

US EPA ARCHIVE DOCUMENT

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Registration Division (H7505C)

FROM: Thomas Dixon, Chief *Thomas Dixon*
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Environmental Fate and Groundwater Branch
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Attached, please find the EAB review of...

Reg./File # : 100-607

Chemical Name: Metalaxyl

Type Product : Fungicide

Product Name : Ridomil

Company Name : Ciba-Geigy

Purpose : Review of groundwater monitoring study (potable water
supplies)

Date Received: 07/20/89

Action Code: 192

Date Completed: 09/22/89

EFGWB#: 90625

Deferrals to: Ecological Effects Branch, EFED
 Science Intergration & Policy Staff, EFED
 Residue Chemistry Branch, HED
 Dietary Exposure Branch, HED
 Toxicology Branch, HED

Review of Metalaxyl Groundwater Study

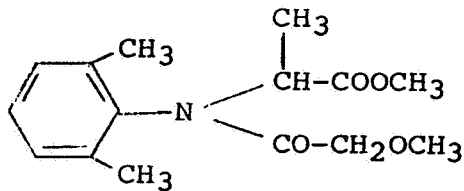
1. CHEMICAL:

Chemical Name: N-(2,6-Dimethylphenyl)-N-(methoxyacetyl)-alanine methyl ester

Common Name: Metalaxyl

Trade Name: Ridomil

Structure:



2. TEST MATERIAL: Not Given. Common formulation is Ridomil 2E which is two pounds AI/gallon emulsifiable concentrate.

3. STUDY/ACTION TYPE: Groundwater Monitoring

4. STUDY IDENTIFICATION: Ciba-Geigy (Agricultural Chemical Division, Greensboro, NC) submitted five volumes in support of amendments to add additional crops to their registration. These volumes provide protocols and monitoring results for sampled wells. An additional unnumbered volume provides market information. They were sent by Mr. Gary Orr and dated May 31, 1989. They are titled as follows:

<u>Volume</u>	<u>Content</u>
1	Transmittal Document
2	Groundwater Sensitivity, Analysis for Ridomil Application
3	Monitoring Domestic Supply Wells for Metalaxyl
4	Monitoring Domestic Supply Wells for Ridomil Protocol
-	Ridomil Fungicide Marketing Information

5. REVIEWED BY:

Harold R. Day
Chemist
Monitoring Section 6

Harold R. Day
9/28/89

6. APPROVED BY:

Marty Williams, Hydrologist
Groundwater Technology Section
EF&GW Branch, EFED (H7507C)

Marty Williams
10/13/89

7. CONCLUSIONS:

A. Under normal use conditions, metalaxyl can be expected to enter groundwater and potable water supplies. Concentrations are expected to range from 0-3 ppb under normal use conditions of 0.5-1 lb/acre.

B. The process of selection of sites by sensitivity is confusing. Volume 2 of the study purports to analyze Ridomil use areas by soil types, layer thickness, climate, etc. The volume lacks a detailed analysis of the sites selected. Volume 3 (Appendix A) states the precipitation/evaporation ratio was the final criteria.

Based just on the soil types described, the Florida and North Carolina sites are appropriate because they are sandy soils, but the Tennessee sites, classed as silt loams, would impede percolation to groundwater. These soils cannot be judged sensitive only because of a shallow bedrock and sinkholes.

C. The sample collection and analytical procedures seem appropriate to the study and are acceptable.

D. Additional details are needed to make a valid study, specifically:

a. A Ridomil label, or if different, a proposed label for the new uses.

b. A detailed explanation of the "sensitivity analysis" of the selected sites in clear terms.

c. The rainfall for all the sites over the sampling period was not provided in the report, although in the conclusions the author stated there was generally low rainfall in Florida over the period. The average annual rainfall for all the sites is 45-50 inches/year. The rainfall information for the test period needs to be added.

d. Degradates of metalaxyl are not mentioned. This point should be addressed. Were they looked for, detected, etc? If not addressed, why not?

E. The data submitted is similar to EPA guidelines for a large-scale retrospective study except for sampling a smaller number of wells.

8. RECOMMENDATIONS:

A. The registrant should be contacted for the needed information described in D. above.

B. This study should be viewed as provisionally acceptable if A is completed.

C. The results of this study should be viewed by HED and LEB for assessment of the human and ecological impacts.

9. BACKGROUND:

Ridomil (metalaxyl) is a ground applied fungicide used to prevent soilborne and foliar fungal attack on vegetables and fruits. Ciba-Geigy's submission is in support of amendments to add registrations for strawberries, grapes, blueberries, stone fruit, walnuts, almonds, sugar beets, hops, alfalfa, and root vegetables.

A proprietary report on Ridomil marketing information indicates the sites chosen do represent typical Ridomil use areas. The North Carolina and Tennessee sites indicate use on tobacco, while the Florida site use is on citrus.

Previous, pertinent, completed reviews on this subject are:

<u>EAB No.</u>	<u>Date</u>	<u>Subject</u>
6330	9/30/86	Ground and Surface Water Monitoring
80334	2/04/88	Reported Metalaxyl Findings in Groundwater
80588	4/12/88	Same subject as above
80054	5/31/88	New Crop Uses
80799	8/17/88	New Label
-	6/17/88	Note on Registration of New Uses (C. Eiden)
90457	5/03/89	Protocol for Groundwater Study
90567	5/24/89	Review Proposed Protocol

Metalaxyl concentrations ranging from 0.5-3 ppb have been reported from previous groundwater monitoring studies (EAB # 5330, 80334, 80588).

A protocol for a small-scale retrospective monitoring study (EAB 90457) was submitted but was judged incomplete. EPA is awaiting submission of a revised, acceptable protocol. The requirements for conducting the small-scale retrospective study are spelled out in detail by EPA. Marketing data were requested by D. Elliott at a meeting with Ciba Geigy (EAB # 90567).

The subject submission includes volumes detailing the soil/strata types and the results of the analyses of wells for metalaxyl residues. Metalaxyl was found (detection limit 0.25 ppb) in 17 of 91 samples collected. The sampling was done quarterly for two years.

10. DISCUSSION:

A. Methods and Materials:

Roux Associates, Inc, contractor for Ciba Geigy, conducted a two-year study to determine the presence of metalaxyl in domestic well water adjacent to treated areas. Representative counties were selected where Ridomil was in use under normal agricultural practices. Four wells in each county were selected with a sample from a nearby county substituted for comparison. See Appendix A for well site details.

The wells selected have the characteristics of being near treated fields, in areas hydrologically sensitive, and they are potable water supplies. Three one-liter samples were collected at each location, packed in ice, and sent for laboratory analysis by gas chromatography using a nitrogen/phosphorous detector.

B. Results

<u>Location of Wells Monitored #</u>	<u>Metalaxyl Concentration (ppb)</u>							
	<u>Sampling Time</u>							
	7/86	10/86	1/87	4/87	7/87	10/87	1/88	4/88
<u>Davidson Co., TN</u>								
R1 (a)	-	-	-	-	*	-	-	-
<u>Robertson Co., TN</u>								
R1 (b)	-	-	-	-	-	-	-	-
R1 (c)	-	-	-	-	-	-	-	-
R1 (d)	-	-	-	0.77	-	*	*	*
<u>Edgecombe Co., NC</u>								
R2 (a)	-	0.74	0.64	2.40	1.40	1.90	*	1.30
R2 (b)	-	-	0.38	0.76	0.27	-	-	-
R2 (c)	-	-	3.00	1.50	1.30	2.20	1.80	1.50
R2 (d)	-	-	-	1.20	-	-	-	-
<u>Hillsborough Co., FL</u>								
R3 (a)	-	-	-	-	-	-	-	-
<u>Hardee Co., FL</u>								
R3 (b)	-	-	-	-	-	-	-	-
R3 (c)	-	-	-	-	-	-	-	-
R3 (d)	-	-	-	-	-	-	-	-

See Appendix A for characteristics of the well locations.

- Below detection limit (0.25 ppb)

* No sample taken or sample lost

C. Registrants's Comments

Metalaxyl was detected in 17 of 91 samples taken in three States: North Carolina, Tennessee, and Florida. Of the positive samples, one was from Tennessee and the others were all in North Carolina.

Although the three sites were hydrologically similar, the higher detection rate in North Carolina may be due to higher rainfall than in Florida. Early sampling in 1986 shows only one positive Tennessee sample and none in Florida which had low rainfall over the sampling period.

D. Reviewer's Comments

- a. All submissions of this type should include a typical label as well as a proposed label for new uses.
- b. The site selection, as described in Volumes 2 and 3, do not adequately describe why the three sites were chosen.
- c. The Florida and North Carolina sites seem appropriate because the soil overlying the bedrock is sandy. The Tennessee sites do not seem appropriate because the overlying soil is a silt loam which would restrict percolation.
- d. It is difficult to judge why most positives were found in the North Carolina wells; the geology of the areas is similar to Florida. The registrant's comment that yearly rainfall was higher in the positive wells seems to be the best explanation (actually normal for NC, low for FL).
- e. Considering the comments about rainfall, it seems prudent to suggest that the geologically similar (sandy soil) areas could leach metalaxyl into ground water. The expected range for these more sensitive areas is 0-2 ppb metalaxyl. Where soil conditions permit less percolation to groundwater as in Tennessee, lesser concentrations, or none, are likely. Previous studies (Oregon, California) also indicate 3 ppb as a typical upper limit for metalaxyl in ground water on normal use conditions. If a heavy runoff, immediately after application occurred, the concentration might exceed 3 ppb, but the data seem to indicate this is a "typical" upper residue limit in well water.
- f. The annual precipitation/evaporation ratio can affect the water available for percolation; hence, the amount of metalaxyl carried to groundwater.
- g. The study design is similar to the Agency's large-scale retrospective study. This Ciba Geigy study follows the approach of measuring groundwater (wells) in typical use areas. The marketing data provided shows Ridimil use in the test areas. Since the study covered two years, seasonal and annual variations can be accounted for.

h. The collection and analytical procedures seem to be in conformance with good practices.

i. From previous EPA actions it is clear this study is required because of the Agency concern about groundwater contamination.

j. A summary of physical/chemical data is included as Appendix B. This appendix also lists the degradates of metalaxyl but no information about their properties. Metalaxyl has a low toxicity (LD50 rat 670 mg/kg).

k. This study is provisionally acceptable if additional information is provided (see 7.D. on p.2).

11. COMPLETION OF ONE-LINER: Included as Appendix B.

12. CBI APPENDIX: A. Well Characteristics.

APPENDIX A

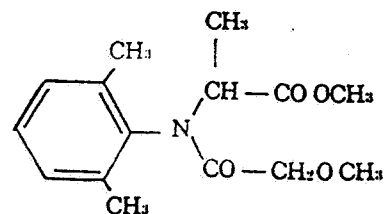
CHARACTERISTICS OF TESTED WELLS

<u>COUNTY STATE</u>	<u>CODE</u>	<u>DEPTH OF WELL (FT)</u>	<u>DEPTH TO WATER(FT)</u>	<u>DISTANCE TO APPLICATION AREA (FT)</u>	<u>YEARS OF APPLICATION</u>
Davidson, TN	R1(a)	55	25	75	3
Robertson, TN	R1(b)	53	40	500	6
Robertson, TN	R1(c)	65	40	600	3
Robertson, TN	R1(d)	110	40	300	6
Edgecombe, NC	R2(a)	15	12	10	3
Edgecombe, NC	R2(b)	20	8-10	250	4
Edgecombe, NC	R2(c)	20	10-12	500	5
Edgecombe, NC	R2(d)	25	10	200	3
Hillsborough, FL	R3(a)	75	5	50	4
Hardee, FL	R3(b)	110	7	70	2
Hardee, FL	R3(c)	25	6	100	1
Hardee, FL	R3(d)	40	7	50	4

From Volume 2 of report

APPENDIX B

ENVIRONMENTAL FATE : GROUND WATER BRANCH
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY



Common Name: METALAXYL
 Chem. Name : N-(2,6-DIMETHYLPHENYL)-N-(METHOXYACETYL)-ALANINE
 : METHYL ESTER
 Synonym : APRON 25WP; CGA 48988; RIDOMIL
 Shaugh. # : 113501
 Type Pest. : FUNGICIDE
 Formulation: EC 2 LBS/GAL; FLOWABLE CONC.
 Uses : CONTROL OF SOIL-BORNE DISEASES CAUSED BY PYTHIUM AND PHYTO-
 : PHORA, AND FOLIAR DISEASES CAUSED BY DOWNY MILDEW.

Date: 06/21/89

CAS Number: 57837-19-1

Empir. Form: C₁₅H₂₁NO₄
 Mol. Weight: 279.33
 Solub.(ppm): 7100 @ 20 C

VP (Torr): 2.2E-6
 Log Kow :
 Henry's :

Hydrolysis (161-1)

pH 5:[*] 200 DA
 pH 7:[*] 200 DA
 pH 9:[*] 115 DA
 pH :[]
 pH :[]
 pH :[]

Photolysis (161-2, -3, -4)

Air :[]
 Soil :[*] STABLE
 Water:[*] 1 WK
 :[]
 :[]
 :[]

MOBILITY STUDIES (163-1)

Soil Partition (Kd)	Rf Factors
1.[#] 0.43-0.48 SAND	1.[#] 70% IN LEACHATE
2.[#] 0.87 SILT LOAM	2.[]
3.[#] 1.40 SANDY CLAY LOAM	3.[]
4.[]	4.[]
5.[]	5.[]
6.[]	6.[]

METABOLISM STUDIES (162-1,2,3,4)

Aerobic Soil (162-1)	Anaerobic Soil (162-2)
1.[#] 7 WK (SOIL?)	1.[#] 9 WK (SOIL?)
2.[]	2.[]
3.[]	3.[]
4.[]	4.[]
5.[]	5.[]
6.[]	6.[]
7.[]	7.[]

Aerobic Aquatic (162-4)	Anaerobic Aquatic (162-3)
1.[]	1.[]
2.[]	2.[]
3.[]	3.[]
4.[]	4.[]

[*] - Acceptable Study. [#] = Supplemental Study

ENVIRONMENTAL FATE & GROUND WATER BRANCH
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY

Page 2

Common Name: METALAXYL

Date: 06/21/89

VOLATILITY STUDIES (163-2,3)

- [#] Laboratory: LOSS DUE TO VOLATILIZATION SHOULD BE <0.5%.
[] Field:

DISSIPATION STUDIES (164-1,2,3,5)

Terrestrial Field (164-1)

- 1.[#] 2 WK (SOIL?). MAJOR DEGRADATE PEAKED DURING THE FIRST
- 2.[] MONTH AT 20%, DECLINED TO 0.5% OF THE APPLIED AT A YEAR.
- 3.[] HOWEVER, IN ANOTHER STUDY THE AMT. REMAINING IN A YEAR WAS
- 4.[] 23% OF THAT APPLIED.
- 5.[]
- 6.[]

Aquatic (164-2)

- 1.[]
- 2.[]
- 3.[]
- 4.[]
- 5.[]
- 6.[]

Forestry (164-3)

- 1.[]
- 2.[]

Other (164-5)

- 1.[]
- 2.[]

ACCUMULATION STUDIES (165-1,2,3,4,5)

Confined Rotational Crops (165-1)

- 1.[#] LETTUCE - .11 PPM; OATS (WHOLE PLANT) .33;
- 2.[] CORN .06 PPM; SOYBEANS 0.8 PPM; SUGARBEETS .16 PPM

Field Rotational Crops (165-2)

- 1.[#] PLANTED IN ROTATION TO POTATOES: CORN .02 PPM;
- 2.[] SUGARBEETS <.05 IN ROOTS; SOYBEANS .83 PPM

Irrigated Crops (165-3)

- 1.[]
- 2.[]

Fish (165-4)

- 1.[] BLUEGILL 1X EDIB; 14X VISC; 6X WHOLE
- 2.[] CATFISH 1X EDIB; 1X VISC; 1X WHOLE

Non-Target Organisms (165-5)

- 1.[#] NO ADVERSE EFFECTS EXPECTED ON AVIAN, MAMMALIAN,
- 2.[] OR FRESHWATER AQUATIC SPECIES.

Common Name: METALAXYL

Date: 06/21/89

GROUND WATER STUDIES (158.75)

1. [#] METALAXYL HAS BEEN REPORTED IN GROUND WATER IN FLORIDA AND
2. [] NORTH CAROLINA.
3. []

DEGRADATION PRODUCTS

1. (N-(2,6-DIMETHYLPHENYL)-N-(2'-METHOXYACETYL) ALANINE IS THE
2. MAJOR DEGRADATE.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.
- 9.
- 10.

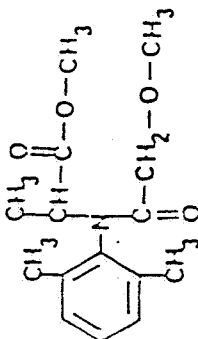
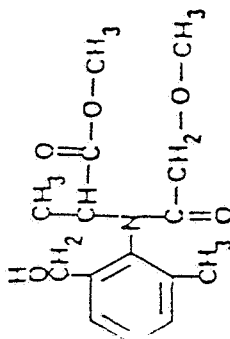
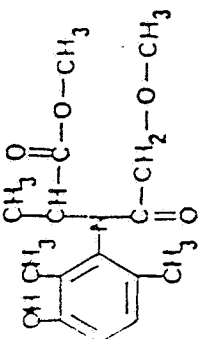
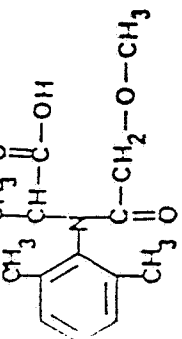
COMMENTS

PARENT COMPOUND LEACHED RAPIDLY IN SAND SOILS WITH UP TO 92% OF RADIOACTIVITY RECOVERED IN LEACHATE. IN SdClm SOILS, MAJORITY OF RADIOACT. WAS IN 6-12 CM SOIL WITH LESS THAN 0.4% IN LEACHATE.

References: EFGWB REVIEWS

Writer : S.J. SIMKO J. HANNAN

Table I. Metaxyl and its metabolites in plants and animals.

Code	Structure	Chemical Name	Common Name/ Abbreviation	Found in:	Reference (MRLD)
I		N-(2,6-dimethylphenyl)- N-(methoxyacetyl)-alanine methyl ester	Metaxyl, CGA-48788	lettuce foliage; grapes and grape leaves potato tubers and foliage potato foliage	UU114379, UU071610, UU071607, UU071606. UU071603, UU071604. UU071609.
II		N-[2-(hydroxymethyl)-6- methylphenyl]-N-(methoxy- acetyl)-alanine methyl ester	CGA-94189	lettuce foliage; grapes and grape leaves ^d potato tubers and foliage ^a potato foliage	UU114379, UU071610, UU071680. UU071607, UU071606. UU071603, UU071604. UU071609.
III		N-(3-hydroxy-2,6-dimethyl- phenyl)-N-(methoxyacetyl)- alanine methyl ester	CGA-100255	lettuce foliage; grapes and grape leaves ^d potato tubers and foliage ^d	UU114379, UU071610, UU071680. UU071607, UU071606. UU071603, UU071604.
IV		N-(2,6-dimethylphenyl)-N- (methoxyacetyl)-alanine	CGA-62826	lettuce foliage ^a grapes and grape leaves ^a potato tubers potato foliage	UU114379, UU071610, UU071607, UU071606. UU071603, UU071604. UU071609, UU071604.

(Continued).