


US EPA ARCHIVE DOCUMENT

DP Barcode : D158131
 PC Code No. : 113501
 EFGWB Out : 3/15/93

TO: Peg Perreault
 Product Manager # 73
 Special Review and Reregistration Division (H7508W)

FROM: Elizabeth Behl, Head 
 Ground Water Technology Section
 Environmental Fate & Ground Water Branch/EFED (H7507C)

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

Attached, please find the EFGWB review of...

Reg./File # : _____

Common Name : Metalaxyl

Product Name : Ridomil, Subdue

Company Name : Ciba

Purpose : Regulatory Options for Metalaxyl and Waiver of Requirement for Retrospective Ground-Water Monitoring Studies

Type Product : Fungicide

Action Code : 665, 660 EFGWB #(s): 91-0141, 90-0510, 90-0429, 90-0383 Total Review Time = 2.0 days

EFGWB Guideline/MRID/Status Summary Table: The review in this package contains...

161-1	162-4	164-4	166-1
161-2	163-1	164-5	166-2
161-3	163-2	165-1	166-3
161-4	163-3	165-2	167-1
162-1	164-1	165-3	167-2
162-2	164-2	165-4	201-1
162-3	164-3	165-5	202-1

Y = Acceptable (Study satisfied the Guideline)/Concur P = Partial (Study partially satisfied the Guideline, but additional information is still needed)
 S = Supplemental (Study provided useful information, but Guideline was not satisfied) N = Unacceptable (Study was rejected)/Non-Concur

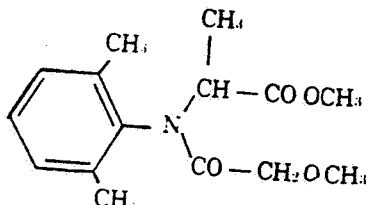
1. CHEMICAL:

Chemical name: N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-alanine methyl ester

Common name: Metalaxyl

Trade name(s): Ridomil, Subdue, Apron, Ridomil/Bravo

Structure:

2. TEST MATERIAL:

Not Applicable.

3. STUDY/ACTION TYPE:

Recommendation of regulatory actions for metalaxyl and waiver of small-scale retrospective studies.

4. STUDY IDENTIFICATION:

Title(s): 1) Letter from Karen Stumpf to Lois Rossi; Metalaxyl Use Information; Metalaxyl Market Direction

Identifying No.: 0081
Record Number: 259,902
Date Sent to EFED: 2/23/90

2) Protocol: Small-Scale Retrospective Ground-Water Monitoring Study for Metalaxyl

Identifying No.: 0081
Record Number: 260,696
Date Sent to EFED: 3/8/90

3) Response to US Environmental Protection Agency Review on "Monitoring Domestic Supply Wells for Metalaxyl"

Identifying No.: 0081
Record Number: 262,730
Date Sent to EFED: 4/13/90

4) Small-Scale Retrospective Ground-Water Monitoring Study for Metalaxyl - Site Characterization Reports for Florida, California, and Wisconsin

Identifying No.: 113501
DP Barcode: 158131
Date Sent to EFED: 11/15/90

Submitted for:

Ciba Corporation
Agricultural Division
P.O. Box 18300
Greensboro, NC 27419

5. REVIEWED BY:

Estella Waldman
Hydrologist
OPP/EFED/EFGBW/Ground-Water Section

Signature: Estella Waldman

Date: 3/9/93

6. APPROVED BY:

Elizabeth Behl
Acting Section Head
OPP/EFED/EFGBW/Ground-Water Section

Signature: Elizabeth Behl

Date: 3/11/93

DP BARCODE: D158131

REREG CASE #

CASE: 819456
SUBMISSION: S385706

DATA PACKAGE RECORD
BEAN SHEET

DATE: 03/15/93
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 635 PROPOSED TEST PROT SUBM
CHEMICALS: 113501 Metalaxyl 100.00 %

ID#: 113501

COMPANY:

PRODUCT MANAGER: 73 LINDA PROPST 703-308-8165 ROOM: CS1 2L5
PM TEAM REVIEWER: CAROL PETERSON 703-305-6598 ROOM: CM2 1121A
RECEIVED DATE: 10/19/90 DUE OUT DATE: 01/27/91

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 158131 EXPEDITE: N DATE SENT: 11/14/90 DATE RET.: / /

CHEMICAL: 113501 Metalaxyl

DP TYPE: 001 Submission Related Data Package

ADMIN DUE DATE: 01/23/91 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	11/15/90	/ /
BRAN: EFGB	11/16/90	03/15/93
SECT: GTS	11/17/90	03/12/93
REVR : EWALDMAN	05/01/92	03/09/93
CONTR:	/ /	/ /

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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MRID's 41672501
41672502
41672503

4

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: 30 350
Date Received: 4-13-90
EFED

1. Product Name				Chemical Name METALAXYL 113501-1	
2. Identifying Number 0031	3. Record Number 262,730	4. Action Code 6600	5. MRID/ Accession Number 41439201	6. Study Guideline or Narrative GROUNDWATER MONITORING ADDITIONAL INFORMATION 1/6/92	

7. Reference No. 1	8. Date Rec'd (EPA) 4-1-90	9. Prod/Review Mgr/DCI CAROL PETERSON	10. PM/RM Team No. 74	11. Date to HED/EFED/RD/BEAD 4-13-90	12. Proj Return Date 7-13-90	13. Date Returned to RD/SRRD
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Instructions
ATTENTION: BETSY BEHL
EFGWB # 90-0510

This Section Applies to Review of Studies Only

14. Check Applicable Box <input type="checkbox"/> Adverse 6(a)(2) Data (405) <input type="checkbox"/> Special Review Data (870) <input checked="" type="checkbox"/> Generic Data (Reregistration)(660) <input checked="" type="checkbox"/> 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? <input type="checkbox"/> Yes (Please identify the study(ies)) <input type="checkbox"/> No	17. Related Actions

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. Polloy Note No. 31 <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria <input checked="" type="checkbox"/> 2 = data of particular concern from registration standard <input type="checkbox"/> 3 = data necessary to determine tiered testing requirements
		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	
		Nondietary Exposure	<input type="checkbox"/> NDE <input type="checkbox"/> AC <input type="checkbox"/> BA	
EFED	X	Ecological Effects Environmental Fate & Groundwater	<input type="checkbox"/> EEB <input type="checkbox"/> EFGWB	B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18 C. Inert Ingredients <input type="checkbox"/> 1 = data in support of continued use of List 1 inert
SRRD		Special Review	<input type="checkbox"/> SR	
		Reregistration	<input type="checkbox"/> RER	
		Generic Chemical Support	<input type="checkbox"/> GSC	
RD		Insecticide-Rodenticide	<input type="checkbox"/> IR	
		Fungicide-Herbicide	<input type="checkbox"/> FH	
		Antimicrobial	<input type="checkbox"/> AM	
		Product Chemistry		
BEAD		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	Pack Number <div style="font-size: 2em; font-family: cursive;">30 350</div> <div style="font-size: 1.5em; font-family: cursive;">EFED</div>	Date Received <div style="font-size: 2em; font-family: cursive;">4-13-90</div>
	<h2 style="margin: 0;">Data Review Record</h2> <p style="font-size: 0.8em; margin: 0;">Confidential Business Information - Does not contain National Security Information (E.O. 12065)</p>		

1. Product Name					Chemical Name METALAXYL 18501-1		
2. Identifying Number 0081	3. Record Number 262 730	4. Action Code 660	5. MRID/ Accession Number 41439201	6. Study Guideline or Narrative GROUNDWATER MONITORING ADDITIONAL INFORMATION 166-3			
7. Reference No. 1	8. Date Rec'd (EPA) 4-1-90	9. Prod/Review Mgr/DCI MILL OLTERSON	10. PM/RM Team No. 74	11. Date to HED/ (EFED)RD/BEAD 4-13-90	12. Proj Return Date MSP 2-13-90	13. Date Returned to RD/SRRD	

Instructions

ATTENTION: ESTY BEHL

EFCWB # 90-0510

R+SP
 coated to
 Harold Day

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 checked="" 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 <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria <input checked="" type="checkbox"/> 2 = data of particular concern from registration standard <input type="checkbox"/> 3 = data necessary to determine tiered testing requirements B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18 C. Inert Ingredients <input type="checkbox"/> 1 = data in support of continued use of List 1 inert
		Toxicology/HFA	<input type="checkbox"/> TOX/HFA	<input type="checkbox"/> PL	
		Toxicology/IR	<input type="checkbox"/> TOX/IR	<input type="checkbox"/> EA	
		Dietary Exposure	<input type="checkbox"/> DEB	<input type="checkbox"/> AC	
		Nondietary Exposure	<input type="checkbox"/> NDE	<input type="checkbox"/> BA	
EFED		Ecological Effects	<input type="checkbox"/> EEB		
	<input checked="" type="checkbox"/>	Environmental Fate & Groundwater	<input type="checkbox"/> EFGWB		
SRRD		Special Review	<input type="checkbox"/> SR		
		Reregistration	<input type="checkbox"/> RER		
		Generic Chemical Support	<input type="checkbox"/> GSC		
RD		Insecticide-Rodenticide	<input type="checkbox"/> IR		
		Fungicide-Herbicide	<input type="checkbox"/> FH		
		Antimicrobial	<input type="checkbox"/> AM		
		Product Chemistry			
BEAD		Precautionary Labeling			
		Economic Analysis			
		Analytical Chemistry			
		Biological Analysis			
<input type="checkbox"/> Confidential Statement of Formula (EPA Form 8570-4) Attached (Trade Secrets)				<input type="checkbox"/> Label Attached	

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United States Environmental Protection Agency
Office of Pesticide Programs
Washington, DC 20460
Data Review Record
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Pack Number
50222
EFED

Date Received
3/8/90

1. Product Name					Chemical Name METALAXYL 113501-1		
2. Identifying Number 0081	3. Record Number 260,696	4. Action Code 665	5. MRID/ Accession Number NA	6. Study Guideline or Narrative Groundwater protocol (166-2)			

7. Reference No. 1	8. Date Rec'd (EPA) 3-6-90	9. Prod/Review Mgr/DCI LAROL PETERSON	10. PM/RM Team No. 74	11. Date to HED/EFED/RD/BEAD 3-8-90	12. Proj Return Date 4-8-90	13. Date Returned to RD/SRRD
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Instructions
PROTOCOL
priority review expedite OK'd by Betsy Behl.
EFGWB # 90-0429

This Section Applies to Review of Studies Only

14. Check Applicable Box <input type="checkbox"/> Adverse 6(a)(2) Data (405) <input type="checkbox"/> Special Review Data (870) <input type="checkbox"/> Generic Data (Reregistration)(660) <input type="checkbox"/> 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? <input type="checkbox"/> Yes (Please identify the study(ies)) <input checked="" type="checkbox"/> No	17. Related Actions

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 <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(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	<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	
		Nondietary Exposure	<input type="checkbox"/> NDE <input type="checkbox"/> AC	
EFED	<input checked="" type="checkbox"/>	Ecological Effects	<input type="checkbox"/> EEB <input type="checkbox"/> BA	B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18
		Environmental Fate & Groundwater	<input type="checkbox"/> EFGWB	
SRRD		Special Review	<input type="checkbox"/> SR	C. Inert Ingredients <input type="checkbox"/> 1 = data in support of continued use of List 1 inert
		Reregistration	<input type="checkbox"/> RER	
		Generic Chemical Support	<input type="checkbox"/> GSC	
RD		Insecticide-Rodenticide	<input type="checkbox"/> IR	
		Fungicide-Herbicide	<input type="checkbox"/> FH	
		Antimicrobial	<input type="checkbox"/> AM	
		Product Chemistry		
BEAD		Precautionary Labeling		
		Economic Analysis		
		Analytical Chemistry		
		Biological Analysis		

<input type="checkbox"/> Confidential Statement of Formula (EPA Form 8570-4) Attached (Trade Secrets)	<input type="checkbox"/> Label Attached
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Office of Pesticide Programs
Washington, DC 20460
Data Review Record
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National Security Information (E.O. 12065)

Pack Number
50222
EFED

Date Received
3/8/90

1. Product Name					Chemical Name		
2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative			
0031	561 198	665	NA	EPA 600/4-90-011			

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	3-6-90	1988 M. J. ...	74	3-8-90	3-11-90	

Instructions

print (copy) ...

EFGWB # 90-0429

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"/> Special Review Data (870)	<input type="checkbox"/> Generic Data (Reregistration)(660) <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 checked="" type="checkbox"/> No	90-0429

18.	To	Type of Review	19. Reviewer	20. Data Review Criteria
HED		Science Analysis & Coordination	<input type="checkbox"/> SAC	A. Policy Note No. 31 <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(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 B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18 C. Inert Ingredients <input type="checkbox"/> 1 = data in support of continued use of List 1 inert
		Toxicology/HFA	<input type="checkbox"/> TOX/HFA	
		Toxicology/IR	<input type="checkbox"/> TOX/IR	
		Dietary Exposure	<input type="checkbox"/> DEB	
		Nondietary Exposure	<input type="checkbox"/> NDE	
EFED		Ecological Effects	<input type="checkbox"/> EEB	
	X	Environmental Fate & Groundwater	<input type="checkbox"/> EFGWB	
SRRD		Special Review	<input type="checkbox"/> SR	
		Reregistration	<input type="checkbox"/> RER	
		Generic Chemical Support	<input type="checkbox"/> GSC	
RD		Insecticide-Rodenticide	<input type="checkbox"/> IR	
		Fungicide-Herbicide	<input type="checkbox"/> FH	
		Antimicrobial	<input type="checkbox"/> AM	
		Product Chemistry		
BEAD		Precautionary Labeling		
		Economic Analysis		
		Analytical Chemistry		
		Biological Analysis		

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United States Environmental Protection Agency
Office of Pesticide Programs
- Washington, DC 20460
Data Review Record
Confidential Business Information - Does not contain
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Pack Number
50156
EFED

Date Received
2/23/90

1. Product Name					Chemical Name METALAXYL 13501-1		
2. Identifying Number 0081	3. Record Number 257,902	4. Action Code 1665 1665	5. MRID/ Accession Number N/A	6. Study Guideline or Narrative Groundwater Monitoring Protocol 166-2			
7. Reference No. 1	8. Date Rec'd (EPA) 2-12-90	9. Prod/Review Mgr/DCI CAROL PETERSON	10. PM/RM Team No. 74	11. Date to HED/ EFED/RD/BEAD 2-20-90	12. Proj Return Date 3-20-90	13. Date Returned to RD/SRRD	

Instructions
Atten: Betsy Behl
EFED = 90-0573
(Reviewer has the complete study).

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 checked="" type="checkbox"/> Generic Data (Reregistration)(660)	<input type="checkbox"/> Product Specific Data (Reregistration)(655)		1	
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 checked="" 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 <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(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	<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	
	Nondietary Exposure	<input type="checkbox"/> NDE	<input type="checkbox"/> AC		
			<input type="checkbox"/> BA		
EFED	<input checked="" type="checkbox"/>	Ecological Effects	<input type="checkbox"/> EEB		B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18
		Environmental Fate & Groundwater	<input type="checkbox"/> EFGWB		
SRRD		Special Review	<input type="checkbox"/> SR		
		Reregistration	<input type="checkbox"/> RER		
		Generic Chemical Support	<input type="checkbox"/> GSC		
RD		Insecticide-Rodenticide	<input type="checkbox"/> IR		
		Fungicide-Herbicide	<input type="checkbox"/> FH		
		Antimicrobial	<input type="checkbox"/> AM		
		Product Chemistry			
BEAD		Precautionary Labeling			
		Economic Analysis			
		Analytical Chemistry			
		Biological Analysis			

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

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Washington, DC 20460
Data Review Record
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Pack Number: 50156
Date Received: 2/23/90
E.F.F.T.

1. Product Name: _____ Chemical Name: METALAXYL 1200-1

2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
000	50156	655	NA	...
		665		

7. Reference No.: 1
8. Date Rec'd (EPA): 5-2-90
9. Prod/Review Mgr/DCI: ...
10. PM/RM Team No.: 74
11. Date to HED/EFED/RD/BEAD: ...
12. Proj Return Date: ...
13. Date Returned to RD/SRRD: ...

Instructions: ...
AG...
BE...
90-0383

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	<input type="checkbox"/> SAC <input type="checkbox"/> PC	A. Policy Note No. 31 <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(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	<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	
		Nondietary Exposure	<input type="checkbox"/> NDE <input type="checkbox"/> AC	
EFED		Ecological Effects	<input type="checkbox"/> EEB <input type="checkbox"/> BA	B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18 C. Inert Ingredients <input type="checkbox"/> 1 = data in support of continued use of List 1 inert
	X	Environmental Fate & Groundwater	<input type="checkbox"/> EFGWB	
SRRD		Special Review	<input type="checkbox"/> SR	
		Reregistration	<input type="checkbox"/> RER	
		Generic Chemical Support	<input type="checkbox"/> GSC	
RD		Insecticide-Rodenticide	<input type="checkbox"/> IR	
		Fungicide-Herbicide	<input type="checkbox"/> FH	
		Antimicrobial	<input type="checkbox"/> AM	
		Product Chemistry		
BEAD		Precautionary Labeling		
		Economic Analysis		
		Analytical Chemistry		
		Biological Analysis		

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



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

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC
SUBSTANCES
March 9, 1993

MEMORANDUM

TO: Lois Rossi
Chief, Reregistration Branch
Special Review and Registration Division (H7508W)

FROM: Elizabeth Behl, Estella Waldman *E. Behl, E. Waldman*
Ground Water Technology Section
Environmental Fate and Ground Water Branch (H7507C)

THRU: Henry Jacoby *H. Jacoby*
Chief, Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

RE: Regulatory Options for Metalaxyl and Waiver of Requirement for
Retrospective Ground-Water Monitoring Studies

The December 1981 Registration Standard for metalaxyl required the completion of ground-water monitoring studies in order to register the compound. In 1987, EPA recommended that retrospective studies be conducted for metalaxyl (memo: Simko to Rossi, 8/19/87) because of its long history of use and the potential for metalaxyl and its major degradate to reach ground water based on its environmental fate characteristics. A study protocol and three site selection reports were submitted to EFGWB by the registrant. Recently, several discussions about this chemical have debated the purpose of the retrospective studies (see attached memorandum).

Metalaxyl was not one of the analytes in the "National Survey of Pesticides in Drinking Water Wells" (NPS). The 1992 "Pesticides in Ground Water Database" reports detections of metalaxyl of up to 3 ppb in ground water from North Carolina and Tennessee. Although it is difficult to assess the range of detections from available sources, there are data which indicate that metalaxyl is a ground-water contaminant, and that it has been detected in

ground water at levels ranging from 0.27 to 236 ppb (see attached memo). The MCL for metalaxyl has been estimated to be approximately 400 ppb.

EFGWB believes that sufficient information is available to regulate metalaxyl, and that additional ground-water studies are not necessary at this time. The information is as follows:

- ◆ laboratory studies indicate that the compound is both persistent and mobile.
- ◆ metalaxyl has been detected in ground water at levels ranging from 0.27 to 236 ppb. These residues can be attributed to normal agricultural use of the compound.
- ◆ an estimated MCL for metalaxyl is 400 ppb (most of the known detections in ground water are less than 10% of this estimated figure).
- ◆ the compound is not oncogenic, mutagenic, or teratogenic, and its acute toxicity is low. There are no known adverse environmental effects such as toxicity to nontarget plants or animals.

Therefore, EFGWB recommends the following regulatory actions for metalaxyl:

- 1) a **ground-water advisory** should be added to all metalaxyl labels. The advisory should state:

"This chemical is known to leach through soil into ground water under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."

- 2) metalaxyl should be classified as a **Restricted Use compound for ground-water concerns**. The Restricted Use Rule requires that a chemical trigger certain persistence and mobility parameters; it also must exhibit a number of detections in ground water. Metalaxyl is rarely chosen as an analyte in most monitoring studies and for this reason, limited monitoring data are available for the compound. However, if more ground-water studies analyzed for metalaxyl, the compound would undoubtedly meet the triggers for Restricted Use (see attached table).

Physical and Chemical Characteristics of METALAXYL
Relative to EPA Restricted Use Criteria (Option 2)

		CHARACTERISTIC	RESTRICTED USE CRITERIA	REPORTED VALUE
PERSISTENCE	1	Field dissipation half-life	> 3 weeks, or	38 - 56 days (S) ¹
	2	Lab-derived aerobic soil metabolism half-life	> 3 weeks, or	7 weeks (S) ¹
	3	Hydrolysis half-life	< 10% in 30 days, or	115 - 200 days (V) ¹
	4	Photolysis half-life	< 10% in 30 days, and	Water: 1 week (V) Soil: Stable (V)
MOBILITY	5	Soil adsorption: K_d	≤ 5 ml/g, or	0.43 - 0.48 ml/g (sand)(S) 0.87 ml/g (silt loam)(S) ¹ 1.40 (sandy clay loam)(S) ¹
	6	Soil adsorption: K_{oc}	≤ 500 ml/g, or	16 ml/g (S) ¹
	7	Depth of leaching in field dissipation study	75 cm, and	91 - 122 cm (S) ¹
DETECTIONS	8	Number of wells and states with detections	25 wells in 4 or more states, or	23 wells in 4 states*
	9	Number of counties with detections > 10% of MCL/HA	3 counties at >40 ppb	1 county above 40 ppb*

Shaded area indicates that parameter exceeds trigger.

Option 2 requires [(1 or 2 or 3 or 4) and (5 or 6 or 7)] and (8 or 9)

*monitoring for metalaxyl has only been conducted in 5 states

June 4, 1992

MEMORANDUM

TO: Lois Rossi
Chief, Reregistration Branch (H7508W)

FROM: Henry Jacoby
Chief, Environmental Fate and Ground Water Branch (H7507C)

RE: Requirement for Retrospective Ground-Water Monitoring Studies for Metalaxyl

PURPOSE:

Retrospective ground-water monitoring studies have been required for the registration of the chemical metalaxyl. A study protocol and three site selection reports have been received by EFGWB. At this time, we are uncertain about how to proceed with this compound, and need a decision from you regarding which regulatory options we should follow. The options, from our perspective, are outlined in this memo. We would like to meet with you to discuss these options and obtain your input sometime in mid-July.

BACKGROUND:

The December 1981 Registration Standard for metalaxyl required the completion of ground-water monitoring studies for registration of the compound. In 1985, Ciba-Geigy voluntarily submitted information regarding detections of metalaxyl in ground water (EAB # 6330). Ciba-Geigy reported detections of metalaxyl in Florida ground water at 3.1 and 4.7 ppb; and in the surface water of the Sacramento River, California. Because of a lack of detailed information about the well construction and aquifer depths, the submitted information was judged inconclusive. In 1987, EPA recommended that retrospective studies be conducted for metalaxyl (memo: Simko to Rossi, 8/19/87) because of its long history of use and the potential for metalaxyl and its major degradate to reach ground water based on its environmental fate characteristics.

Laboratory studies indicate that metalaxyl is persistent and mobile in the environment. Results of laboratory and field leaching studies indicate that both the parent and the primary degradate (CGA-62826) may leach in most soils (Metalaxyl Registration Standard, 1987). Tests indicate that metalaxyl is not oncogenic, mutagenic, or teratogenic, and that

acute toxicity is low (memo: Barbehenn to Rossi, 7/17/87). The MCL and HAL for metalaxyl have not been established.

The following information describes the existing monitoring data for metalaxyl that are presently available to the EPA:

GROUND-WATER SAMPLING:

1) A ground-water monitoring study was conducted in **Suwanee County, Florida** in **1980**. No residues of metalaxyl or its degradate CGA-62826 were found in any of the ground-water samples from Day 26 to Day 227. Metalaxyl residues were detected in soil samples on Days 26 and 85 at concentrations ranging from 59 to 670 ppb. Residues were detected to a depth of two feet.

2) A ground-water monitoring study was conducted from **1980 - 1982** for metalaxyl on the Tobacco Experimental Farm in **Maryland**. Soil sample residues ranged from 2.5 to 6080 ppb from Day 0 (the day of application) to 135 days after application. Up to 3710 ppb were detected in the 0" - 18" soil sample 121 days after application. Ground-water samples contained metalaxyl residues ranging from **0.002 to 0.236 ppm** were detected from the day of application to 30 days after application. No detections were noted in ground-water samples after the 30-day sampling round.

3) Four wells in **Florida** were monitored for metalaxyl from **1983 - 1985**. Two ground-water samples yielded positive results; concentrations were **3.1 and 4.7 ppb**. However, water tables in these wells were deep (> 100 feet).

4) A monitoring study for metalaxyl was done in **Oregon** from **1983 - 1985**. Inadequate information was submitted and no conclusions were drawn.

5) Twelve drinking water wells were monitored in **North Carolina, Florida, and Tennessee** from **1986 - 1988**. Four of the North Carolina wells contained metalaxyl residues; one well in Tennessee also contained residues. No residues were detected in the Florida wells. Metalaxyl was found in ground water because of normal use of the compound at concentrations ranging from **0.27 to 3.0 ppb**. The highest concentrations were found in wells located up to 500 feet from the treated area. There are several problems with the study including: age of the wells (many were very old); screened intervals were unknown; only four wells were sampled in each use area; distances from use area to sampled well were variable and ranged from 10 to 600 feet; information about ground-water flow direction was inadequate; and CGA-62826 was not monitored.

6) Metalaxyl and CGA-62826 were detected in ground water in western **Washington** in **1992**. The 6(a)2 information did not report residue levels or exact well locations.

7) Metalaxyl detections in ground water were reported in **North Carolina** as 6(a)2 information in **1992**. The detections ranged from **66 - 815 ppb** at one location in the

eastern part of the state, and have been attributed to point source (mixing/loading) problems. No information is available about the exact location of the well or the conditions pertaining to this detection.

SURFACE WATER SAMPLING:

1) Surface water samples were taken from the **Sacramento River in California** from **1983 - 1985**. During the second and third years of sampling, metalaxyl residue concentrations ranged from **0.25 to 3.5 ppb**. A drinking water well which drew water from the river was also tested; no residues were detected.

REGULATORY OPTIONS:

Metalaxyl has been detected in ground water in several states as a result of field monitoring studies. Concentrations in ground water range up to 4.7 ppb from normal field use of the compound, and up to 3 ppb have been detected in wells located approximately 500 feet from treated fields.

At this point, from our perspective, the Agency has several regulatory options with respect to metalaxyl:

- 1) A ground-water label advisory for all metalaxyl formulations can be established.
- 2) An MCL or lifetime Health Advisory for metalaxyl should be developed. Metalaxyl is not considered to be toxic at relatively high levels; however, these levels should be quantified, considering the concentrations that have been detected in drinking water in North Carolina.
- 3) Restrictions on use sites or usage rates for metalaxyl can be imposed.
- 4) Metalaxyl can be classified as a restricted use chemical.
- 5) Metalaxyl could be managed via State Management Plans.

Sufficient information is currently available to EFGWB to recommend Options 1, 2, and 4. EFGWB has required three small-scale retrospective studies on metalaxyl use for which inadequate monitoring data exist. This information is needed prior to the recommendation of Option 3. It would also be useful for representatives of EFGWB to meet with you to discuss further regulatory options and conditions under which the retrospective ground-water monitoring studies may no longer be necessary. Please let me know at your earliest convenience about the date when a meeting can be arranged.

cc: Daniel Barolo
Anne Barton
Estella Waldman

Environmental Fate & Effects Division
 PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
METALAXYL

Last Update on March 15, 1993

[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

LOGOUT	Reviewer: EW	Section Head: RB	Date: 3/15/93
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Common Name: METALAXYL

Smiles Code: c(cc(C)c1N(C(=O)COC)C(C(=O)OC)C)cc1C

PC Code # : 113501 CAS #: 57837-19-1 Caswell #:

Chem. Name : N-(2,6-DIMETHYLPHENYL)-N-(METHOXYACETYL)-ALANINE
 METHYL ESTER

Action Type: FUNGICIDE

Trade Names: APRON 25WP; CGA 48988; RIDOMIL
 (Formul'tn): EC 2 LBS/GAL; FLOWABLE CONC.

Physical State:

Use : CONTROL OF SOIL-BORNE DISEASES CAUSED BY PYTHIUM AND PHYTO-
 Patterns : PHORA, AND FOLIAR DISEASES CAUSED BY DOWNY MILDEW.
 (% Usage) :

Empirical Form: $C_{15}H_{21}NO_4$
 Molecular Wgt.: 279.34 Vapor Pressure: $2.20E-6$ Torr
 Melting Point : 71.8-72.C °C Boiling Point: °C
 Log Kow : pKa: @ °C
 Henry's : E Atm. M3/Mol (Measured) $1.14E-10$ (calc'd)

Solubility in ...					Comments
Water	7.10E	3	ppm	@20.0 °C	
Acetone	E		ppm	@ °C	
Acetonitrile	E		ppm	@ °C	
Benzene	55.00E		ppm	@ °C	
Chloroform	E		ppm	@ °C	?
Ethanol	E		ppm	@ °C	
Methanol	E		ppm	@ °C	
Toluene	E		ppm	@ °C	
Xylene	E		ppm	@ °C	
	E		ppm	@ °C	
	E		ppm	@ °C	

Hydrolysis (161-1)
 [V] pH 5.0:200 DA
 [V] pH 7.0:200 DA
 [V] pH 9.0:115 DA
 [] pH :
 [] pH :
 [] pH :

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METALAXYL

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

[V] Water: 1 WK

[] :
[] :
[] :

[V] Soil : STABLE

[] Air :

Aerobic Soil Metabolism (162-1)

[S] 7 WK (SOIL?)

[]
[]
[]
[]
[]
[]

Anaerobic Soil Metabolism (162-2)

[S] 9 WK (SOIL?)

[]
[]
[]
[]
[]
[]

Anaerobic Aquatic Metabolism (162-3)

[S] 21.7 AND 26.9 DAYS IN SEDIMENT AND WATER PHASES, RESPECTIVELY.

[]
[]
[]
[]
[]
[]

Aerobic Aquatic Metabolism (162-4)

[S] 55.11 DAYS IN SOIL + WATER.

[]
[]
[]
[]
[]
[]

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Soil Partition Coefficient (Kd) (163-1)

[S] 0.43-0.48 SAND
[S] 0.87 SILT LOAM
[S] 1.40 SANDY CLAY LOAM
[]
[]
[]

Soil Rf Factors (163-1)

[S] 70% IN LEACHATE
[]
[]
[]
[]
[]

Laboratory Volatility (163-2)

[S] LOSS DUE TO VOLATILIZATION SHOULD BE <0.5%.
[]

Field Volatility (163-3)

[]
[]

Terrestrial Field Dissipation (164-1)

[S] 2 WK (SOIL?). MAJOR DEGRADATE PEAKED DURING THE FIRST
[] MONTH AT 20%, DECLINED TO 0.5% OF THE APPLIED AT A YEAR.
[] HOWEVER, IN ANOTHER STUDY THE AMT. REMAINING IN A YEAR WAS
[] 23% OF THAT APPLIED.
[]
[] 3 STUDIES PRODUCED HALF-LIVES OF 38, 50 AND 56 DAYS. PARENT AND
[] CGA LEACHED TO 36-48" SOIL DEPTH
[]
[]
[]

Aquatic Dissipation (164-2)

[S] 20 DAYS FROM PADDY WATER AND 24 DAYS FROM SOIL.
[S] 5 DAYS FROM PADDY WATER AND 11 DAYS FROM SOIL.
[]
[]
[]
[]

Forestry Dissipation (164-3)

[]
[]

Environmental Fate & Effects Division
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Long-Term Soil Dissipation (164-5)

[]
[]

Accumulation in Rotational Crops, Confined (165-1)

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

Accumulation in Rotational Crops, Field (165-2)

[S] PLANTED IN ROTATION TO POTATOES: CORN .02 PPM;
[] SUGARBEETS <.05 IN ROOTS; SOYBEANS .83 PPM

Accumulation in Irrigated Crops (165-3)

[]
[]

Bioaccumulation in Fish (165-4)

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

Bioaccumulation in Non-Target Organisms (165-5)

[S] NO ADVERSE EFFECTS EXPECTED ON AVIAN, MAMMALIAN,
[] OR FRESHWATER AQUATIC SPECIES.

Ground Water Monitoring, Prospective (166-1)

[]
[]
[]
[]

Ground Water Monitoring, Small Scale Retrospective (166-2)

[] Requirement for ground-water monitoring studies has been
[] waived pending regulatory action.

[]
[]

Ground Water Monitoring, Large Scale Retrospective (166-3)

[]
[]
[]
[]

Ground Water Monitoring, Miscellaneous Data (158.75)

[S] METALAXYL HAS BEEN REPORTED IN GROUND WATER IN FLORIDA,
[] NORTH CAROLINA, AND TENNESSEE. Concentrations range from 0.27-
[] 236 ppb.

Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
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Field Runoff (167-1)

[]
[]
[]
[]

Surface Water Monitoring (167-2)

[]
[]
[]
[]

Spray Drift, Droplet Spectrum (201-1)

[]
[]
[]
[]

Spray Drift, Field Evaluation (202-1)

[]
[]
[]
[]

Degradation Products

(N-(2,6-dimethylphenyl)-N-(2'-methoxyacetyl) alanine is the major degradate.

Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY

METALAXYL

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Comments

Parent compound leached rapidly in sand soils with up to 92% of radioactivity recovered in leachate. In SdClLm soils, majority of radioact. was in 6-12 cm soil with less than 0.4% in leachate. Soil Koc = 16.

References: EFGWB REVIEWS
Writer : SJS, PJH, SLL, EW, RJM