder			166
	Pinto Bean Beans			166
	Red Kidney Bean Forage			235
	Red Kidney Bean Fodder			189
	Red Kidney Bean Beans			189
	Navy Bean Forage			207-210
	Navy Bean Fodder			141-174
	Navy Bean Beans			141-174
Lima Bean Forage	256			

(continued)

Table 1. Summary of Sample Storage Intervals for Plant and Animal Commodity Samples from Residue Studies Submitted to EPA

<u>Crop or Species</u>	<u>Substrate</u>	<u>Ciba-Geigy Report No.</u>	<u>MRID No.^a</u>	<u>Storage Intervals Ranges, Days</u>
Pod Vegetables	Lima Bean Fodder			168
	Lima Bean Beans			219
	Lima Bean Dry Beans			168
Potatoes	Tubers	85077	<u>00148103</u>	216
	Fruit			234-346
	Fresh Bulbs			240-377
Potatoes	Immature Tubers	88112	40838301	416-595
	Mature Tubers			249-560
	Whole Tubers			247
	Wet Peel			247
	Sliced & Peeled Tubers			247
	Potato Chips			248
	Steamed Wet Peel			248
	Dry Peel			249
	Potato Flakes			249
Potatoes	Tubers	81010	<u>00071615</u>	5-1116
Radishes	Tops	88112	40838301	408-537
	Roots			408-537
Raspberries	Fruit	85002	<u>00148440</u>	99-146
Raspberries	Fruit	82080	<u>00127769</u>	79-146
Rye	Forage	79099	<u>00104390</u>	107
	Fodder			76
	Beans			76
Soybeans	Forage	85002	<u>00148440</u>	84-140
	Fodder			25-59
	Beans			25-59
Soybeans	Forage	79099	<u>00104390</u>	44-171
	Fodder			22
	Beans			22

(continued)

Table 1. Summary of Sample Storage Intervals for Plant and Animal Commodity Samples from Residue Studies Submitted to EPA

<u>Crop or Species</u>	<u>Substrate</u>	<u>Ciba-Geigy Report No.</u>	<u>MRID No.^a</u>	<u>Storage Intervals Ranges, Days</u>
Soybeans	Forage	81010	<u>00071615</u>	379-434
	Fodder			276-336
	Grain			213-296
	Hulls			384
	Meal			384
	Soapstock			373-384
	Crude Oil			344
	Refined Oil			384
	Soybeans (Rotational)			Forage
Fodder		22-688		
Beans		22-688		
Soapstock		373-378		
Hulls		384		
Meal		384		
Refined Oil		384		
Crude Oil		344		
Grain		213-296		
Spinach		Leaves	82050	<u>00114378</u>
Spinach	Leaves	88113	40790201	147-447
Spinach	Leaves	81010	<u>00071615</u>	55-250
Sugar Beets	Early Forage	79099	<u>00104390</u>	213
	Late Forage			87
	Roots			87
Sugar Beets	Tops	87077	40569301	253-399
	Roots			60-399
	Cossetts			61
	Pulp			61
	Molasses			139
	Sugar			61

(continued)

Table 1. Summary of Sample Storage Intervals for Plant and Animal Commodity Samples from Residue Studies Submitted to EPA

<u>Crop or Species</u>	<u>Substrate</u>	<u>Ciba-Geigy Report No.</u>	<u>MRID No.^a</u>	<u>Storage Intervals Ranges, Days</u>
Sugar Beets	Tops	88112	40838301	352-399
	Roots			60-399
	Cossetts			139
	Pulp			61
	Molasses			139
	Sugar			61
Sweet Potatoes	Early Forage	79099	<u>00104390</u>	110
	Roots			33
	Tops			33
Tobacco	Green Leaves	85002	<u>00148440</u>	-100
Tomatoes	Mature Fruit	85109	00157480	73-306
Tomatoes	Mature Fruit	85002	<u>00148440</u>	100-306
	Unwashed Fruit			73-74
	Washed Fruit			73
Tomatoes	Fruit	81010	<u>00071615</u>	31-306
	Washed Whole Fruit			73-74
	Unwashed Whole Fruit			59-74
	Cold Pack Peeled Fruit			74
	Cold Pack Whole Fruit			74
	Peeled Fruit			73
	Peels			67-73
	Puree			73
	Seeds and Peel			73
	Juice			73
Watermelon	Fruit	81010	<u>00071615</u>	295-337
Wheat	Forage	79099	<u>00104390</u>	22-402
	Straw			138
	Grain			145

(continued)

Table 1. Summary of Sample Storage Intervals for Plant and Animal Commodity Samples from Residue Studies Submitted to EPA

<u>Crop or Species</u>	<u>Substrate</u>	<u>Ciba-Gelgy Report No.</u>	<u>MRID No.^a</u>	<u>Storage Intervals Ranges, Days</u>
Wheat (Rotational)	Fall Forage	82061	<u>00114376</u>	22-998
	Spring Forage			182-854
	Straw			138-906
	Grain			145-818
	Bran			720-779
	Shorts			720-779
	Red Dog Flour			722-779
Wheat (Winter)	Fall Forage	81010	<u>00071615</u>	354-392
	Spring Forage			255-324
	Straw			193-225
	Grain			193-225
Dairy Cattle	Milk	82052	<u>00071674</u>	36-55
	Blood			29-44
	Tenderloin			28-42
	Round Muscle			28-42
	Omental Fat			28-42
	Perirenal Fat			28-42
	Liver			4-18
	Kidney			4-18
Dairy Cattle	Milk	82069	<u>00117969</u>	29-272
	Tenderloin			28-340
	Round Muscle			28-338
	Perirenal Fat			28-336
	Omental Fat			28-226
	Liver			4-310
	Kidney			4-366
	Blood			29-44

(continued)

Table 1. Summary of Sample Storage Intervals for Plant and Animal Commodity Samples from Residue Studies Submitted to EPA

<u>Crop or Species</u>	<u>Substrate</u>	<u>Ciba-Geigy Report No.</u>	<u>MRID No.^a</u>	<u>Storage Intervals Ranges, Days</u>
Dairy Cattle	Milk	82061	<u>00114376</u>	29-272
	Tenderloin			28-340
	Round Muscle			28-338
	Perirenal Fat			28-338
	Omental Fat			4-310
	Liver			4-366
	Kidney			29-44
	Blood			
Dairy Cattle	Milk	83032	<u>00128738</u>	29-272
	Tenderloin			28-340
	Round Muscle			28-338
	Perirenal Fat			28-338
	Omental Fat			28-336
	Liver			4-310
	Kidney			4-366
	Blood			29-44
Dairy Cattle	Milk	81010	<u>00071615</u>	234-272
	Tenderloin			314-340
	Round Muscle			312-338
	Perirenal Fat			312-338
	Omental Fat.			310-336
	Liver			284-310
	Kidney			301-366
Poultry Tissues	Eggs	81010	<u>00071615</u>	34-55
	Skin			34-55
	Fat			34-55
	Liver			35-56
	Breast & Thigh			36-57

^a Underlining indicates those references cited in the Guidance Document dated 9/88 as containing data useful for tolerance assessment.