

US EPA ARCHIVE DOCUMENT

not in file

Shaughnessy Number: 113501

Date Out of EFGWB: ~~APR 11 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)

Packet Number: **49136**
Date Received: **13-22-89**
EFED

1. Product Name: **Metalaxyl** Chemical Name: _____

2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
100-4-2	242577	177		

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

Instructions: **METALAXYL**

This Section Applies to Review of Studies Only

14. Check Applicable Box
 Adverse 6(a)(2) Data (405) Generic Data (Reregistration) (660)
 Special Review Data (870) 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 <input type="checkbox"/> PC <input type="checkbox"/>	A. Policy Note NS 31 <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(e)(2)(B) flagging criteria <input type="checkbox"/> 2 = data of particular concern from registration standard <input type="checkbox"/> 3 = data necessary to determine tiered testing requirements
	Toxicology/HFA	TOX/HFA <input type="checkbox"/> PL <input type="checkbox"/>	
	Toxicology/IR	TOX/IR <input type="checkbox"/>	
	Dietary Exposure	DEB <input type="checkbox"/> EA <input type="checkbox"/>	
EFED	Nondietary Exposure	NDE <input type="checkbox"/> AC <input type="checkbox"/>	B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18
	Ecology	EEB <input type="checkbox"/>	
SRRD	Environmental Fate & Groundwater	EFGWB <input type="checkbox"/>	C. Inert Ingredients <input type="checkbox"/> 1 = data in support of continued use of List 1 inert
	Special Review	SR <input type="checkbox"/>	
	Reregistration	REP <input type="checkbox"/>	
RD	Generic Chemical Support	GSC <input type="checkbox"/>	
	Insecticide-Rodenticide	IR <input type="checkbox"/>	
	Fungicide-Herbicide	FH <input type="checkbox"/>	
	Antimicrobial	AM <input type="checkbox"/>	
BEAD	Product Chemistry		
	Precautionary Labeling		
	Economic Analysis		
	Analytical Chemistry		
	Biological Analysis		

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

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 <i>Metolachlor</i>				Chemical Name			
2. Identifying Number <i>10-623</i>	3. Record Number <i>242077</i>	4. Action Code <i>177</i>	5. MRID/Accession Number	6. Study Guideline or Narrative			
7. Reference No. <i>1</i>	8. Date Rec'd (EPA) <i>3/17</i>	9. Prod/Review Mgr/DCI <i>ROSSI</i>	10. PM/RM Team No. <i>21</i>	11. Date to HED/EFED/RD/BEAD <i>3/21</i>	12. Proj Return Date <i>4/21</i>	13. Date Returned to RD/SRRD	

Instructions

This Section Applies to Review of Studies Only

14. Check Applicable Box				15. No. of Individual Studies Submitted	
<input type="checkbox"/> Adverse 6(a)(2) Data (405)	<input type="checkbox"/> Generic Data (Reregistration) (660)	<input type="checkbox"/> Special Review Data (870)		<input type="checkbox"/> Product Specific Data (Reregistration) (655)	
16. Have any of the above studies (in whole or in part) been previously submitted for review?				17. Related Actions	
<input type="checkbox"/> Yes (Please identify the study(ies))				<input type="checkbox"/> No	
18.	To	Type of Review	19. Reviews Also Sent to		20. Data Review Criteria
HED		Science Analysis & Coordination	<input type="checkbox"/> SAC	<input type="checkbox"/> PC	A. Policy Note No. 31
		Toxicology/HFA	<input type="checkbox"/> TOX/HFA	<input type="checkbox"/> PL	
		Toxicology/IR	<input type="checkbox"/> TOX/IR		
		Dietary Exposure	<input type="checkbox"/> DEB	<input type="checkbox"/> EA	
EFED		Nondietary Exposure	<input type="checkbox"/> NDE	<input type="checkbox"/> AC	2 = data of particular concern from registration standard
	<input checked="" type="checkbox"/>	Ecology		<input type="checkbox"/> BA	
SRRD		Environmental Fate & Groundwater	<input type="checkbox"/> EEB		3 = data necessary to determine tiered testing requirements
		Special Review	<input type="checkbox"/> EFGWB		
		Reregistration			
RD		Generic Chemical Support	<input type="checkbox"/> SR		B. Section 18
		Insecticide-Rodenticide	<input type="checkbox"/> RER		
		Fungicide-Herbicide	<input type="checkbox"/> GSC		
		Antimicrobial	<input type="checkbox"/> IR		
		Product Chemistry	<input type="checkbox"/> FH		
BEAD		Precautionary Labeling	<input type="checkbox"/> AM		C. Inert Ingredients
		Economic Analysis			
		Analytical Chemistry			
		Biological Analysis			1 = data in support of continued use of List 1 inert
<input type="checkbox"/> Confidential Statement of Formula (EPA Form 8570-4) Attached (Trade Secrets)			<input type="checkbox"/> Label Attached		

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

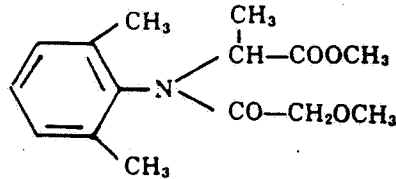
1. CHEMICAL:

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/EFGBW/Ground-Water Section

Signature:

Elizabeth Behl

Date:

4/28/89

6. APPROVED BY:

PH Patrick W. Holden
Chief
OPP/EFED/EFGBW/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 [FRSIR], 7/9/87). Tests indicate that metalaxyl is not oncogenic, mutagenic, or teratogenic, and that acute toxicity is low (memo: Barbehem 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 [FRSIR], 7/9/87).