US EPA ARCHIVE DOCUMENT

Date Out: 18 FEB 1994 2/21/94

Chemical Code: 113501
DP Barcode: D197035

ENVIRONMENTAL FATE AND GROUND WATER BRANCH

Review Action

To: Linda Probst, Product Manager #73
Special Review and Reregistration Division (7508W)

From: Paul J. Mastradone, Chief Paul J Mastradone
Environmental Chemistry Review Section 1
Environmental Fate & Ground Water Branch/EFED (7507C)

E. Behl, Chief
Ground Water Technology Section
Environmental Fate & Ground Water Branch/EFED (7507C)

Th. u: Henry Jacoby, Chief Henry Jacoby 2/21/94
Environmental Fate & Ground Water Branch/EFED (7507C)

Attached, please find the EFGWB review of...

Common Name:	Metalaxyl	**Trade name:**	Ridomil
Company Name:	Ciba-Geigy		
ID #:	113501		
Purpose:	Prepare EFGWB Science Chapter for Metalaxyl RED.		

Type Product:	**Action Code:**	**EFGWB #(s):**	**Review Time:**
Fungicide	606	94-0150	10 Days

STATUS OF STUDIES IN THIS PACKAGE:

Guideline #	MRID	Status[1]

2035648

STATUS OF DATA REQUIREMENTS ADDRESSED IN THIS PACKAGE:

Guideline #	Status[2]

[1]Study Status Codes: A=Acceptable U=Upgradeable C=Ancillary I=Invalid.
[2]Data Requirement Status Codes: S=Satisfied P=Partially satisfied N=Not satisfied R=Reserved W=Waived.

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

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC
SUBSTANCES

18 FEB 1994

Chemical Barcode #: 113501
DP Barcode #: D197035
EFGWB#: 94-0150

MEMORANDUM

SUBJECT: Metalaxyl - RED Candidate - Environmental Fate and Ground Water Assessment

FROM: Henry M. Jacoby, Chief
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (7507C)

TO: Lois Rossi, Chief
Reregistration Branch
Special Review and Reregistration Division (7508W)

Evert Byington, Chief
Science Analysis and Coordination Staff
Environmental Fate and Effects Division (7507C)

Attached is the environmental fate and ground water package for the metalaxyl List A RED. The package contains an environmental fate and groundwater assessment and a summary of the reviews of environmental fate studies received by EFGWB. The following environmental fate assessment has not changed from the previous assessment completed on May 11, 1993.

EFGWB notes that although four data requirements remain unfulfilled (aerobic aquatic metabolism--162-4, field dissipation for terrestrial uses--164-1, aquatic field dissipation--164-2, accumulation in irrigated crops--165-3), there is sufficient information available from the acceptable and supplemental studies to make a sound qualitative assessment of the fate of metalaxyl in the environment.

If SRRD believes that a more thorough environmental fate assessment is needed, EFGWB recommends that the additional information needed to fulfill data requirements be submitted. The additional information required will make the studies more complete and result in a better quantitative assessment. However, the environmental fate of metalaxyl is presently predictable by the weight of evidence from the various degradation, metabolism, mobility, dissipation, accumulation and ground and surface water studies.

Based on all the data submitted, EFGWB concludes that the primary routes of dissipation of metalaxyl in surface soils appear to be aerobic soil metabolism (half-life ≈40 days), leaching (K_ds 0.4-1.4) and plant uptake (residues accumulate in plants up to 12 months after application). In aquatic systems, such as rice culture, EFGWB can only tentatively identify a route of dissipation, since the compound is stable to hydrolysis (half-life ≈200 days at pH 5 and 7 and 115 days at pH 9), photolysis on water (half-life ≈400 days) and soil (no difference between irradiated or samples incubated in the dark) and does not volatilize appreciably. However, metalaxyl degrades moderately under aerobic aquatic (half-life ≈55 days) and anaerobic aquatic (half-life ≈30 days) conditions, which are probably the main routes of dissipation in aquatic systems with leaching, surface mobility and plant uptake. Sensitized aqueous photodegradation may also be important in dissipation of metalaxyl and residues from aquatic systems.

Under field conditions, the fate of metalaxyl in soil is similar to that under laboratory conditions with reported half-lives of 14 to 56 days under terrestrial field conditions. In two aquatic field dissipation studies, metalaxyl dissipated from rice paddy water with half-lives of 5 and 20 days, and from soil with half-lives of 11 and 24 days. The major soil degradation product formed in the field studies was CGA-62826.

Both laboratory and field studies indicate that metalaxyl and its primary degradate CGA-62826 are persistent and mobile and might leach to ground water in many soils. For this reason, the Agency required Ciba Corporation to conduct several ground-water monitoring studies as a condition of product registration and reregistration. Metalaxyl leaching was further confirmed by detections in several ground-water monitoring studies conducted in the United States. Detections in these studies typically ranged up to 3 ppb; however, in one study, concentrations have been reported as high as 236 ppb, but are not likely to be the result of normal field use.

In 1993, EFGWB reviewed the status of the ground-water monitoring requirement for metalaxyl and decided that sufficient information was available to regulate the chemical. It was also decided that additional ground-water studies were not necessary at that time, and a ground-water label advisory and Restricted Use classification were recommended. The retrospective ground-water monitoring studies were placed on reserve in 1993.

When evaluated under the Office of Pesticide Program's "New Paradigm," metalaxyl exceeds levels of concern (LOCs) for mobility and persistence, and is likely to impact ground-water quality. Information about the LOC exceedences for ground water is detailed in Appendix A. Metalaxyl is not oncogenic, mutagenic or teratogenic, its acute toxicity is low, and the risks to nontarget species are also low. Based on our current knowledge about human and ecological endpoints, metalaxyl is not likely to exceed these other risk-based levels of concern. Because certain LOCs have been exceeded, EFGWB recommended that a label advisory for

(3)

ground water be added to the metalaxyl label. Also recommended was Restricted Use classification based on ground-water concerns.

At the present time, 10 data requirements are fulfilled and 4 data requirements remain unfulfilled. The supplemental and unacceptable studies previously reviewed rnay be upgradable to acceptable with the submission of additional information or explanation.

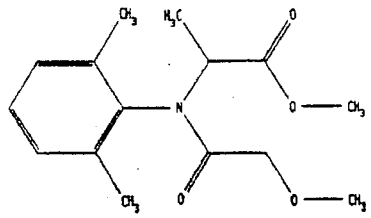
In general, the inadequacies of the unacceptable studies are related mainly to the lack of complete storage stability data for soil samples. For the stored soil samples, the limited data available indicate that the parent and its residues are stable; however, storage stability data was only presented for lengths of time that were always less than the actual storage times.

1.0 CHEMICAL:

Common Name: Metalaxyl

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

Chemical Structure:



Formulations:

Emulsifiable concentrate, granular, flowable, and wettable powder.

Physical/Chemical properties:

Molecular formula: $C_{15}H_{21}NO_4$.
Molecular weight: 279.3.
Physical state: Colorless crystals.
Melting point: 71.8-72.3 C.
Vapor pressure (20 C): 0.293 mPa (2.2 X 10^{-6} Torr).
Solubility (20 C): 7.1 g/L water; 550 g/L benzene; 750 g/L methylene chloride; 650 g/L methanol; 130 g/L octan-1-ol; 270 g/L propan-2-ol

2.0 TEST MATERIAL: N/A

3.0 STUDY/ACTION TYPE: Prepare EFGWB Science Chapter for Metalaxyl List A RED.

4.0 STUDY IDENTIFICATION: No new studies submitted.

5.0 REVIEWED BY:

Richard J. Mahler
Hydrologist, Section 1
EFGWB/EFED

Signature: Richard J. Mahler
Date: 18 FEB 1994

Estella Waldman
Hydrologist, GWTS
EFGWB/EFED

Signature: Estella Waldman
Date: 18 FEB 1994

6.0 APPROVED BY:

Paul J. Mastradone,
Chief, Review Section 1
EFGWB/EFED

Signature: Paul J Mastradone
Date: 18 FEB 1994

E. Behl, Chief
Ground Water Tech. Section
EFGWB/EFED

Signature: E Behl
Date: 18 FEB 1994

7.0 CONCLUSION:

EFGWB notes that although four data requirements remain unfulfilled, there is sufficient information available from the acceptable and supplemental studies to make a sound qualitative assessment of the fate of metalaxyl in the environment. The additional information required will make the studies more complete and result in a better quantitative assessment. However, the environmental fate of metalaxyl is presently predictable by the weight of evidence from the various degradation, metabolism, mobility, dissipation, accumulation and ground and surface water studies, which indicate that the primary routes of dissipation are aerobic metabolism, leaching and plant uptake. In general, the inadequacies of the unacceptable studies are related mainly to the lack of complete storage stability data for soil samples. For the stored soil samples, the limited data indicate that the parent and its residues are stable; however, storage stability data were only presented for lengths of time that were always less than the actual storage times.

Environmental fate assessment:

Based on all the data submitted, EFGWB concludes that the primary routes of dissipation of metalaxyl in surface soils appear to be aerobic soil metabolism (half-life ~40 days), leaching (K_ds 0.4-1.4), and plant uptake (residues accumulate in plants up to 12 months after application). In aquatic systems, such as rice culture, EFGWB can only tentatively identify a route of dissipation, since the compound is stable to hydrolysis (half-life ~200 days at pH 5 and 7 and 115 days at pH 9), photolysis on water (half-life ~400 days) and soil (no difference between irradiated or samples incubated in the dark) and does not volatilize appreciably. However, metalaxyl degrades moderately under aerobic aquatic (half-life ~55 days) and anaerobic aquatic (half-life ~30 days) conditions, which are probably the main routes of dissipation in aquatic systems together with leaching, surface mobility and plant uptake. Sensitized aqueous photodegradation may also be important in dissipation of metalaxyl and residues from aquatic systems.

Terrestrial and aquatic field studies demonstrate that the compound is less stable in the field than the laboratory data indicates, and it is also mobile under normal use conditions.

(6)

At the present time, 10 data requirements are fulfilled and 4 data requirements remain unfulfilled. The supplemental and unacceptable studies previously reviewed may be upgradable to acceptable with the submission of additional information or further explanation.

Based on a review of all studies submitted, both acceptable and unacceptable, the following detailed environmental fate of metalaxyl can be ascertained:

Metalaxyl was found to be moderately stable under normal environmental conditions. At 20 °C the calculated hydrolytic half-life was 200 days at pH 5 and 7, and 115 days at pH 9. Metalaxyl is photolytically stable in water when exposed to natural sunlight, with a half-life of 400 days, and less than 10% of the material photolyzed during the 28 day test period. Studies also indicated that metalaxyl was stable to photodegradation on soil, since test results indicated no difference between the irradiated sample and the control sample. The aerobic soil metabolism half-life was determined to be about 40 days.

Other laboratory studies demonstrated that less than 0.5 % of the applied metalaxyl would be lost to volatilization. Metalaxyl and its degradates readily leach (K_d = 0.43 to 1.40 in sand to sandy clay loams, respectively) in sandy soils and those low in organic matter. It is considered to be a strong leacher, since 57 and 92% of the applied was detected as parent in leachates of unaged 30 cm long soil columns of two sandy soils; while approximately 44 and 34%, and 31 and 18% of the applied was parent and the degradate CGA-62826 (N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine) in the leachates of aged soil columns of a sand and silty loam soils, respectively.

Under field conditions, the fate of metalaxyl is soil is similar to that under laboratory conditions with reported half-lives of 14 to 56 days under terrestrial field conditions. In two aquatic field dissipation studies, metalaxyl dissipated from rice paddy water with half-lives of 5 and 20 days, and from soil with half-lives of 11 and 24 days. The major soil degradation product formed in the field studies was CGA-62826.

Fish accumulation did not exceed 7X when fish were exposed to metalaxyl at 1 ppm in water, and residues were found to accumulate in the nonedible portions over the edible portions in a ratio of about 4:1 to 15:1. Residues declined rapidly during depuration. In addition, a separate fish accumulation study using catfish showed accumulation of 1X and rapid depuration.

As detailed above, both laboratory and field studies indicate that metalaxyl is persistent and mobile and may leach in many soils. For this reason, the December 1981 Registration Standard required the completion of ground-water monitoring studies for metalaxyl. 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

(1)

metalaxyl and its major degradate (CGA-62826) to reach ground water. On March 9, 1993, a memorandum was sent from the Ground Water Section to Lois Rossi (Special Review and Reregistration Division) that discussed the status of the ground-water monitoring requirement for metalaxyl. In the memo, it was stated that sufficient information was available to regulate metalaxyl and that additional ground-water studies were not necessary at that time. The retrospective ground-water monitoring studies were placed on reserve in 1993 (DP Barcode D158131, 3/15/93).

Monitoring data presented to the Agency and in the "Pesticides and Groundwater Database" (Hoheisel et al., 1992) demonstrate that metalaxyl and its primary degradate (CGA-62826) have the potential to leach to ground water. Metalaxyl has been detected in ground water in five states at levels typically ranging up to 3 ppb. Concentrations have been reported as high as 236 ppb, but are not likely to be the result of normal field use. The MCL and HAL for metalaxyl have not been established, but an MCL for metalaxyl has been estimated by OPP to be approximately 400 ppb. Metalaxyl 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 at the levels that normally occur in ground water.

Although metalaxyl does not pose a threat to nontarget species, it does exceed the Level of Concern (LOC) for ground water in several areas including persistence, mobility, and ground-water quality. These are explained in further detail in Appendix A. Because of the LOC exceedences, EFGWB recommended a ground-water label advisory and Restricted Use classification for metalaxyl (Memo from H. Jacoby to L. Rossi, 1992). In the future, if the Agency decides that metalaxyl should be classified as a Restricted Use compound for ground-water concerns, additional monitoring may be required.

Since no one has raised any toxicological concerns about the levels of residues in surface water, these requirements are presently in reserve.

Detailed Environmental Fate Summary: 00104493

Hydrolysis--161-1--Metalaxyl was found to be moderately stable to hydrolysis under normal environmental conditions. At 20°C, the calculated half-life was 200 days at pH 5 and 7 and 115 days at pH 9.

Photolysis in Water--161-2--^{14}C-Metalaxyl was photolytically stable in water when exposed to natural sunlight, with a half-life of 400 days. Less than 10% of the material photolyzed during the 28 day test period. CGA-62826, the major degradation product, was 5.7% of applied in the day 14 irradiated sample and 6.1% in the 28 day sample. Total radiocarbon remaining as metalaxyl was 88.5% for the irradiated samples and 89.9% for the dark controls.

Photolysis on soil--161-3--Metalaxyl was stable to photodegradation on a silty loam soil exposed to a xenon arc lamp. The results indicated no difference between the degradation of the irradiated sample and the control sample (residues degraded at a rate comparable to the aerobic metabolism study).

Aerobic soil metabolism-162-1--The aerobic soil metabolism half-life of metalaxyl was determined to be about 40 days. The only major degradate was CGA-62826 which was identified as N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine. This in turn breaks down to non-extractable material and CO_2. CGA-62826 accumulates to 53.6% of the applied at 66 days and thereafter degrades to 23% of the applied at 360 days. At 12 months, metalaxyl parent accounts for <2% of the applied and nonextractable residues account for 38.3% of the applied.

Anaerobic soil metabolism--162-2--The aerobic soil degraded parent metalaxyl to 60% of the applied at 31 days, and then anaerobic conditions were established. After 66 days, the parent declined to 49.4% and after 89 days it had declined to 32.5%. The major degradation product was CGA-62826 which accumulated to 52.4% after 89 days. CO_2 was not a major degradate and non-extractables did not exceed 10% of the applied.

Anaerobic aquatic metabolism--162-3: Metalaxyl degraded in the anaerobic aquatic environment with a half-life of 26.9 days in soil + water; while the half-lives were 21.7 and 29.9 days, respectively, in the sediment and water phases. Metalaxyl accounted for 96.35 % (1.72 ppm) at the start of the study and decreased to 1.25% (0.02 ppm) after 100 days post-treatment and was not detected after that time. CGA-62826 increased up to 85.53% at 265 days after treatment and then decreased to 48.07% by the termination of the study (Day 385). The metabolite N-(3-hydroxy-2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine (CGA-119857) accounted for up to 16.25% at the end of the study, while CO_2 accounted for only 1.35% (0.02 ppm) of the initially-applied radioactivity.

Aerobic aquatic metabolism--162-4: Metalaxyl degraded in the aerobic aquatic environment with a half-life of 55.11 days in soil + water. The reported half-lives were ~70 and ~41 days, respectively, in the sediment and water phases (EFGWB notes that the registrant did not provide any of the individual data related to the regression analysis of metalaxyl concentration in the sediment and water). Parent metalaxyl (65.36%) and CGA-62826 (20.56%) were the only major metalaxyl residues found in soil/water extracts after 30 days of incubation. Unextractable residues accounted for 3.47%, while CO_2 was <0.5% of the applied radioactivity.

This study did not satisfy the data requirements because the registrant did not provide any data related to the concentration of metalaxyl in the sediment or water individually. The only data in the report was data related to the concentration of

metalaxyl in the sediment/water combined. This data is needed so EFGWB can verify the calculations.

Leaching and adsorption/desorption--163-1--In unaged leaching studies, parent ^{14}C-metalaxyl leached rapidly in sand soil with up to 92% of the radioactivity recovered in the leachate. In the sandy clay loam and silt loam soils, the majority of the radioactivity was recovered in the 6-24 cm soil layers with <0.6% in the leachates.

In aged leaching studies, 79.2% of the applied radioactivity was found in the leachate and 16.1% remained in the soil in the sand soil column. Of the activity found in the leachate, 56% was parent, 31% was CGA-62826, and 12% was unaccounted for. In the silt loam soil, 48.7% was in the leachate and 34.9% remained in the column. Approximately 70% of the radioactivity found in the leachate was parent, 18% was CGA-62826 and 11% was unaccounted for.

Adsorption/desorption studies using radiolabeled metalaxyl demonstrate k_{ads} values of 0.43, 0.48, 0.87 and 1.40 for sand, silt loam and sandy clay loam soil.

Laboratory volatility--163-2--Volatilization studies demonstrated that <0.5% of the applied metalaxyl would be lost due to volatilization, and that volatilization is not a major route of metalaxyl dissipation.

Terrestrial Field Dissipation--164-1--At the present time, none of the submitted field dissipation studies completely satisfy the data requirements for Field Dissipation For Terrestrial Uses. However, EFGWB believes that little further information will be gained from the submission of additional field dissipation studies. Sufficient data has been presented that demonstrates metalaxyl and its primary degradate CGA-62826, are capable of leaching to the 36-48 inch soil depth (which is further confirmed by groundwater and drinking water studies where metalaxyl and its degradate CGA-62826 were detected). Furthermore, there is sufficient data from the submitted studies that demonstrate that the route of dissipation is probably leaching, aerobic soil metabolism and plant uptake. The reported half-lives of metalaxyl at the various field locations, where the studies were considered supplemental, varied from 14 to 56 days.

EFGWB notes that the field dissipation half-lives determined from four previously reviewed unacceptable field dissipation studies were ~27, 36, 148 and 296 days (although the data in the latter two studies were too variable to accurately assess the dissipation).

Three other field dissipation studies produced the following results:

1. In one study, metalaxyl dissipated with a half-life of 56 days from the upper 6 inches of bareground plots of loamy sand soil in California after a broadcast application of

metalaxyl (Ridomil 2E, 2 lb/gallon EC) at 8 lb ai/A. The degradate, CGA-62826, was detected in the 0- to 6-inch soil depth at all sampling intervals. Metalaxyl and CGA-62826 leached to the 36- to 48-inch soil depth; leaching correlated with significant amounts of irrigation water applied to the plots. This study is scientifically sound, but is not acceptable because adequate freezer storage stability data were not provided.

2. In the 2nd study, metalaxyl dissipated with a half-life of 50 days from the upper 6 inches of plots of sandy loam soil planted to young citrus in California following the last of three applications (3-month intervals) of metalaxyl (Ridomil 2E, 2 lb/gallon EC) at 4.4 lb ai/A (13.2 lb ai/A total). The degradate, CGA-62826, was detected in the 0- to 6-inch soil depth at most sampling intervals. Metalaxyl leached to the 24- to 36-inch soil depth and CGA-62826 leached to the 36- to 48-inch soil depth. This study is scientifically sound, but is not acceptable because adequate freezer storage stability data was not provided.

3. In the last study, metalaxyl dissipated with half-lives of 38-39 days from the upper 6 inches of bareground and cropped (tobacco) plots of loamy sand soil in North Carolina after a single broadcast application of metalaxyl (Ridomil 2E, 2 lb/gallon EC) at 4.3 lb ai/A. The degradate, CGA-62826, was detected in the 0- to 6-inch soil depth at most sampling intervals. Metalaxyl and CGA-62826 leached to the 36- to 48-inch soil depth; however, leaching patterns were confounded with apparent contamination during sampling. This study is scientifically sound, but is not acceptable because the patterns of leaching of metalaxyl and CGA-62826 were confounded by an apparent problem with contamination during sampling; and adequate freezer storage stability data were not provided.

Aquatic Field Dissipation--164-2: Metalaxyl dissipated from rice paddy water with calculated half-lives of 5 and 20 days and from soil with half-lives of 11 and 24 days. The studies were not acceptable because soil samples containing metalaxyl and its major degradate, CGA-62826, were stored frozen for up to 436 days before analysis; however, storage stability experiments with soil was performed for only up to 180 days. Therefore, the registrant should provide data that shows metalaxyl and CGA-62826 are stable when stored frozen for up to 436 days to upgrade the study to acceptable.

Accumulation in fish--165-4--Parent metalaxyl bioaccumulation factors (BCF) in whole fish of $\leq$7X were found when bluegill sunfish were exposed to 1 ppm ^{14}C-metalaxyl in a continuous flow-through system for 29 days. Bioaccumulation in edible and non-edible tissues ranged from 0.60 to 0.98 and 3.25 to 14.65, respectively. Residues declined rapidly during depuration. In another fish accumulation study with catfish, BCFs were below 1X in the edible, non-edible and whole fish portions at all exposure

sampling times. Greater than 80% of the residues were recovered after 14 days of depuration.

8.0 RECOMMENDATIONS:

8.1 EFGWB notes that although four data requirements remain unfulfilled, there is sufficient information available from the acceptable and supplemental studies to make a sound qualitative assessment of the fate of metalaxyl in the environment.

If SRRD believes that a more thorough environmental fate assessment is needed, EFGWB recommends that the additional information needed to fulfill data requirements be submitted. The additional information required will make the studies more complete and result in a better quantitative assessment. However, the environmental fate of metalaxyl is presently predictable by the weight of evidence from the various degradation, metabolism, mobility, dissipation, accumulation and ground and surface water studies, which indicate that the primary routes of dissipation are aerobic metabolism, leaching, surface mobility and plant uptake. In general, the inadequacies of the studies are related mainly to the lack of complete storage stability data for soil samples. The limited storage data available indicate that the parent and its residues are stable; however, storage stability data was only presented for lengths of time that were always less than the actual storage times.

Metalaxyl exceeds the Level of Concern for ground water in several areas detailed in Appendix A. For this reason, EFGWB recommended that a ground-water advisory be added to all metalaxyl labels (the label has since been amended). EFGWB also recommended that metalaxyl be considered as a Restricted Use compound for ground-water concerns.

8.2 The status of the Environmental Fate Data Requirements for reregistration of metalaxyl for what is classified as a terrestrial food crop use is as follows:

Environmental Fate Data Requirements		Status of Data Requirement	MRID No.
Degradation			
161-1	Hydrolysis	Fulfilled	00104493 ✓
162-1	Photodegradation in water	Fulfilled (GT;09/7/89)	OK HoF 41156001 ✓
162-3	Photodegradation on soil	Fulfilled	00100455
Metabolism			
162-1	Aerobic (Soil)	Fulfilled	00104494
162-2	Anaerobic (Soil)	Fulfilled	00104494

Environmental Fate Data Requirements	Status of Data Requirement	MRID No.
162-3 Anaerobic aquatic	Fulfilled (RJM;05/11/93)	42259801
162-4 Aerobic aquatic	Not fulfilled (RJM;05/11/93)	42259802
Mobility		
163-1 Leaching, Adsorption/ Desorption	Fulfilled	00100464 00100465 00100466
163-2 Laboratory volatility	Fulfilled	00100455
Dissipation		
164-1 Soil	Not fulfilled (RJM;05/11/93)	41765001 41765002 41809301
164-2 Aquatic field	Not fulfilled (RJM;05/11/93)	42259803 42259804
Accumulation		
165-3 In irrigated crops	Not fulfilled	
165-4 In Fish	Fulfilled	00100468 00100470
Ground Water		
166-2 Small-scale retrospective	Reserved	NA (D158131)

In summary, the following studies are not considered fully satisfied at this time:

Aerobic aquatic metabolism--162-4

Field dissipation for terrestrial uses--164-1

Aquatic field dissipation--164-2

Accumulation in irrigated crops--165-3

9.0 BACKGROUND:

Metalaxyl is a systemic fungicide used to control air- and soil-borne diseases on a wide range of crops, as well as foliar diseases caused by the downy mildews. Foliar sprays comprised of metalaxyl and conventional protectant fungicides are recommended for the control of airborne diseases on hops, potatoes, tobacco,

and vines. Metalaxyl alone is used as a soil application for the control of soil-borne pathogens causing root and lower stem rots on crops such as avocados and citrus, and is also used for primary systemic infections of downy mildew on hops and in tobacco seedbeds. Metalaxyl is used as a seed treatment for the control of systemic downy mildews and damping off of various crops such as corn, peas, sorghum, and sunflowers. Single active ingredient formulations include emulsifiable concentrate, granular, flowable, and wettable powder. Multiple active ingredient formulations include thiabendazole, captan, PCNB, and chloroneb.

10.0 DISCUSSION OF INDIVIDUAL STUDIES: N/A

11.0 COMPLETION OF ONE-LINER: N/A

12.0 CBI APPENDIX: All data reviewed here are considered "company confidential" by the registrant and must be treated as such.

14

APPENDIX A

GROUND WATER ASSESSMENT
METALAXYL

Background

The December 1981 Registration Standard for metalaxyl required the completion of ground-water monitoring studies for the chemical. In 1985, Ciba Corporation (formerly Ciba-Geigy) voluntarily submitted information regarding detections of metalaxyl in ground water and surface water (EAB #6330). Because of a lack of detailed information about 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. A study protocol and three site selection reports were submitted to EFGWB by the registrant.

On March 9, 1993, a Memorandum was sent from the Ground Water Section to Lois Rossi (Special Review and Reregistration Division) that discussed the status of the ground-water monitoring requirement for metalaxyl. In the memo, it was stated that sufficient information was available to regulate metalaxyl and that additional ground-water studies were not necessary at that time. Recommendations for a ground-water label advisory and Restricted Use were proposed. The retrospective ground-water monitoring studies were placed on reserve in 1993. In the future, if the Agency decides that metalaxyl should be classified as a Restricted Use compound for ground-water concerns, additional monitoring will be required.

Environmental Fate Assessment

Data currently available to EPA indicate that metalaxyl and its degradate are mobile and persistent. The 1992 "Pesticides in Ground Water Database" (Hoheisel et al., 1992) reports detections of metalaxyl typically up to 3 ppb in ground water from North Carolina and Tennessee. Additional information in EFGWB files indicates detections of metalaxyl in Maryland, Florida, and Washington as high as 236 ppb. The MCL and lifetime HA for metalaxyl have not been established, but an MCL for metalaxyl has been estimated to be approximately 400 ppb. Metalaxyl 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 at the levels typically found in ground water.

Although the risk to nontarget species is low, metalaxyl does exceed the Level of Concern (LOC) for ground water in several areas including mobility, persistence, and ground water quality.

Metalaxyl exceeds the following Levels of Concern for ground water:

- **MOBILITY.** The mobility LOC for ground water is exceeded if the Kd ≤ 5 mL/gm or the Koc is ≤ 500 mL/gm. Metalaxyl Kd's range from 0.43 to 1.40 mL/gm in sands to sandy clay loams.

- **PERSISTENCE.** The LOC for persistence is exceeded if the soil metabolism half-life > 2 to 3 weeks. Terrestrial field dissipation half-lives for metalaxyl range from 14 to 56 days.

- **RISK TO GROUND-WATER QUALITY.** Metalaxyl has been detected in ground water in five states at levels ranging up to 3.0 ppb. Detections were also observed up to 236 ppb in one study, but the results are questionable. Metalaxyl is registered for use on over 100 crops. Considering its widespread use, EFGWB is concerned about the degradation of water quality that may occur in metalaxyl use areas.

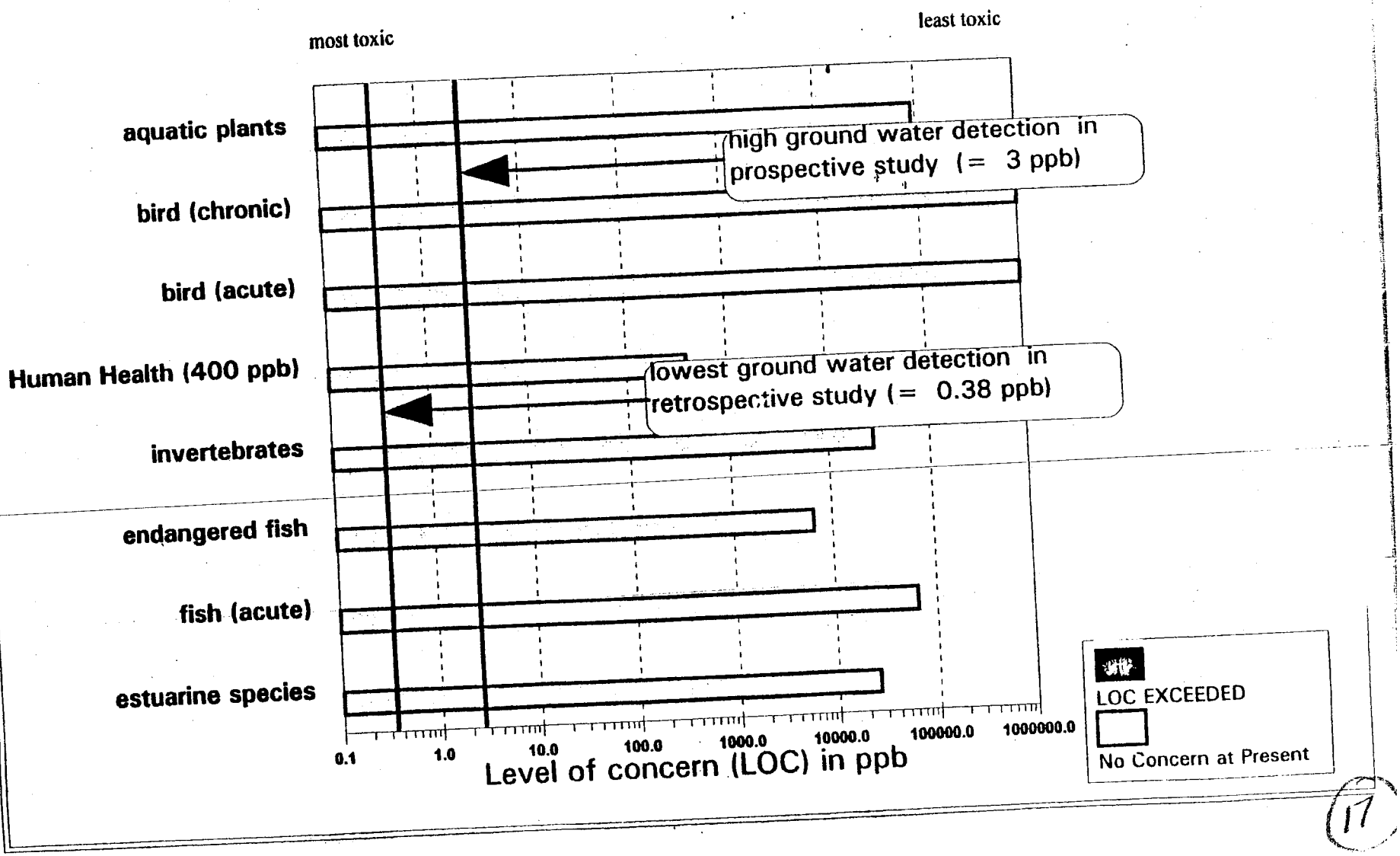
Recommendations

Metalaxyl exceeds the Level of Concern for ground water in several areas. For this reason, EFGWB recommends that metalaxyl be considered as a Restricted Use compound for ground-water concerns. In the future, if metalaxyl is proposed as a candidate for Restricted Use, additional monitoring requirements will be imposed.

Data requirements not satisfied

166-2. Small-Scale Retrospective Ground-Water Monitoring. *All studies placed in reserve.*

Comparison of Detections in Ground Water with Levels of Concern
METALAXYL (Ridomil)



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Memorandum

SUBJECT: Amendment to Ground Water Assessment of Metalaxyl for Registration Eligibility Document

FROM: Estella Waldman, Hydrologist
Ground Water Section
Environmental Fate and Ground Water Branch

Elizabeth Behl, Chief
Ground Water Section
Environmental Fate and Ground Water Branch

THRU: Henry M. Jacoby, Chief
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (7507C)

TO: Linda Propst
Product Manager #73
Special Review and Reregistration Division (7508W)

Evert Byington, Chief
Science Analysis and Coordination Staff
Environmental Fate and Effects Division (7507C)

This document is presented as an amendment to the original ground-water assessment that was completed for the Registration Eligibility Document (RED). The document was prepared to provide further justification for the recommendations stated in the original RED. Also, one new recommendation has been added in order to be consistent with the regulations considered appropriate for other chemicals.

Recommendations

1. EFGWB recommends that the metalaxyl label be amended to include a ground-water advisory. This 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. EFGWB recommends that metalaxyl be considered a Restricted Use compound for ground-water concerns. The triggers for the Restricted Use Rule were developed to indicate the potential for a pesticide to leach to ground water. As illustrated on Figure 1, metalaxyl exceeds all seven of the proposed persistence and mobility triggers for Restricted Use, indicating that it has high potential to move to ground water. Limited monitoring has been conducted for metalaxyl, and few detections have been found in ground water to date. With an extensive monitoring program in metalaxyl use areas, it is likely that metalaxyl would also meet the detections trigger (number 8) for classification as a Restricted Use chemical.

3. EFGWB requests that the registrant propose a level in ground water that, if reached, would be appropriate for some form of regulatory action.

Discussion

In the initial ground-water assessment for the RED, metalaxyl was shown to exhibit the properties and characteristics associated with chemicals that have been detected in ground water. Metalaxyl is a persistent pesticide with an aerobic soil metabolism half-life of approximately six weeks. In addition, metalaxyl is very mobile with Kd values ranging from 0.43 to 1.40 L/kg in three different soils. Considering the nature of the chemical; i.e., highly persistent under certain conditions and very mobile in many soils, there is a strong possibility of movement to ground water, especially in vulnerable areas. This has been confirmed by the detections reported in the "Pesticides in Ground Water Database" (Hoheisel et al., 1992) which indicate that metalaxyl has had an impact on ground-water quality.

Metalaxyl is not oncogenic, mutagenic or teratogenic, its acute toxicity is low, and the risks to nontarget species are also low. Based on our current knowledge about human and ecological endpoints, metalaxyl is not likely to exceed the risk-based levels of concern. However, because the Level of Concern for ground-water quality has been exceeded by metalaxyl, EFGWB recommends several actions. A ground-water label advisory (previously recommended in 1993) should be placed on the metalaxyl label. Metalaxyl should also be considered for classification as a restricted use chemical for ground-water concerns. When compared to several other pesticides that have been recommended for restricted use (Figure 2), metalaxyl (parent) is shown to be extremely mobile and moderately persistent. The

degradate of metalaxyl (not illustrated on the figure), is also very mobile and is more persistent than the parent.

EFGWB also recommends that the registrant propose, as a condition of reregistration eligibility, to establish a level of metalaxyl in ground water that would necessitate further regulatory action. If this level were to be detected in ground water, regulatory action would be taken.

FIGURE 1

Physical and Chemical Characteristics of METALAXYL
Relative to EPA Restricted Use Criteria

		CHARACTERISTIC	RESTRICTED USE CRITERIA	REPORTED VALUE
PERSISTENCE	1	Field dissipation half-life	> 3 weeks, or	40 days (≈6 weeks)
	2	Lab-derived aerobic soil metabolism half-life	> 3 weeks, or	40 days (≈6 weeks)
	3	Hydrolysis half-life	< 10% in 30 days, or	≈200 days
	4	Photolysis half-life	< 10% in 30 days, and	≈400 days
MOBILITY	5	Soil adsorption: K_d	≤ 5 ml/g, or	0.43 - 1.40 ml/g
	6	Soil adsorption: K_{oc}	≤ 500 ml/g, or	16
	7	Depth of leaching in field dissipation study	75 cm, and	48 inches (122 cm)
DETECTIONS	8	Number of wells and states with detections	25 wells in 4 or more states, or	17 wells in 2 states
	9	Number of counties with detections > 10% of MCL/HA	3 counties at >40 ppb	0 counties above 40 ppb

Shaded area indicates that parameter exceeds trigger.

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

FIGURE 2

Physical and Chemical Characteristics of METALAXYL
Relative to Other Pesticides

	CHARACTERISTIC	Metalaxyl	Alachlor	Acetochlor	Picloram	Tebuthiuron
PERSISTENCE	Field dissipation half-life	40 days	18 days	36 days	278 days	2 years
	Lab-derived aerobic soil metabolism half-life	≈6 weeks	3 weeks	245 days	324 days	35.4 months
	Hydrolysis half-life	≈200 days	stable	stable	stable	>64 days
	Photolysis half-life	≈400 days	NA	stable	>384 hrs	39.7 days
MOBILITY	Soil adsorption: K_d	0.43 - 1.40	0.62 - 8.13	0.81-7.5	0.07-0.98	0.11-1.82
	Soil adsorption: K_{oc}	16 ml/g	190 (est)	74-428	16	4
	Depth of leaching in field dissipation study	48 inches	NA	12 inches	NA	>72 inches

NA = data not available