Shaughnessy Number: 113501

Date Out of EFGWB: APR 21 1989

MAY - 3 1989

TO: Lois Rossi
Product Manager 21
Registration Division (H7505C)

FROM: Patrick Holden, Chief
Ground-Water Section
Environmental Fate & Ground-Water Branch/EFED (H7507C)

THRU: Henry Jacoby, Chief (Acting)
Environmental Fate & Ground-Water Branch/EFED (H7507C)

Attached, please find the EFGWB review of:

Reg./File #: _____

Chemical Name: Metalaxyl

Type Product: Fungicide

Company Name: Ciba-Geigy Corporation

Purpose: Review proposed protocol for small-scale retrospective ground-water monitoring study.

Date Received: 3/17/89 ACTION CODE: 177

Date Completed: 4/21/89 EFGWB #(s): 90457

Monitoring study requested: X Total Review Time: 1 day

Monitoring study voluntarily: ____

Deferrals To: ____ Biological Effects Branch

____ Science Integration & Policy Staff, EFED

____ Non-Dietary Exposure Branch, HED

____ Dietary Exposure Branch, HED

____ Toxicology Branch, HED

Use this form for individual studies & to submit pesticide applications.

United States Environmental Protection Agency
Office of Pesticide Programs
Washington, DC 20460

Data Review Record

Confidential Business Information - Does not contain National Security Information (E.O. 12065)

Pack Number	Date Received
49136 EFED	3-22-89

1. Product Name: Metalaxyl — Chemical Name:

2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
72-2	242577	197		

7. Reference No.	8. Date Rec'd (EPA)	9. Prod/Review Mgr/DCI	10. PM/RM Team No.	11. Date to HED/ EFED/RD/BEAD	12. Proj Return Date	13. Date Returned to RD/SRRD
1	3/17	Rossi	21	3/21	4/21	

Instructions: METALAXYL

This Section Applies to Review of Studies Only

14. Check Applicable Box
- ☐ Adverse 6(a)(2) Data (405)
- ☐ Special Review Data (870)
- ☐ Generic Data (Reregistration) (660)
- ☐ Product Specific Data (Reregistration) (655)

15. No. of Individual Studies Submitted: 1

16. Have any of the above studies *(in whole or in part)* been previously submitted for review?
- ☐ Yes *(Please identify the study(ies))*:
- ☐ No

17. Related Actions:

18.	To	Type of Review	19. Reviews Also Sent to	20. Data Review Criteria
HED		Science Analysis & Coordination	☐ SAC ☐ PC	A. Policy Note No. 31
		Toxicology/HFA	☐ TOX/HFA ☐ PL	☐ 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria
		Toxicology/IR	☐ TOX/IR	☐ 2 = data of particular concern from registration standard
		Dietary Exposure	☐ DEB ☐ EA	
		Nondietary Exposure	☐ NDE ☐ AC	☐ 3 = data necessary to determine tiered testing requirements
EFED		Ecological Effects	☐ BA	
	X	Environmental Fate & Groundwater	☐ EEB	B. Section 18
SRRD		Special Review	☐ EFGWB	☐ 1 = data in support of section 3 in lieu of section 18
		Reregistration		
		Generic Chemical Support	☐ SR	C. Inert Ingredients
RD		Insecticide-Rodenticide	☐ RER	☐ 1 = data in support of continued use of List 1 inert
		Fungicide-Herbicide	☐ GSC	
		Antimicrobial	☐ IR	
		Product Chemistry	☐ FH	
		Precautionary Labeling	☐ AM	
BEAD		Economic Analysis		
		Analytical Chemistry		
		Biological Analysis		

☐ Confidential Statement of Formula (EPA Form 8570-4) Attached *(Trade Secrets)*

☐ Label Attached

EPA Form 8570-17 (Rev. 11-88)
Previous editions are obsolete.

White - Data Coordinator
Yellow - Data Review Section
Pink - PM/RM/DCI
Green - Return with completed review

Use this form for individual studies & to submit pesticide applications.

United States Environmental Protection Agency
Office of Pesticide Programs
Washington, DC 20460

Data Review Record

Confidential Business Information - Does not contain National Security Information (E.O. 12065)

Pack Number	Date Received
49136 EFED	3-22-89

1. Product Name: Metalaxyl — Chemical Name:

2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
150-L-22	242677	177		

7. Reference No.	8. Date Rec'd (EPA)	9. Prod/Review Mgr/DCI	10. PM/RM Team No.	11. Date to HED/ EFED/RD/BEAD	12. Proj Return Date	13. Date Returned to RD/SRRD
1	3/17	[illegible]	21	3/21	4/21	

Instructions

This Section Applies to Review of Studies Only

14. Check Applicable Box

- ☐ Adverse 6(a)(2) Data (405)
- ☐ Special Review Data (870)
- ☐ Generic Data (Reregistration)(660)
- ☐ Product Specific Data (Reregistration)(655)

15. No. of Individual Studies Submitted

16. Have any of the above studies *(in whole or in part)* been previously submitted for review?

- ☐ Yes *(Please identify the study(ies))*
- ☐ No

17. Related Actions

18. To	Type of Review	19. Reviews Also Sent to	20. Data Review Criteria
HED	Science Analysis & Coordination	☐ SAC ☐ PC	A. Policy Note No. 31
	Toxicology/HFA	☐ TOX/HFA ☐ PL	☐ 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria
	Toxicology/IR	☐ TOX/IR	
	Dietary Exposure	☐ DEB ☐ EA	☐ 2 = data of particular concern from registration standard
	Nondietary Exposure	☐ NDE ☐ AC	
EFED	Ecological Effects	☐ BA	☐ 3 = data necessary to determine tiered testing requirements
X	Environmental Fate & Groundwater	☐ EEB	
SRRD	Special Review	☐ EFGWB	
	Reregistration		B. Section 18
	Generic Chemical Support	☐ SR	☐ 1 = data in support of section 3 in lieu of section 18
RD	Insecticide-Rodenticide	☐ RER	
	Fungicide-Herbicide	☐ GSC	C. Inert Ingredients
	Antimicrobial		☐ 1 = data in support of continued use of List 1 inert
	Product Chemistry	☐ IR	
	Precautionary Labeling	☐ FH	
BEAD	Economic Analysis	☐ AM	
	Analytical Chemistry		
	Biological Analysis		

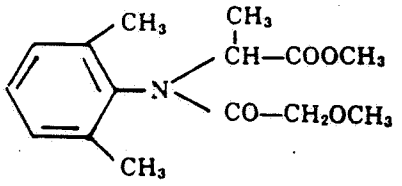
☐ Confidential Statement of Formula (EPA Form 8570-4) Attached *(Trade Secrets)*

☐ Label Attached

REVIEW OF PROTOCOL FOR SMALL-SCALE RETROSPECTIVE GROUND-WATER MONITORING STUDY

1. CHEMICAL:

Chemical name: N-(2,6-Dimethylphenyl)-N-(methoxyacetyl)-alanine methyl ester
Common name: Metalaxyl
Trade name: Ridomil, Subdue, Apron, Proturf
Structure:



2. TEST MATERIAL:

Not Applicable.

3. STUDY/ACTION TYPE:

Review proposed protocol for small-scale retrospective ground-water monitoring study.

4. STUDY IDENTIFICATION:

Title: Small Scale Retrospective Study for Metalaxyl in Ground-Water- Protocol.

Author(s): Roux Associates
The Huntington Atrium
775 Park Avenue, Suite 255
Huntington, New York 11743

Submitted for: Agricultural Division
Ciba-Geigy Corporation
Post Office Box 18300
Greensboro, NC 27419

Identifying No.: 100-628
Action Code: 177
Accession Number: not given
Record Number: 242077
Date Sent to EFED: 3/21/89

5. REVIEWED BY:

Elizabeth Behl
Hydrogeologist Consultant to
OPP/EFED/EFGWB/Ground-Water Section

Signature: Eliz. Behl
Date: 4/28/89

6. APPROVED BY:

for Patrick W. Holden
Chief
OPP/EFED/EFGWB/Ground-Water Section

Signature: Henry M. Jacoby

Date: 5/1/89

7. CONCLUSIONS:

The data package is incomplete, and therefore, cannot be fully screened to complete the review of this protocol for the small-scale retrospective ground-water monitoring study. Three monitoring sites are proposed representing tobacco, citrus, and lettuce crops. The protocol asserts that the justification of the selection of the monitoring sites is contained in "the Sensitivity Analysis and Preliminary Site Selection reports that accompany this protocol" (p. 5, last sentence). Neither of these reports have yet been submitted to EPA. This information is required in order to approve the number and location of the monitoring sites. As per conversation with Mario Fiol (RD, 4/24/89) and Karen Stumpf (Ciba-Geigy, 4/25/89) these reports will be remitted to EPA as soon as possible.

The protocol is being returned. We are retaining a copy of the protocol in our EFGWB files for easy access in the future. When the registrant submits the above reports the protocol can be fully screened.

8. RECOMMENDATIONS:

1) The registrant should submit the ground water monitoring study protocol and all reports necessary to enable the reviewer to assess the protocol.

9. BACKGROUND:

Metalaxyl is a systemic fungicide registered since 1979 for use on over 100 agricultural crops, ornamentals and turf. Some principle uses are tobacco, ornamentals, turf, fruit, citrus, non-bearing nursery stock, seed treatment, vegetables and peanuts. It is applied to soil or foliage at rates ranging from 0.135 to 8.0 # a.i./acre. Methods of application include: foliar application, soil application (broadcast or band), drenching, sprinkler or drip irrigation, and soil mixing.

Metalaxyl is moderately stable to hydrolysis and photodegradation under normal environmental conditions. Results of laboratory and field leaching studies indicate that both the parent and the primary degradate (CGA-62826) can leach in most soils (Metalaxyl Registration Standard [FRSTR], 7/9/87). Tests indicate that metalaxyl is not oncogenic, mutagenic, or teratogenic, and that acute toxicity is low (memo: Barbehenn to Rossi, 7/17/87).

Metalaxyl has been reported in ground water in Florida and North Carolina, according to EPA's Pesticides in Ground Water Database (4/19/89). Data submitted to EPA for review are inadequate to determine leaching potential, yet laboratory studies indicate that the parent and major degradate can rapidly leach. Therefore, a small-scale retrospective ground-water study was required (Metalaxyl Registration Standard [FRSTR], 7/9/87).