DP Barcode: D156807, D160964, D165800, D168591, D171750, D168595, D168596, D168603, D168611, D168614, D168617, D171750, D171758, D171820, D171833, D171835, D171838, D174288, D174299, D174358, D174393, D174402, D174832, D175967, D178644, D178671

PC Code No.: 113501

TO: Susan Lewis, Product Manager #21 MAY 13 1993
Registration Division (H7505C)

Linda Propst, Product Manager #73
Special Review and Reregistration Division (H7508W)

FROM: Paul J. Mastradone, Ph.D., Chief MAY 11 1993
Environmental Chemistry Review Section #1
Environmental Fate & Ground Water Branch/EFED (H7507C)

THRU: Henry Jacoby, Chief Henry Jacoby 5/13/93
Environmental Fate & Ground Water Branch/EFED (H7507C)

Attached, please find the EFGWB review of...

Reg./File # :100-601, 100-607, 100-628, 100-629, 100-630, 100-639, 100-658, 1F03993.

Common Name :Metalaxyl

Product Name :RIDOMIL

Company Name :CIBA GEIGY

Purpose :Review questions related to field dissipation studies, rotational restriction, tolerances, amendments, aerobic and anaerobic aquatic and field dissipation studies.

Type Product :Fungicide Action Code:230, 330, 400, 614, and 627 Review Time: 25.0 days

EFGWB #s:91-0058, 91-0383, 91-0717, 91-0954, 91-0955, 91-0956, 91-0958, 91-0959, 91-0960, 91-0961, 92-0274, 92-0275, 92-0296, 92-0297, 92-0298, 92-0299, 92-0532, 92-0533, 92-0553, 92-0660, 92-0941 and 92-0957.

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

161-1			162-4	42259802	S	164-4			166-1		
161-2			163-1			164-5			166-2		
161-3			163-2			165-1	42196501	S	166-3		
161-4			163-3			165-2			167-1		
162-1			164-1	41765001,-02, 41809301	N	165-3			167-2		
162-2			164-2	42259803, 4229804	S	165-4			201-1		
162-3	42259801	S	164-3			165-5			202-1		

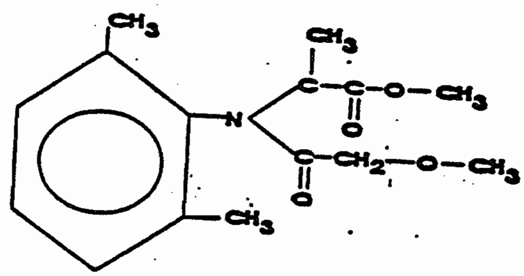
Y = Acceptable (Study satisfied the Guideline)/Concur P = Partial (Study partially satisfied the Guideline, but additional information is still needed)
S = Supplemental (Study provided useful information, but Guideline was not satisfied) N = Unacceptable (Study was rejected)/Non-Concur

1.0 CHEMICAL:

Common Name: Metalaxyl

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

Chemical Structure:



Chemical/physical properties:

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:

Study 1, 2 and 8: ^{14}C-metalaxyl
Study 3 - 7 : Ridomil 2E (Emulsifiable Concentrate)

3.0 STUDY/ACTION TYPE:

3.1 Review anaerobic aquatic metabolism study (EFGWB # 92-0941/D178671), aerobic aquatic metabolism study (EFGWB # 92-0941/D178671), aquatic field dissipation studies (EFGWB # 92-0941/D178671), field dissipation studies (EFGWB #/DP Barcode: 91-0958/D168595, 91-0959/D168591, 91-0960/D168596, 91-0961/D168603, 91-0955/D168614, 91-0954/D168611, 91-0956/D168617), confined accumulation in rotational crop study (EFGWB #92-0553/D174832), and field accumulation in rotation crops (EFGWB #92-0957/D178644) submitted by the registrant.

3.2 Review questions related to the need for field dissipation studies on new wettable powder formulation (EFGWB # 91-0383/D160964).

3.3 Review requests to revise the rotation restriction for corn (Ridomil 2E, 100-607; Ridomil MZ 58, 100-629) from 12 to 9 months (EFGWB # 92-0296/D171838, 92-0297/D171835 & 92-0957/D178644).

3.4 Review petition for establishing tolerances (1F3993) for cereal grain (formerly grain crops), cereal forage and fodder and soybean forage, hay and straw (EFGWB # 92-0299/D171833).

3.5 Review amendment application to change "Grain Crops" to "Cereal Crops" to coincide with proposed tolerance requested in 3.3 above (EFGWB # 92-0298/D171820).

3.6 Review requests for new uses of metalaxyl on water seeded rice (EFGWB # 92-0941/D178671), Ginseng (EFGWB #92-074/D171750 and EFGWB # 92-0275/D171758), non-grass animal feeds (forage and hay, EFGWB # 92-0660/D175967), grass forage, fodder and hay (EFGWB # 92-0532/D174299), and *Brassica* (Cole) leafy vegetable crop grouping (EFGWB # 92-0533/D174358).

4.0 STUDY IDENTIFICATION:

4.1 The following environmental fate studies were submitted for review:

Biever, R. 1992. Ridomil 2E (metalaxyl): An aquatic dissipation study for water seeded rice in Memphis, Tennessee. SLI Report No. 91-11-4013, SLI Study No. 1781-0490-6242-330 and Ciba-Geigy Corporation Protocol No. 79-90. Unpublished report performed by Springborn Laboratories, Inc. Wareham, MA and Agricenter International, Inc. Memphis, TN and Submitted by Ciba-Geigy Corporation, Greensboro, NC. 173 pp. (MRID 422598-04)

Braxton, S.M., and R.M. Bird. 1991. Ridomil 2E - field dissipation - tobacco and bare soil - North Carolina. ETI Study No. 23TBBS; ChemAlysis Laboratory Project No. 80203. Unpublished study performed by Environmental Technologies Institute, Inc., Raleigh, NC, and ChemAlysis, Inc., Laurel, MD, and submitted by Ciba-Geigy Corporation, Greensboro, NC. (MRID 41765002)

Dickson, G. W. 1983. Rotational crop studies with metalaxyl. Laboratory Project ID EIR-82011. Unpublished study performed and submitted by Ciba-Geigy, Greensboro, NC. (MRID 41870308)

Guy, S.O. 1988a. Field dissipation study on Ridomil 5G for terrestrial uses on bareground in Hollandale, MN. Laboratory Study Number 1641-87-71-07-15B-01. Unpublished study performed by Landis Associates, Inc., Valdosta, GA, and submitted by Ciba-Geigy Corporation, Greensboro, NC. (MRID 40985401)

Guy, S.O. 1988b. Field dissipation study on Ridomil 5G for terrestrial uses on tomatoes in Hollandale, MN. Laboratory Study Number 1641-87-71-07-15B-01. Unpublished study performed by Agri-Growth Research, Inc.,

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Hollandale, MN, and Tegeris Laboratories, Inc., Laurel, MD; prepared by Landis Associates, Inc., Valdosta, GA; and submitted by Ciba-Geigy Corporation, Greensboro, NC. (MRID 40985402)

Honeycutt, R. 1980. Identification of four sugar conjugate metabolites of ϕ-^{14}C-CGA-48988 (metalaxyl). Laboratory Project ID ABR-80035. Unpublished study performed and submitted by Ciba-Geigy Corporation, Greensboro, NC. 272 pp. 25. (MRID 421965-03)

Jones, P.A. 1988a. Field dissipation study on Ridomil 5G on bare ground, Madera, California. Laboratory Project ID 87031. Field Project ID PAL-EF-87-30F. Unpublished study performed by Pan-Agricultural Laboratories, Inc., Madera, CA, and Tegeris Laboratories, Inc., Laurel, MD; and submitted by Ciba-Geigy Corporation, Greensboro, NC. (MRID 40985403)

Jones, P.A. 1988b. Field dissipation study on Ridomil 5G on tomatoes, Madera, California. Laboratory Project ID 87031. Field Project ID PAL-EF-87-30F. Unpublished study performed by Pan-Agricultural Laboratories, Inc., Madera, CA, and Tegeris Laboratories, Inc., Laurel, MD; and submitted by Ciba-Geigy Corporation, Greensboro, NC. (MRID 40985404)

Leech, G. and T. Wiepke. 1992. Aquatic dissipation of metalaxyl (Ridomil 2E) in a California rice paddy. Pan-Agricultural Laboratories, Inc. Study No. EF-90-326, Twin City Testing Corporation Study No. 31/90-CGA.1 and Ciba-Geigy Protocol No. 91/90. Performed by Pan-Agricultural Laboratories, Inc., Madera, CA and Twin City Testing Corporation, St. Paul, MN and submitted by Ciba-Geigy Corporation, Greensboro, NC. 272 pp. (MRID 422598-03)

LeRoy, R.L. 1990a. Terrestrial field dissipation of Ridomil 2E on bare ground. Pan-Ag Study No. EF-88-04B; ChemAlysis Study No. 80202. Unpublished study performed by Pan-Agricultural Laboratories, Inc., Madera, CA, and ChemAlysis, Inc., Laurel, MD, and submitted by Ciba-Geigy Corporation, Greensboro, NC. (MRID 41765001)

LeRoy, R.L. 1990b. Terrestrial field dissipation of Ridomil 2E on citrus. Pan-Ag Study No. EF-88-04A; ChemAlysis Study No. 80201. Unpublished study performed by Pan-Agricultural Laboratories, Inc., Madera, CA, and ChemAlysis, Inc., Laurel, MD, and submitted by Ciba-Geigy Corporation, Greensboro, NC. (MRID 41809301)

Madrid, S. 1981. Uptake, balance and metabolism of ϕ-^{14}C-CGA-48988 (metalaxyl) in field grown potatoes. Laboratory Project ID ABR-81037. Unpublished study performed and submitted by Ciba-Geigy Corporation, Greensboro, NC. 32 pp. (MRID 421965-02)

McFarland, J. 1992. Uptake and metabolism of Metalaxyl in greenhouse rotational crops following target tobacco grown in soil treated with [phenyl-^{14}C]-metalaxyl. Laboratory Project ID ABR-91084. Unpublished

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study performed and submitted by Ciba-Geigy Corporation, Greensboro, NC. 272 pp. (MRID 421965-01)

Vithala, R. 1992. Anaerobic aquatic metabolism of ^{14}C-metalaxyl. Laboratory Project ID 005/001/007/89. Unpublished study performed by Center for Hazardous Materials Research, Pittsburgh, PA and submitted by Ciba-Geigy Corporation, Greensboro, NC. 229 pp. (MRID 422598-01)

Vithala, R. 1991. Aerobic aquatic metabolism of ^{14}C-metalaxyl. Laboratory Project ID 005/002/008/89. Unpublished study performed by Center for Hazardous Materials Research, Pittsburgh, PA and submitted by Ciba-Geigy Corporation, Greensboro, NC. 130 pp. (MRID 422598-01)

4.2 Letter from Ciba-Geigy dated 1/22/91 related to understanding of agreements reached at the 1/17/91 meeting, and to question if a field dissipation study would need to be performed with the new 50WP formulation of metalaxyl. (No MRID Number)

4.3 Application to revise rotation restriction for corn from 12 months to 9 months. (No MRID Number)

4.4 Petition (dated May 3, 1991, to S. Lewis, PM 21 from K. Stumpf, Senior Regulatory Specialist, Ciba-Geigy) to amend tolerances in cereal grains (formerly grain crops) and soybean forage, hay and straw. (No MRID Number)

4.5 Amendment application dated May 3, 1991 to change "Grain Crops" to "Cereal Grains" in the Directions for Use instructions on the label. (No MRID Number)

4.6 Various amendment applications to add new uses of metalaxyl on water-seeded rice, Ginseng, non-grass animal feeds (forage and hay), grass forage, fodder and hay, and *Brassica* (Cole) leafy vegetable crops grouping were submitted for review.

5.0 REVIEWED BY:

Richard J. Mahler
Hydrologist, Review Section 1,
EFGWB, EFED

Signature: Richard J. Mahler

Date: 11 MAY 1993

6.0 APPROVED BY:

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

Signature: Paul J. Mastradone

Date: 11 MAY 1993

7.0 CONCLUSION:

7.1 GENERAL:

EFGWB notes that although six 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 metalaxal 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 route of dissipation is probably aerobic metabolism, leaching and plant uptake. In general, the inadequacies of the studies are related mainly to the lack of complete storage stability data for plant and soil samples. The crop accumulation studies imply that the residues are stable in crops and/or decrease linearly; therefore, a correction can be applied for the decrease of the parent and its degradates. 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.

7.1.1 ENVIRONMENTAL FATE DATA REVIEWED IN THIS PACKAGE:

7.1.1.1 Anaerobic aquatic metabolism: EFGWB concludes that this study is acceptable and provides information that shows metalaxyl to degrade 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.

7.1.1.2 Aerobic aquatic metabolism: EFGWB concludes that this study provides supplementary information that shows metalaxyl to degrade 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).

This study does 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.

7.1.1.3 Terrestrial Field Dissipation:

At the present time, none of the seven 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 residues 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.

7.1.1.3.1 Previously Reviewed Studies: EFGWB notes that 4 of the 7 submitted field dissipation studies were previously reviewed on 5/14/90 (EFGWB # 90-350); therefore, only the summaries of those previously reviewed studies are presented below. For further details refer to the specific reviews. EFGWB notes that the field dissipation half-lives determined from the 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).

1. While the highest recommended rate (3.0 lb ai/A) for tomatoes was used in these studies, the highest rate recommended on the product label was not used. For example, metalaxyl can be applied to citrus at an application rate of 2.0-4.0 lb/treated acre at the beginning of the growth season with an additional 2 applications made as needed for a total application of up to 12 lb ai/A/year.

2. Although metalaxyl appears to be stable in soil stored frozen for up to 7 months, further details of the freezer storage stability study are required before any conclusions can be reached in regards to the storage stability of metalaxyl.

> 1. The study author needs to explain in greater detail exactly what occurred at the 7-month sampling interval that resulted in the "anomaly" as stated on page 241, 2nd paragraph of the study (Guy, S.O. 1988a under Section 4.3 above).
>
> 2. Since the storage stability study was carried out for up to 12 months, this information should be provided to EFGWB for review. This information is needed to demonstrate that metalaxyl and its degrades are stable when stored frozen for up to at least 1 year. Although soil samples were stored frozen for up to 1 year and 41 days prior to analysis in the terrestrial field dissipation portion of this study, EFGWB concludes that additional storage stability data for up to 12 months will suffice.
>
> 3. Because of the variation in the mean values reported, EFGWB needs to look at the individual replicates (including those for the 9 and 12 months sampling) in order to be able to determine if the variation in results are too great to make any meaningful conclusions in regards to freezer storage stability of metalaxyl.

3. Previously reviewed Studies 1 (MRID 40985403) and 2 (MRID 40985404) are scientifically valid, and may partially satisfy the data requirements if there is satisfactory resolution of the storage stability problems as discussed in the DER. The registrant also needs to provide more details related to cultural practices performed on the tomato crop at the test site (see DER for Study 2 for further information).

4. Previously reviewed Studies 3 (MRID 40985401) and 4 (MRID 40985402) had data that were too variable to accurately assess the dissipation rate of metalaxyl on soil; therefore these studies probably cannot be resolved with the submission of additional data and new studies must be conducted.

5. EFGWB concludes that parent metalaxyl applied at a 3.0 lb ai/A rate probably dissipates with a half-life of 27 to 36 days under the conditions of the experiment that was conducted in Madera, California (Studies 1 and 2).

7.1.1.3.2 <u>Studies Reviewed With This Action</u>: Three field dissipation studies were submitted.

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, N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine (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 for the following reason:

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, N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine (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 for the following reasons adequate freezer storage stability data were 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, N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine (CGA-62826), was detected. 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 for the following reasons:

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.

7.1.1.4 Aquatic Field Dissipation: Two studies were submitted. EFGWB concludes that both studies are scientifically valid and provide supplemental information that shows metalaxyl to dissipate from rice paddy water with calculated half-lives of 5 and 20 days and from soil with a 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 will have to provide data that shows metalaxyl and CGA-62826 are stable when stored frozen for up to 436 days.

7.1.1.5 Confined Accumulation in Rotational Crops: EFGWB concludes that this study provide supplemental data that shows metalaxyl residues are present in rotational crops planted 232 days after treatment. The study is not acceptable because:

The samples were stored frozen prior to extraction and analysis; however, neither the length of storage nor data showing storage stability was presented in the report.

In order for this study to satisfy the confined accumulation in rotational crops data requirement the registrant should provide the supporting storage stability data for plant and soil samples.

EFGWB notes that two reports[1] were submitted as confined accumulation in rotational crops studies. Upon a cursory review it was ascertained that the studies were related to identification of residues in target tobacco and potato plants and were not pertinent to confined accumulation in rotational crops studies. Consequently no DER has been prepared for these two studies since they were not reviewed.

7.1.1.6 Field Accumulation in Rotational Crops:

EFGWB notes that the submitted field accumulation in rotational crops study was previously reviewed on 5/5/80 (EFGWB # 322).

At the present time, the submitted accumulation in field rotational crop studies partially satisfy the data requirements. However, EFGWB does not generally require or review field accumulation in rotational crop studies until confined rotational crop studies have been received, reviewed and assessed as having satisfied the data requirements (Confined studies are needed to specifically identify individual residues). As has been noted above, the confined accumulation study does not satisfy the data requirements; therefore, until EFGWB has received and reviewed an acceptable confined accumulation in rotational crops study, the requirement for the field accumulation in crops study is reserved.

7.1.2 ENVIRONMENTAL FATE ASSESSMENT:

Based on all the data submitted, EFGWB concludes that the primary routes of dissipation of metalaxyl in surface soils appears 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 not 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. Furthermore, metalaxyl is moderately stable under anaerobic aquatic (half-life ≈30 days) and aerobic aquatic (half-life ≈55 days) metabolism.

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[1]Honeycutt, R. 1980. Identification of four sugar conjugate metabolites of ϕ-^{14}C-CGA-48988 (metalaxyl). Laboratory Project ID ABR-80035. Unpublished study performed and submitted by Ciba-Geigy Corporation, Greensboro, NC. 272 pp. 25. (MRID 421965-03)

Madrid, S. 1981. Uptake, balance and metabolism of ϕ-^{14}C-CGA-48988 (metalaxyl) in field grown potatoes. Laboratory Project ID ABR-81037. Unpublished study performed and submitted by Ciba-Geigy Corporation, Greensboro, NC. 32 pp. (MRID 421965-02)

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

At the present time, 10 data requirements are fulfilled and 6 data requirements remain unfulfilled (refer to pages 11 and 12 for details). Of the 16 studies submitted (several were previously reviewed, two were not pertinent to environmental fate studies and the balance were new submissions) one was partially acceptable and the remainder were either supplemental or unacceptable. Many of the numerous supplemental and unacceptable studies reviewed in this package may be upgradable to acceptable with the submission of additional information or explanation.

Metalaxyl is registered for extensive use on numerous agricultural crops. Metalaxyl has those characteristics generally attributed to pesticides that leach. Based on modeling simulation, EFGWB predicted that metalaxyl can leach into ground water from currently registered uses. Available data from monitoring studies indicate the presence of metalaxyl in ground water at around 4 ppb.

Since neither EEB and TB/HED have identified any hazards of concern regarding metalaxyl or its degradates, we defer to RD concerning the need for a ground-water label advisory or other ground-water regulatory actions.

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 that less than 10% of the material photolyzed during the 28 day test period. Studies also indicated that metalaxyl was stable to photodegradation on soil. 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 leachate 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 CGA-62826 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.

The rotational crop data demonstrated the need for a rotational crop restriction of 12 months or longer because some crops (winter wheat forage, soybean grain and fodder, sweet potato foliage) will take up metalaxyl residues of concern when planted 12 months or more after treatment of a prior crop. Accumulation in field rotational crops are required to determine the need for additional inadvertent tolerances.

Results from surface and ground water monitoring were considered not adequate to meet the groundwater data requirements. However, in a memo from Behl and Waldman to Rossi dated March 9, 1993, it was concluded: "EFGWB believes that sufficient information[2] is available to regulate metalaxyl, and that additional ground-water studies are not necessary at this time."

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

7.1.3 <u>ENVIRONMENTAL FATE REQUIREMENTS</u>:

The following environmental fate data requirements are fulfilled:

<u>Hydrolysis--161-1</u>

<u>Photolysis in Water--161-2</u>

<u>Photolysis on soil--161-3</u>

<u>Aerobic soil metabolism-162-1</u>

<u>Anaerobic soil metabolism--162-2</u>

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[2]This information is as follows: 1) laboratory studies indicate that metalaxyl is both persistent and mobile, 2) metalaxyl has been detected under normal agricultural use in ground water at levels from 0.27 to 236 ppb, 3) an estimated MCL for metalaxyl is 400 ppb, while most of the known detections in ground water are <10% of the MCL, and 4) metalaxyl is not oncogenic, mutagenic, or teratogenic and its acute toxicity is low; and there is no known adverse environmental effects such as toxicity to non target plants or animals.

Anaerobic aquatic metabolism--162-3

Leaching and adsorption/desorption--163-1

Laboratory volatility--163-2

Accumulation in fish--165-4

Photolysis in water--161-2

The following environmental fate data requirements are not fulfilled:

Aerobic aquatic metabolism--162-4

Field dissipation for terrestrial uses--164-1

Aquatic field dissipation--164-2

Confined accumulation in rotational crops--165-1

Field accumulation in rotational crops--165-2[3]

Accumulation in irrigated crops--165-3

The following environmental fate study is not required at the present time because the data requirements have been waived:

Ground water-small retrospective--166-2

The following environmental fate data requirements are not required at the present time because of use pattern:

Photolysis in air--161-4

Field volatility--163-3

Forestry dissipation--164-3

The following environmental fate data is not required because data requirements are not being imposed at the present time:

Dissipation for combination products and tank mix uses--164-4

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[3]Field tests are required to determine the need for additional inadvertent tolerances.

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The following environmental fate data are not required[4] (provided that neither EEB nor HED requires these data):

<u>Droplet size spectrum--201-1</u>

<u>Drift-field evaluation--202-1</u>

7.2 FIELD DISSIPATION WAIVER

The formulation can appreciably affect the dissipation of a pesticide in the field. In general, the greater the surface area, the more rapid will be the dissipation. For example, the use of granules, emulsions and micro-encapsulations usually increases the persistence of pesticides, because the pesticide becomes slowly available for dissipation due to the relatively small surface area. Conversely, wettable powders and dusts have the most surface area, and hence have the tendency to degrade the quickest of all formulations. Since no acceptable field dissipation data has been reviewed, EFGWB cannot make a determination for justifying a waiver of the use of the 50WP. from a scientific viewpoint, it would appear that the use of the granular and emulsion formulations result in a "worst case" scenario in relation to persistence; therefore, there does not appear to be a need to specifically use the new 50WP formulation of metalaxyl in a field dissipation study, at the present time.

7.3 ROTATION RESTRICTION REVISION REQUEST:

The Registration Standard for metalaxyl dated December, 1981, stated that no environmental fate data were required with the exception of ground water monitoring. These data were re-reviewed for applicability to current EFGWB guidelines. Studies for three data categories, including confined accumulation in rotational crops were found to be inadequate and further studies were required (see "Guidance for the Reregistration of Pesticide Products Containing Metalaxyl," dated September 1988).

The now unacceptable data indicate that metalaxyl will be taken up by some crops when planted 12 months or more after treatment. Since the confined rotational crop studies do not now satisfy the data requirements, EFGWB does not have the data to support the request to revise the rotation restriction for corn from 12 to 9 months.

However, since the registrant has requested rotational crop tolerances through Dietary Exposure Branch on cereal grains crop grouping, of which corn is a member, EFGWB has no scientific objection to allowing the proposed rotational interval for corn when the tolerances are granted.

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[4]Spray drift data are required by 40 CFR Sec. 158.142 when aerial application and/or mist blower or other ground application are proposed and it is expected that the detrimental effect level of nontarget organisms (humans, domestic animals, fish, wildlife, and nontarget plants) expected to be present are exceeded.

7.4 TOLERANCE AMENDMENT:

The registrant is petitioning to establish tolerances in cereal grains (i.e. wheat, barley, rye, oats, millet, rice, field corn, sweet corn and popcorn, buckwheat and triticale), cereal forage and fodder, and soybean forage, hay and straw.

Since tolerances are the purview of Dietary Exposure Branch (DEB), EFGWB defers to DEB on the request for establishment of tolerances.

7.5 AMENDMENT TO CHANGE "GRAIN CROPS" TO "CEREAL GRAINS":

The registrant is applying for an amendment to change "Grain Crops" heading to "Cereal Grains" to coincide with the proposed tolerance amendment as stated above under section 7.5. Since the amendment only proposes the name change from "Grain Crops" to "Cereal Grains" on the label Directions for Use, EFGWB does not foresee any problem with this request.

7.6 REQUESTS FOR NEW USES OF METALAXYL ON VARIOUS CROPS:

Metalaxyl is registered for extensive use on numerous agricultural crops. Metalaxyl has those characteristics generally attributed to pesticides that leach. Based on modeling simulation, EFGWB predicted that metalaxyl can leach into ground water from currently registered uses. Available data from monitoring studies indicate the presence of metalaxyl in ground water at around 4 ppb. EFGWB concludes that additional proposed uses of metalaxyl will also contribute to the contamination of ground water. The package received by EFGWB provides very little information concerning the total amount of additional metalaxyl which could be used, and where that use would occur if the new uses requests are approved.

8.0 RECOMMENDATIONS:

8.1 ENVIRONMENTAL FATE DATA SUBMITTED BY REGISTRANT:

Inform the registrant of the points identified in the submitted studies that need to be addressed before the studies can be accepted as satisfying the data requirements. Specific problems with each study are listed in the individual Data Evaluation Records (DER).

8.2 FIELD DISSIPATION WAIVER: See conclusions.

8.3 ROTATION RESTRICTION REVISION REQUEST:

A review of submitted confined rotational crop data indicate, in some cases, the persistence of metalaxyl residues beyond 12 months in rotational crops; however, these residues can be expected to be covered by existing tolerances.

8.4 TOLERANCE AMENDMENT:

Requests sent to EFGWB seeking tolerances should be sent to DEB for their review.

8.5 AMENDMENT TO CHANGE "GRAIN CROPS" TO "CEREAL GRAINS":

See conclusions.

8.6 REQUESTS FOR NEW USES OF METALAXYL ON VARIOUS CROPS:

The Ground-Water Section of EFGWB will be evaluating the results of several monitoring studies done previously by Ciba-Geigy (see Section 4.4 for study identification and review of same contained in this report) to determine the impact (if any) on future ground-water monitoring requirements. These studies will be submitted to OPP by Ciba-Geigy. At present, it is clear from field studies, and the Pesticides in Ground Water Database (4/19/89) that metalaxyl can leach to ground water as a result of normal agricultural use.

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.

9.1 ENVIRONMENTAL FATE DATA SUBMITTED BY REGISTRANT:

The registrant is responding the 1988 Registration Standard.

9.2 FIELD DISSIPATION WAIVER:

Ciba-Geigy is planning to develop a wettable powder formulation. The registrant wants to know if any additional field dissipation studies will be needed with the new formulation.

9.3 ROTATION:

Based on a review of the now unacceptable confined rotational data, the following can be concluded:

Rotational crop uptake was studied using ^{14}C- and unlabeled metalaxyl. The rotational crop data demonstrated the need for a 12 month rotational crop restriction. The radiolabeled studies using a 0.4 lb. ai/A rate of application applied six times with a rotation interval of between 33 and 36 weeks showed residues as high as 0.11 ppm for lettuce, 0.33 ppm in spring oats, 0.16 ppm in sugarbeets and 0.8 ppm in soybeans. These levels were detected only as total ^{14}C-residues. The non-radiolabeled studies using a 3.0-6.0 lb. ai/A application rate applied in one dose (or six 0.5 - 1 lb. doses for winter wheat and sugarbeets) showed residues at longer rotational intervals even at the lower application rate: 13 1/2 mo. (0.09 ppm, winter wheat forage), 10 mo. (0.21 ppm, sugarbeet forage), 13 1/2 mo. (0.35 ppm, soybean grain, 1.4 ppm, soybean fodder), and 13 mo. (0.12 ppm, sweet potato foliage). Sweet potato roots, corn grain, and sugarbeet roots had less than 0.05 ppm metalaxyl residues, however the method sensitivity needed to be about 0.02 ppm.

Until adequate data are received, a 12 month rotational crop interval is imposed for all crops for which tolerances are not established.

9.4 TOLERANCE AMENDMENT:

CIBA-GEIGY is requesting to establish tolerances for the combined residues of metalaxyl and its metabolites in or on cereal grains, formerly grain crops (i.e. wheat, barley, rye, oats, millet, rice, field corn, sweet corn and popcorn, buckwheat and triticale), cereal forage and fodder and soybean forage, hay and straw.

Metalaxyl is registered for extensive use on numerous agricultural crops. Metalaxyl has those characteristics generally attributed to pesticides that leach. Based on modeling simulation, EFGWB predicted that metalaxyl can leach into ground water from currently registered uses. Available data from monitoring studies indicate the presence of metalaxyl in ground water at around 4 ppb. EFGWB concludes that additional proposed uses of metalaxyl will also contribute to the contamination of ground water.

Registration Division should continue the regulation of this chemical within the frame work of the Agricultural Chemicals in Ground Water Strategy and Ground Water Restricted Use Rule.

9.5 AMENDMENT TO CHANGE "GRAIN CROPS" TO "CEREAL GRAINS":

The registrant has submitted an amendment application requesting to change the "Grain Crops" heading to "Cereal Grains" to coincide with the proposed tolerance petition to establish tolerances in cereal grains (i.e. wheat, barley, rye, oats, millet, rice, field corn, sweet corn and popcorn, buckwheat and triticale).

9.6 REQUESTS FOR NEW USES OF METALAXYL ON VARIOUS CROPS:

The registrant has submitted amendment applications requesting new uses of metalaxyl on water seeded rice, Ginseng, non-grass animal feeds grass forage, fodder and hay, and Brassica (Cole) leafy vegetable crop grouping.

10.0 DISCUSSION OF INDIVIDUAL STUDIES: See attached reviews of studies in the Data Evaluation Records where appropriate.

11.0 COMPLETION OF ONE-LINER: Updated by the addition of pertinent data from the studies reviewed in these actions.

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

Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
METALAXYL
Last Update on May 7, 1993
[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

LOGOUT	Reviewer: RJM	Section Head:	Date:

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

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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Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
METALAXYL
Last Update on May 7, 1993
[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

Photolysis (161-2, -3, -4)
[V] Water: 1 WK
[ ] :
[ ] :
[ ] :

[V] Soil : STABLE
[ ] Air :

Aerobic Soil Metabolism (162-1)
[S] ~7 WK (SOIL?)
[V] 40 DAYS
[ ]
[ ]
[ ]
[ ]
[ ]

Anaerobic Soil Metabolism (162-2)
[V] 60 DAYS
[ ]
[ ]
[ ]
[ ]
[ ]
[ ]

Anaerobic Aquatic Metabolism (162-3)
[V] 21.7 AND 26.9 DAYS IN SEDIMENT AND WATER PHASES, RESPECTIVELY.
[ ]
[ ]
[ ]
[ ]
[ ]
[ ]

Aerobic Aquatic Metabolism (162-4)
[S] 55.11 DAYS IN SOIL + WATER. 70 DAYS IN SOIL AND 41 DAYS IN H2O.
[ ]
[ ]
[ ]
[ ]
[ ]
[ ]

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Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
METALAXYL
Last Update on May 7, 1993
[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

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)
[ ]
[ ]

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Long-Term Soil Dissipation (164-5)
[ ]
[ ]

Accumulation in Rotational Crops, Confined (165-1)
[✓] 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; RAPID DEPURATION.
[ ] CATFISH 1X EDIB; 1X VISC; 1X WHOLE; RAPID DEPURATION.

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.

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.

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. Up to 31% of CGA-62826 was detected in leachates.

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

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METALAXYL

Table of Contents

INTRODUCTION

Metalaxyl is a systemic fungicide used to control air- and soil-borne diseases on a wide range of crops, and 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 thiabendazol, captan, PCNB, and chloroneb.

DATA EVALUATION RECORD

STUDY 1

CHEMICAL METALAXYL 162-3

FORMULATION--00--ACTIVE INGREDIENT

STUDY MRID 422598-01
Vithala, R. 1992. Anaerobic aquatic metabolism of ^{14}C-metalaxyl. Laboratory Project ID 005/001/007/89. Unpublished study performed by Center for Hazardous Materials Research, Pittsburgh, PA and submitted by Ciba-Geigy Corporation, Greensboro, NC. 229 pp.

DIRECT REVIEW TIME = 2

REVIEWED BY: Richard J. Mahler, Hydrologist
Environmental Chemistry Review Section 1, EFGWB

SIGNATURE: Richard J. Mahler

DATE: 11 MAY 1993

APPROVED BY: Paul J. Mastradone, Chief
Environmental Chemistry Review Section 1, EFGWB

SIGNATURE: Paul J Mastradone

DATE: [illegible]

CONCLUSIONS:

Metabolism--Anaerobic Aquatic

EFGWB concludes that this study is acceptable and provides information that shows metalaxyl to degrade in the anaerobic aquatic environment with a half-life of 29.9 days in soil + water; while the half-lives were 21.7 and 26.9 days, respectively, in the sediment and water phases.

METHODOLOGY:

The anaerobic aquatic metabolism of ^{14}C-metalaxyl (N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine methyl ester, specific activity of 33.71 uCi/mg, radiopurity of 94.13%) was added at a concentration of 1.78 ppm (which is about 3X greater than the highest recommended application rate) to a 2-mm sieved, non-sterilized Louisiana rice paddy clay soil sediment (8% sand, 24%

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silt, 68% clay, 3.6% organic matter, pH 7.3, CEC 28.9 meq/100g and bulk density 1.20 g/cc) and water mixture (uncharacterized). Prior to applying the treatments, the sediment/water mixture was pre-incubated under anaerobic conditions in flasks in the dark at a temperature of 24.6-25.4°C for about 115 days to activate soil microorganisms. The treated sediment/water mixture was then anaerobically incubated for 385 days in the dark at a temperature of 24.6-25.4°C. The mixture was continuously purged with humidified N gas at 50-60 ml/min., to flush volatile compounds formed, in a series of trapping solution consisting of ethylene glycol, 1*N* sulfuric acid and 5% sodium hydroxide solutions (Figure 4).

Samples of the sediment/water mixture were collected immediately after treatment (Day 0) and at 6, 13, 21, 28, 41, 70, 149, 198, 265, and 385 days after treatment. Replicate samples were centrifuged, and each sediment sample was then extracted with methanol, 1% aqueous trifluoroacetic acid and 1% NaOH solution. Duplicate aliquots the sediment extracts and water supernatant samples were analyzed by Liquid Scintillation Counting (LSC). The extraction procedure for the sediment and water samples is shown in Figure 5.

Aliquots of the water supernatant samples and sediment extracts were analyzed by HPLC equipped with a UV (230nm) and a radioactive flow detector connected in series, for identification of metalaxyl and metabolites formed in quantities $\geq$ 0.01 ppm (Figures 2 and 3). Two dimensional thin-layer co-chromatography and/or mass spectral analyses were used as confirmatory analytical methods for the identification of metalaxyl and its metabolites.

The half-life of ^{14}C-metalaxyl was determined by inputting data on concentration of metalaxyl versus time into a linear regression program.

All test sediment, water supernatant samples, and trapping solutions were analyzed immediately after sampling.

<u>DATA SUMMARY</u>:

The material balance of the test system ranged from 85.23% to 111.68% of the applied radioactivity (Tables I and II).

^{14}C-metalaxyl metabolized with a half-life of 29.9 days (R^2 = 0.9810**) in soil + water; while the half-lives were 21.7 and 26.9 days, respectively, in the sediment and water phases (Figure 6 and Table A).

Metalaxyl accounted for 96.35 % (1.72 ppm) at the start of the study and decreased to 1.25% (0.02ppm) after 100 days post-treatment and was not detected after that time (Table III-IX). N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine (CGA-62626) 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, Table I) of the initially-applied radioactivity. No other volatile compounds were formed during the study period.

The proposed metabolic pathway of ^{14}C-metalaxyl under anaerobic aquatic conditions is through hydroxylation of the phenyl ring and/or demethylation of the ester group. This results in the formation of the metabolites CGA-119857, CGA-62826 and hydroxy metalaxyl. The subsequent removal of the methoxy group is through CGA 62826 and hydroxy metalaxyl to form the acetamide of CGA-62826.

REVIEWER'S COMMENTS:

Characteristics of the test water (pH, hardness, sediment load, etc.) used in the study, were not reported. These characteristics are needed to demonstrate that the physical, chemical and biological parameters of the pond water are within normal ranges. EFGWB generally requires this information before accepting a study. However, lack of this information in the present study probably has a minimum effect on the results of the study since the registrants reported that they used water from a rice paddy.

In future studies, like this one, EFGWB highly recommends that the registrants report the characteristics of the test water used.

Metalaxyl   Sha # 113501

Page_____ is not included in this copy.

Pages 30 through 50 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

_✓_ FIFRA registration data.

____ The document is a duplicate of page(s) __________.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

METALAXYL

Table of Contents

INTRODUCTION

Metalaxyl is a systemic fungicide used to control air- and soil-borne diseases on a wide range of crops, and 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 thiabendazol, captan, PCNB, and chloroneb.

DATA EVALUATION RECORD

STUDY 2

CHEM METALAXYL 162-4

FORMULATION--00--ACTIVE INGREDIENT

STUDY MRID 422598-02
Vithala, R. 1991. Aerobic aquatic metabolism of ^{14}C-metalaxyl. Laboratory Project ID 005/002/008/89. Unpublished study performed by Center for Hazardous Materials Research, Pittsburgh, PA and submitted by Ciba-Geigy Corporation, Greensboro, NC. 130 pp.

DIRECT REVIEW TIME = 1

REVIEWED BY: Richard J. Mahler, Hydrologist
Environmental Chemistry Review Section 1, EFGWB

SIGNATURE: Richard J. Mahler

DATE: 11 MAY 1993

APPROVED BY: Paul J. Mastradone, Chief
Environmental Chemistry Review Section 1, EFGWB

SIGNATURE: Paul J Mastradone

DATE: 11 MAY 1993

CONCLUSIONS:

Metabolism--Aerobic Aquatic

1. EFGWB concludes that this study provides supplementary information that shows metalaxyl to degrade 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 analysis of metalaxyl concentration in the sediment and water).

2. This study does 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.

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The only data in the report was related to the concentration of metalaxyl and residues in the sediment/water combined.

3. If the registrant provides the required data, this study will be acceptable.

METHODOLOGY:

The aerobic aquatic metabolism of ^{14}C-metalaxyl (N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine methyl ester, specific activity of 33.71 *u*Ci/mg, radiopurity of 94.13%) was added at a concentration of 1.52 ppm (which is about 3X greater than the highest recommended application rate) to a 2-mm sieved, non-sterilized Louisiana rice paddy clay soil sediment (8% sand, 24% silt, 68% clay, 3.6% organic matter, pH 7.3, CEC 28.9 meq/100g and bulk density 1.20 g/cc) and water (uncharacterized) mixture. Prior to applying the treatments, the sediment/water mixture was pre-incubated under aerobic conditions in flasks in the dark at a temperature of 25.16± 0.09°C for about 4 days to activate soil microorganisms. The treated sediment/water mixture was then aerobically incubated for 30 days in the dark at a temperature of 25.16± 0.09°C. The mixture was continuously purged with humidified N gas at 50-60 ml/min., to flush volatile compounds formed, in a series of trapping solution consisting of ethylene glycol, 1*M* sulfuric acid and 5% sodium hydroxide solutions (Figure 4).

Samples of the sediment/water mixture were collected immediately after treatment (Day 0) and at 3, 9, 18, 24 and 30 days after treatment. Replicate samples were centrifuged, and each sediment sample was then extracted with methanol, 1% aqueous trifluoroacetic acid and 1% NaOH solution. Duplicate aliquots the sediment extracts and water supernatant samples were analyzed by Liquid Scintillation Counting (LSC). The extraction procedure for the sediment and water samples is shown in Figure 5.

Aliquots of the water supernatant samples and sediment extracts were analyzed by HPLC equipped with a UV (230nm) and a radioactive flow detector connected in series, for identification of metalaxyl and metabolites formed in quantities ≥ 0.01 ppm (Figures 2 and 3). Two dimensional thin-layer co-chromatography and/or mass spectral analyses were used as confirmatory analytical methods for the identification of metalaxyl and its metabolites.

The half-life of ^{14}C-metalaxyl was determined by inputting data on concentration of metalaxyl versus time into a linear regression program.

All test sediment, water supernatant samples, and trapping solutions were analyzed immediately after sampling.

STUDY AUTHOR'S DATA SUMMARY:

The material balance of the test system ranged from 89.94% to 101.33% of the applied radioactivity (Tables I and II).

^{14}C-metalaxyl metabolized with a half-life of 55.11 days (R^2 = 0.9012**) in soil + water; while the half-lives were 70.28 and 41.23 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).

Metalaxyl accounted for 95.81 % (1.46 ppm) at the start of the study and decreased to 65.36% (0.99 ppm) after 30 days post-treatment (Tables V and VI). N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine (CGA-62826) increased from 2.11% (0.03 ppm) at Day 0 to 20.56% (0.31 ppm) at 30 days after treatment. The metabolite N-(3-hydroxy-2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine (CGA-119857) was not detected in the study, while CO_2 accounted for <0.5% (0.005 ppm, Table II and IV) of the initially-applied radioactivity. No other volatile compounds were formed during the study period. One unknown was reported to occur as a contaminant in concentrations between 0.65-1.43% (0.01-0.02 ppm) in the sediment/water samples.

REVIEWER'S COMMENTS:

1. Although the study author reported half-lives for metalaxyl in sediment and water individually, no data was provided in tabular form so that EFGWB could verify the calculations.

2. Characteristics of the test water, including pH and dissolved oxygen content, were not reported. These characteristics are needed to demonstrate that the physical, chemical and biological parameters of the pond water are within normal ranges. EFGWB generally requires this information before accepting a study. However, lack of this information in the present study probably has a minimum effect on the results since the registrants reported that they used water and sediment from a rice paddy.

   In future studies, like this one, EFGWB highly recommends that the registrants report the characteristics of the test water used.

3. EFGWB notes that in this study 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.

Metalaxyl Sha # 113501

Page_____ is not included in this copy.

Pages 56 through 71 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

__✓__ FIFRA registration data.

____ The document is a duplicate of page(s) __________.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

DATA EVALUATION RECORD

STUDY 3

CHEM 113501	Metalaxyl	§164-1

FORMULATION--12--EMULSIFIABLE CONCENTRATE (EC)

STUDY ID 41765001
LeRoy, R.L. 1990a. Terrestrial field dissipation of Ridomil 2E on bare ground. Pan-Ag Study No. EF-88-04B; ChemAlysis Study No. 80202. Unpublished study performed by Pan-Agricultural Laboratories, Inc., Madera, CA, and ChemAlysis, Inc., Laurel, MD, and submitted by Ciba-Geigy Corporation, Greensboro, NC.

DIRECT REVIEW TIME = 12

REVIEWED BY: L. Binari — TITLE: Staff Scientist

EDITED BY: K. Ferguson — TITLE: Task Leader
W. Martin — Staff Scientist

APPROVED BY: W. Spangler — TITLE: Project Manager

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APPROVED BY: R. Mahler
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TEL: 703-305-7991
SIGNATURE: Richard J. Mahler — MAY 11 1993

CONCLUSIONS:

Field Dissipation - Terrestrial

1. EFGWB concludes that 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, N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine (CGA-62826), was detected in the 0- to 6-inch soil depth at all sampling intervals. Furthermore, 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.

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2. This study provides supplemental information but is not acceptable because adequate freezer storage stability data was not provided.

3. In order for this study to partially satisfy the data requirements for a terrestrial field dissipation study, the registrant should provide the supporting storage stability data for the soil samples.

4. Resolution of the storage stability deficiency will not alter the above conclusion related to leaching of metalaxyl residues.

METHODOLOGY:

Metalaxyl (Ridomil 2E, 2 lb/gallon EC, Ciba-Geigy) was broadcast-applied once at 8 lb ai/A to three plots (each 15 x 80 feet) of loamy sand soil (82% sand, 11% silt, 7% clay, 0.4% organic matter, pH 6.3, CEC 2.6 meq/100 g) located in Madera, California, on May 5, 1988. The plots were disked and smoothed 1 month prior to treatment; a 15-foot buffer zone separated each treated plot. An untreated plot (15 x 80 feet) was maintained as a control; a 280-foot buffer zone separated the treated and untreated plots. Five soil samples (0- to 48-inch depth) were collected from each plot prior to treatment; at 1 hour posttreatment; at 1, 7, 14, 29 days; and at 2, 3, 6, 9, 12, 15, 18, 24, and 27 months posttreatment using excavation and coring techniques. Through 29 days posttreatment, samples from the 0- to 6-inch soil layer were collected using a can excavation technique; a metal can with the top and bottom removed was inserted into the soil, and all of the soil within the can was scooped out to a depth of 6 inches. Then, the deeper soil layers were collected by placing a hydraulic zero-contamination soil probe (2-inch diameter) through the excavated casing to remove a 6- to 48-inch core. At sampling intervals after 29 days posttreatment, 0- to 48-inch soil cores were collected using the hydraulic probe only. Soil samples were divided into 0- to 6-, 6- to 12-, 12- to 18-, 18- to 24-, 24- to 36-, and 36- to 48-inch segments. Soil samples were composited according to plot, depth, and sampling interval. Soil samples were stored frozen for approximately 3 to 9 months prior to extraction; extracts were stored for up to 242 days prior to analysis.

Prior to analysis, composited samples were thawed, air-dried overnight, and homogenized by hand-mixing. Subsamples (50 g) were extracted three times with methanol:water (1:1, v:v) for 5 minutes. Extracts were separated from the soil by centrifugation, filtered, and combined. Following the addition of saturated NaCl solution and 1 N HCl, the extract was partitioned three times with methylene chloride:ethyl acetate (1:1, v:v). Organic phases were filtered through sodium sulfate, combined, and evaporated to dryness; the residue was redissolved in methylene chloride. The methylene chloride sample was evaporated to dryness and the degradate N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine (CGA-62826) was derivatized with BF3-butanol reagent; metalaxyl was not derivatized by this method. Metalaxyl and the derivative of CGA-62826 were diluted with 0.1 M sodium phosphate (dibasic):7% sodium sulfate (1:10, v:v), then partitioned three times with hexane. Organic phases were filtered through sodium sulfate, (dibasic):7% sodium sulfate (1:10, v:v), then partitioned three times with hexane. Organic phases were filtered through sodium sulfate, combined, and evaporated to dryness. The residue was redissolved in isooctane and analyzed for metalaxyl and the butyl ester derivative of CGA-62826 using capillary column GC with N/P detection; the detection limit for both metalaxyl and CGA-62826 was 0.02 ppm. Selected extracts were analyzed by GC/MS to confirm the presence of metalaxyl and CGA-62826. Recovery efficiencies from soil samples fortified at 0.025-1.00 ppm with metalaxyl ranged from 68 to 132% (mean 100%) of the applied, and with CGA-62826 ranged from 60 to 142% (mean 95%). Results were expressed on a dry soil basis and corrected for procedural recovery efficiencies of <100%.

DATA SUMMARY:

Metalaxyl dissipated with a registrant-calculated half-life of 56 days from the upper 6 inches of field plots of loamy sand soil in California following a single broadcast application of metalaxyl (Ridomil 2E, 2 lb/gallon EC) at 8 lb ai/A on May 5, 1988 (Figure 1). In the 0- to 6-inch soil depth, metalaxyl ranged from an average of 2.434 to 3.574 ppm during the initial 30 days after treatment (maximum of 3.667 ppm at 14 days) with no discernable pattern, then decreased to 0.708-0.789 ppm at 2-3 months, 0.395 ppm at 6 months, and 0.04 ppm at 12 months; metalaxyl was not detected (<0.02 ppm) at 18 months (Table I). Downward movement of metalaxyl resulted in maximum concentrations of 0.290 ppm at 3 months posttreatment in the 6- to 12-inch depth, 0.124 ppm at 3 months in the 12- to 18-inch depth, 0.037 ppm at 29 days in the 18- to 24-inch depth, 0.022 ppm at 2 months in the 24- to 36-inch depth, and 0.049 ppm at 3 months in the 36- to 48-inch depth (Tables II-VI).

In the 0- to 6-inch soil depth, the degradate

N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine (CGA-62826)

increased to an average of 0.647 ppm (maximum 1.649 ppm) at 1 day posttreatment; ranged from 0.077 to 0.138 ppm between 7 days and 6 months; and was <0.021 ppm (detection limit) at 9 months, 0.037 ppm at 12 months, and 0.025 ppm at 18 months (Table VII). At lower soil depths, CGA-62826 was detected at maximums of 0.149 ppm at 2 months posttreatment in the 6- to 12-inch depth, 0.176 ppm at 3 months in the 12- to 18-inch depth, 0.125 ppm at 3 months in the 18- to 24-inch depth, 0.092 ppm at 9 months in the 24- to 36-inch depth, and 0.089 ppm at 9 months in the 36- to 48-inch depth (Tables VIII-XII).

The dissipation of metalaxyl from the 0- to 6-inch soil layer and downward movement of metalaxyl and CGA-62826 into the lower soil depths correlated with irrigation events. No irrigation water was applied to the treated plots during the initial 30 days after treatment, then the plots were irrigated with 18.43 inches of water between 31 and 60 days posttreatment (11.97 inches on day 46), 15.39 inches between 61 and 90 days, and 35.72 inches between 91 and 182 days; respective sampling intervals after 29 days were at 61, 91, and 183 days (2, 3, and 6 months) posttreatment (Table XIII). During the study (5/5/88-8/8/90), rainfall plus irrigation totaled 129 inches, air temperatures ranged from 23 to 108 F, and soil temperatures at the 2-inch depth ranged from 35 to 122 F and at the 8-inch depth ranged from 39 to 123 F.

REVIEWERS' COMMENTS:

1. Adequate freezer storage stability data were not provided. In a storage stability experiment, loamy sand soil was fortified with metalaxyl and CGA-62826 at 0.5 ppm, then stored frozen for up to 6 months. Metalaxyl comprised 109-124% of the applied after 3 months of storage and 82-87% after 6 months; CGA-62826 comprised 90-106% and 69-86%, respectively (Table XV). The results indicate that degradation may have occurred during storage. However, there were not enough storage sampling intervals or spiked soil samples at each interval for the results to be conclusive; only two soil samples were spiked for each storage interval. The study author reported that the 6-month stability experiment was adequate to cover the holding times for the samples in this study. However, using dates of extraction and analysis provided in Table XVI, the reviewer determined that soil samples were stored up to approximately 9 months prior to extraction, then extracts were stored up to an additional 8 months (242 days) prior to analysis. In the 0- to 6-inch soil samples, CGA-62826 was detected at 0.103-0.173 ppm at day 0 posttreatment and 0.103-1.649 ppm at 1 day indicating that degradation may have occurred during storage; those soil samples were stored 136-137 days prior to extraction and the extracts were stored an additional 43-44 days prior to analysis. Storage stability studies for metalaxyl and CGA-62826 must be conducted for the maximum length of time that soil samples were stored prior to extraction and analysis. In addition, the registrant must demonstrate that metalaxyl and CGA-62826 were stable in the soil extracts for the maximum length of time that the extracts were stored prior to analysis.

   At approximately 16 months posttreatment, three soil samples (50 g) each were fortified with metalaxyl or CGA-62826 at 0.1 ppm in the field, then analyzed after 8 months of storage; recoveries of metalaxyl ranged from 86 to 102% of the applied and of CGA-62826 ranged from 122 to 136%. However, the field spike samples were shipped from the field facility to the analytical laboratory after only 4 days of storage, whereas, the Pesticide Residue Sample History Sheets indicate that the field test samples were stored at the field facility for 10-34 days prior to shipment to the analytical laboratory. In addition, the shipping period for the 0- to 29-day soil samples was only 1-2 days, but was 14-23 days for the 2- to 18-month samples. The shipping period for the field spike samples could not be determined because the Pesticide Residue Sample History Sheet for the field spike samples was incomplete. Therefore, the results from the field spike samples may not be relevant to the field test samples, because they were not handled similarly. According to the Pesticide Residue Sample History Sheet, four soil samples were spiked with metalaxyl and four samples were spiked with CGA-62826, but results were provided for only three out of the four field spike samples for each compound.

2. Recovery efficiencies from soil samples fortified at 0.025-1.00 ppm with metalaxyl ranged from 68 to 132% (mean 100.1 ± 13.4%) of the applied and with CGA-62826 ranged from 60 to 142% (mean 95.4 ± 16.1%). It is preferred that recovery efficiencies be in the range of 70 to 120% of the applied. Although the recovery efficiencies in this study exceeded the 70 to 120% range, it appears that the majority of the recovery efficiencies were within that range. The study author presented mean recovery efficiencies for metalaxyl and CGA-62826 from fortified soil samples according to soil depth. There did not appear to be any significant differences in the mean recovery efficiencies from the various soil depths; therefore, the Dynamac reviewer calculated overall mean recovery efficiencies for extracting metalaxyl and CGA-62826 from fortified soil samples using the data presented in Table XVII.

3. Petri dishes were used to determine the amount of spray solution that intercepted the soil. Three 3 1/2-inch diameter glass Petri dishes were placed in each plot prior to treatment. Immediately posttreatment, the Petri dishes were collected, covered, sealed with tape, then frozen until shipped 27 days after collection to the analytical laboratory for analysis; the length of time between collection and analysis was not reported. The analytical laboratory reported that 1.910-3.769 mg of metalaxyl was detected in the Petri dishes (Table XVIII). With an application rate of 8.0 lb ai/A (5.557 mg ai/dish), an average of 47% (range 34.4 to 67.8%) of the theoretical was applied to the treated plots.

4. The spray solution was sampled from the tank following treatment, but results from analysis of the sprayate samples were not reported.

5. The test soil collected in 1-foot increments to a depth of 4 feet was characterized by A&L Western Agricultural Laboratories as a loamy sand at each depth (Table XIX); the study author reported the soil series as Hanford sandy loam.

6. There was no slope to the field in the area of the test plots. The depth to the water table was 95 feet; it was reported that no subsurface drainage system existed at the test site.

7. Prior to this study, the test site had been fallow for 3 years with no chemical application during that period.

8. During the study, the test site also received one application of paraquat (5/19/88) and four applications of glyphosate (6/30/88, 7/18/88, 11/22/88, and 3/15/89).

9. Soil samples collected at 24 and 27 months posttreatment were not analyzed.

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Metalaxyl Sha # 113501

Page_____ is not included in this copy.

Pages 79 through 146 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

DATA EVALUATION RECORD

STUDY 4

CHEM 113501 Metalaxyl §164-1

FORMULATION--12--EMULSIFIABLE CONCENTRATE (EC)

STUDY ID 41809301
LeRoy, R.L. 1990b. Terrestrial field dissipation of Ridomil 2E on citrus. Pan-Ag Study No. EF-88-04A; ChemAlysis Study No. 80201. Unpublished study performed by Pan-Agricultural Laboratories, Inc., Madera, CA, and ChemAlysis, Inc., Laurel, MD, and submitted by Ciba-Geigy Corporation, Greensboro, NC.

DIRECT REVIEW TIME = 12

REVIEWED BY: L. Binari TITLE: Staff Scientist

EDITED BY: K. Ferguson TITLE: Task Leader
W. Martin Staff Scientist

APPROVED BY: W. Spangler TITLE: Project Manager

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APPROVED BY: R. Mahler
TITLE: Hydrologist
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TEL: 703-305-7991

SIGNATURE: Richard J. Mahler MAY 11 1993

CONCLUSIONS:

Field Dissipation - Terrestrial

1. EFGWB concludes that 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, N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine (CGA-62826), was detected in the 0- to 6-inch soil depth at most sampling intervals. Furthermore, metalaxyl leached to the 24- to 36-inch soil depth and CGA-62826 leached to the 36- to 48-inch soil depth.

2. This study provides supplemental information but is not acceptable because adequate freezer storage stability data was not provided.

3. In order for this study to partially satisfy the data requirements for terrestrial field dissipation uses, the registrant must provide the supporting storage stability data for the soil samples.

4. Resolution of the storage stability deficiency will not alter the above conclusion related to leaching of metalaxyl residues.

METHODOLOGY:

Metalaxyl (Ridomil 2E, 2 lb/gallon EC, Ciba-Geigy) was broadcast-applied three times at 4.4 lb ai/A/application at 3-month intervals to three plots (each 20 x 108 feet) of tree seedlings planted in sandy loam soil (72% sand, 23% silt, 5% clay, 0.4% organic matter, pH 6.3, CEC 3.3 meq/100 g) located in Madera, California, between May 5 and November 4, 1988. The treated plots were established in an orchard that had been planted to young citrus (type and age of trees were not specified) in early spring (date not specified); the berm of a tree row separated each treated plot. An untreated plot (20 x 108 feet) was maintained as a control; a 371-foot buffer zone separated the treated and untreated plots. Five soil samples (0- to 48-inch depth) were collected from each plot just prior to and 0, 1, 7, 14, 29, 61, and 91 days after the first application; at 0, 14, 28, and 90 days after the second application; and at 0, 1, 3, 7, 14, 28, 61, 95, 181, 272, 367, 458, and 546 days after the third (and final) application using excavation and coring techniques. At all sampling intervals through 28 days after the third application, samples from the 0- to 6-inch soil layer were collected using a can excavation technique; a metal can with the top and bottom removed was inserted into the soil and all of the soil within the can was scooped out to a depth of 6 inches. Then, the deeper soil layers were collected by placing a hydraulic zero-contamination soil probe (2-inch diameter) through the excavated casing to remove a 6- to 48-inch core. At all sampling intervals after 28 days following the third application, 0- to 48-inch soil cores were taken using the hydraulic probe only. Soil samples were divided into 0- to 6-, 6- to 12-, 12- to 18-, 18- to 24-, 24- to 36-, and 36- to 48-inch segments. Soil samples were composited according to plot, depth, and sampling interval. Soil samples were stored frozen between 14 and 349 days prior to extraction; extracts were stored for up to 166 days prior to analysis.

Prior to analysis, composited samples were thawed, air-dried overnight, and homogenized by hand-mixing. Subsamples (50 g) were extracted three times with methanol:water (1:1, v:v) for 5 minutes. Extracts were separated from the soil by centrifugation, filtered, and combined. Following the addition of saturated NaCl solution and 1 N HCl, the extract was partitioned three times with methylene chloride:ethyl acetate (1:1, v:v). Organic phases were filtered through sodium sulfate, combined, and evaporated to dryness; the residue was redissolved in methylene chloride. The methylene chloride sample was evaporated to dryness and the degradate, N-(2,6-dimethylphenyl)-N-redissolved in methylene chloride. The methylene chloride sample was evaporated to dryness and the degradate, N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine (CGA-62826), was derivatized with BF3-butanol reagent; metalaxyl was not derivatized by this method. Metalaxyl and the derivative of CGA-62826 were diluted with 0.1 M sodium phosphate (dibasic):7% sodium sulfate (1:10, v:v), then partitioned three times with hexane. Organic phases were filtered through sodium sulfate, combined, and evaporated to dryness. The residue was redissolved in isooctane and analyzed for metalaxyl and the butyl ester derivative of CGA-62826 using capillary column GC with N/P detection; the detection limit for metalaxyl and CGA-62826 was 0.02 ppm. Selected extracts were analyzed by GC/MS to confirm the presence of metalaxyl and CGA-62826. Recovery efficiencies from soil samples fortified at 0.025-1.00 ppm with metalaxyl ranged from 61 to 134% (mean 96%) of the applied, and with CGA-62826 ranged from 56 to 138% (mean 96%). Results were expressed on a dry soil basis and corrected for procedural recovery efficiencies of <100%.

DATA SUMMARY:

Metalaxyl dissipated with a registrant-calculated 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/application (13.2 lb ai/A total) between May and November, 1988. In the 0- to 6-inch soil depth, metalaxyl increased from an average of 0.719-1.096 ppm at 0-1 days after the third application to an average of 2.066 ppm (maximum 2.216 ppm) at 14 days, then decreased to 1.016 ppm at 28 days, 0.385 ppm at 3 months, and 0.103 ppm at 6 months; metalaxyl was not detected (<0.02 ppm) at 9-18 months (Table I). Downward movement of metalaxyl resulted in maximum concentrations of 0.451 ppm at 28 days after the second application in the 6- to 12-inch depth, 0.212 ppm at 3 days after the third application in the 12- to 18-inch depth, 0.057 ppm at 2 months after the third application in the 18- to 24-inch depth, 0.155 ppm at 14 days after the first application in the 24- to 36-inch depth, and 0.021 ppm at 14 days after the first application in the 36- to 48-inch depth (Tables II-VI).

In the 0- to 6-inch soil depth, the degradate

N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine (CGA-62826)

increased to an average of 1.948 ppm (maximum 2.586 ppm) at 28 days after the third application, then decreased to 0.756 ppm at 2 months and 0.305 ppm at 3 months, ranged from <0.021 (detection limit) to 0.132 ppm between 6 and 15 months, and was <0.021 ppm at 18 months (Table VII). At lower soil depths, CGA-62826 was detected at maximums of 1.338 ppm at 2 months after the third application in the 6- to 12-inch depth, 0.544 ppm at 2 months after the third application in the 12- to 18-inch depth, 0.308 ppm at 2 months after the third application in the 18- to 24-inch depth, 0.199 ppm at 3 months after the third application in the 24- to

36-inch depth, and 0.112 ppm at 3 months after the third application in the 36- to 48-inch depth (Tables VIII-XII).

During the study (5/5/88-5/4/90), rainfall plus irrigation totaled 64.7 inches, air temperatures ranged from 23 to 106 F, and soil temperatures at the 2-inch depth ranged from 35 to 119 F and at the 8-inch depth ranged from 39 to 123 F.

REVIEWERS' COMMENTS:

1. Adequate freezer storage stability data were not provided. In a storage stability experiment, sandy loam soil was fortified with metalaxyl and CGA-62826 at 0.5 ppm, then stored frozen for up to 6 months. After 3 and 6 months of storage, metalaxyl comprised 94-122% of the applied and CGA-62826 comprised 93-117%, indicating that metalaxyl and CGA-62826 are stable in soil frozen for up to 6 months (Table XIII). However, there were not enough storage sampling intervals or spiked soil samples at each interval for the results to be conclusive; only two soil samples were spiked for each storage interval. The study author reported that the 6-month stability experiment was adequate to cover the holding times for the samples in this study. However, using dates of extraction and analysis provided in Table XIV, the Dynamac reviewer determined that soil samples were stored up to 349 days (11.6 months) prior to extraction, then extracts were stored up to an additional 166 days (5.5 months) prior to analysis. In the 0- to 6-inch soil samples, CGA-62826 was detected at 0.083-0.101 ppm at day 0 and 0.091-0.160 ppm at 1 day after the first application, indicating that degradation may have occurred during storage; those soil samples were stored 159-160 days prior to extraction and the extracts were stored an additional 83-85 days prior to analysis. Storage stability studies for metalaxyl and CGA-62826 must be conducted for the maximum length of time that soil samples were stored prior to extraction and analysis. In addition, the registrant must demonstrate that metalaxyl and CGA-62826 were stable in the soil extracts for the maximum length of time that the extracts were stored prior to analysis.

   Fortified field spikes were prepared and analyzed for the bareground terrestrial field dissipation study also conducted by Pan-Agricultural Laboratories (Study 1, MRID 41765001); the results from the analysis of the field spike samples for the bareground field dissipation study were also presented in this study document. On September 14, 1989 (approximately 16 months after the first application), three soil samples (50 g) were each fortified with metalaxyl or CGA-62826 at 0.1 ppm in the field, then analyzed after 8 months of storage; recoveries of metalaxyl ranged from 86 to 102% of the applied and of CGA-62826 ranged from 122 to 136%. However, the field spike samples were shipped from the field facility to the analytical laboratory after only 4 days of storage (Pesticide Residue Sample History Sheet; Study 1, MRID 41765001), whereas, the Pesticide Residue Sample History Sheets indicate that the field test samples from this study were stored at the field facility for 3-34 days prior to shipment to the analytical laboratory. In addition, the shipping period for the field test samples ranged from

1 to 27 days; the shipping period for the field spike samples could not be determined because the Pesticide Residue Sample History Sheet for the field spike samples was incomplete. Therefore, the results from the field spike samples may not be relevant to the field test samples, because they were not handled similarly. According to the Pesticide Residue Sample History Sheet, four soil samples were spiked with metalaxyl and four samples were spiked with CGA-62826, but results were provided for only three out of the four field spike samples for each compound.

2. Recovery efficiencies from soil samples fortified at 0.025-1.00 ppm with metalaxyl ranged from 61 to 134% (mean 95.6 $\pm$ 13.8%) of the applied and with CGA-62826 ranged from 56 to 138% (mean 95.7 $\pm$ 16.4%). It is preferred that recovery efficiencies be in the range of 70 to 120% of the applied. Although the recovery efficiencies in this study exceeded the 70 to 120% range, it appears that the majority of the recovery efficiencies were within that range. The study author presented mean recovery efficiencies for metalaxyl and CGA-62826 from fortified soil samples according to soil depth. There did not appear to be any significant differences in the mean recovery efficiencies from the various soil depths; therefore, the Dynamac reviewer calculated overall mean recovery efficiencies for extracting metalaxyl and CGA-62826 from fortified soil samples using the data presented in Table XV.

3. Petri dishes were used to determine the amount of spray solution that intercepted the soil. Three 3 1/2-inch diameter glass Petri dishes were placed in each plot prior to each application. Immediately posttreatment, the Petri dishes were collected, covered, sealed with tape, then frozen until shipped 10-17 days after collection to the analytical laboratory for analysis; the length of time between collection and analysis was not reported. The analytical laboratory reported that 0.539-1.461 mg of metalaxyl was detected in the Petri dishes for the second and third applications (Table XVI). With an application rate of 4.4 lb ai/A (2.99 mg ai/dish), an average of 32% (range 18.0 to 48.9%) of the theoretical was applied to the treated plots. Results from analysis of the Petri dishes from the first application were not provided.

4. Based on the information in the Pesticide Residue Sample History Sheets, sprayate samples were collected the day of each application and shipped to the analytical laboratory within 10-27 days; however, results from analysis of the sprayate samples were not reported.

5. The test site was not adequately described. The age of the citrus trees and type were not specified. It was also not specified when the trees were planted. It was reported that the plots were smoothed on January 20, 1988, and the trees were planted in early spring prior to the first application on May 5, 1988.

6. The test soil collected in 1-foot increments to a depth of 4 feet was characterized by A&L Western Agricultural Laboratories as a sandy loam in the 0- to 12-inch depth and a loamy sand in the 12- to 24-, 24- to

36-, and 36- to 48-inch depths (Table XVII); the study author reported the soil series as Hanford sandy loam.

7. There was no slope to the field in the area of the test plots. The depth to the water table was 95 feet; it was reported that no subsurface drainage system existed at the test site.

8. Prior to this study, the test site had been fallow for 3 years with no chemical application during that period.

9. During the study, the test site also received one application of paraquat (5/19/88), two applications of glyphosate (6/30/88 and 1/18/89), and one application of carbaryl (4/24/89).

10. Soil samples collected at 21 months posttreatment were not analyzed.

Metalaxyl Sha # 113501

Page_____ is not included in this copy.

Pages 153 through 189 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

✓ FIFRA registration data.

____ The document is a duplicate of page(s) ________.

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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

DATA EVALUATION RECORD

STUDY 5

CHEM 113501 Metalaxyl §164-1

FORMULATION--12--EMULSIFIABLE CONCENTRATE (EC)

STUDY ID 41765002
Braxton, S.M., and R.M. Bird. 1991. Ridomil 2E - field dissipation - tobacco and bare soil - North Carolina. ETI Study No. 23TBBS; ChemAlysis Laboratory Project No. 80203. Unpublished study performed by Environmental Technologies Institute, Inc., Raleigh, NC, and ChemAlysis, Inc., Laurel, MD, and submitted by Ciba-Geigy Corporation, Greensboro, NC.

DIRECT REVIEW TIME = 14

REVIEWED BY: L. Binari TITLE: Staff Scientist

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W. Martin Staff Scientist

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CONCLUSIONS:

Field Dissipation - Terrestrial

1. 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, N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine (CGA-62826), was detected. Metalaxyl and CGA-62826 leached to the 36- to 48-inch soil depth; however, leaching patterns were confounded with apparent contamination during sampling.

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2. This study provides supplementary information, but is not acceptable for the following reasons:

   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.

3. Because the patterns of leaching of metalaxyl and its degradate CGA-62826 could not be accurately assessed due to an apparent problem with contamination during sampling, the problems with this study probably cannot be resolved by the submission of additional data. However, because the leaching assessment of metalaxyl and residues has been verified by data from other submitted field dissipation studies (DERs for Studies 3 and 4), this study does not have to be repeated.

METHODOLOGY:

Metalaxyl (Ridomil 2E, 2 lb/gallon EC, Ciba-Geigy) was broadcast-applied once at 4.28 lb ai/A to a bareground plot (100 x 100 feet) of loamy sand soil (80% sand, 14% silt, 6% clay, 0.8% organic matter, pH 5.4, CEC 1.5 meq/100 g) located in Maxton, North Carolina, on June 29, 1988; the plot was disked to an 8-inch depth immediately posttreatment. An adjacent plot (100 x 100 feet) was treated once with metalaxyl at 4.30 lb ai/A on June 20, 1988, disked immediately posttreatment, then planted to tobacco at 3 days posttreatment. A 15-foot buffer zone separated the bareground and cropped plots. Two untreated plots (each 50 x 84 feet) were maintained as controls; a 130-180 foot buffer zone separated the treated and untreated plots. The bareground plot was sampled prior to treatment and at 0, 2, 6, 9, 14, 30, 63, 89, 126, 203, 275, 364, 456, 534, 624, and 723 days posttreatment. The tobacco plot was sampled prior to treatment and at 0, 1, 3, 7, 12, 30, 39, 60, 73, 94, 127, 211, 270, 360, 465, 543, 633, and 732 days posttreatment. Each treated plot was divided into three subplots; five soil samples (0- to 48-inch depth) were collected per subplot (fifteen samples total) at each sampling interval using excavation and coring techniques. To collect samples from the unvegetated 0- to 6-inch soil layer, a plastic casing (4-inch diameter x 6-inch length) was inserted into the soil and the soil within the casing was removed to a depth of 6 inches. Then, a hydraulic zero-contamination soil probe (1.75-inch diameter liner) was placed in the excavated casing to remove a 6- to 48-inch core. In the tobacco plot at 0, 1, and 3 days posttreatment, 0- to 6-inch soil samples were excavated as described, then soil cores (6- to 24- and 24- to 48-inch depths) were collected using a split spoon probe mounted on a slide hammer tower rig. In the tobacco plot at 7 days posttreatment and thereafter, the hydraulic soil probe was used to collect 6- to 48-inch cores. Soil samples were divided into 0- to 6-, 6- to 12-, 12- to 18-, 18- to 24-, 24- to 36-, and 36- to 48-inch segments. Soil samples were composited according to subplot, depth, and sampling interval. Soil samples from the treated plots were stored frozen approximately 1-11 months prior to extraction; extracts of soil from the treated tobacco and bareground plots were stored for up to 82 and 207 days, respectively, prior to analysis.

Prior to analysis, composited samples were thawed, air-dried overnight, and homogenized by hand-mixing. Subsamples (50 g) were extracted three times with methanol:water (1:1, v:v) for 5 minutes. Extracts were separated from the soil by centrifugation, filtered, and combined. Following the addition of saturated NaCl solution and 1 N HCl, the extract was partitioned three times with methylene chloride:ethyl acetate (1:1, v:v). Organic phases were filtered through sodium sulfate, combined, and evaporated to dryness; the residue was redissolved in methylene chloride. The methylene chloride sample was evaporated to dryness and the degradate, N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine (CGA-62826), was derivatized with BF3-butanol reagent; metalaxyl was not derivatized by this method. Metalaxyl and the derivative of CGA-62826 were diluted with 0.1 M sodium phosphate (dibasic):7% sodium sulfate (1:10, v:v), then partitioned three times with hexane. Organic phases were filtered through sodium sulfate, combined, and evaporated to dryness. The residue was redissolved in isooctane and analyzed for metalaxyl and the butyl ester derivative of CGA-62826 using capillary column GC with N/P detection; the detection limit for both metalaxyl and CGA-62826 was 0.02 ppm. Selected extracts were analyzed by GC/MS to confirm the presence of metalaxyl and CGA-62826. Recovery efficiencies from soil samples fortified at 0.025-1.00 ppm with metalaxyl ranged from 67 to 131% (mean 98%) of the applied and with CGA-62826 ranged from 53 to 135% (mean 94%). Results were expressed on a dry soil basis and corrected for procedural recovery efficiencies of <100%.

DATA SUMMARY:

Bareground plot: Metalaxyl (CGA-48988) dissipated with a registrant-calculated half-life of 38 days ($r^2 = 0.78$) from the upper 6 inches of a bareground plot of loamy sand soil in North Carolina following a single broadcast application of metalaxyl (Ridomil 2E, 2 lb/gallon EC) at 4.28 lb ai/A on June 29, 1988 (Figure 5). In the 0- to 6-inch soil depth, metalaxyl averaged 4.642 ppm (maximum of 6.061 ppm) immediately posttreatment; ranged from 1.181 to 1.883 ppm between 2 and 14 days with no discernable pattern; decreased to 0.132 ppm at 30 days and 0.043 ppm at 60 days; and was <0.020 (detection limit) at 275-534 days (Table IV). At lower soil depths, metalaxyl was detected at maximums of 1.371 ppm at 2 days posttreatment in the 6- to 12-inch depth, 0.417 ppm at 30 days in the 12- to 18-inch depth, 0.145 ppm at 63 and 89 days in the 18- to 24-inch depth, 0.146 ppm at 89 days in the 24- to 36-inch depth, and 0.590 ppm at day 0 in the 36- to 48-inch depth (Table IX). Metalaxyl was detected in the 36- to 48-inch depth at 0 and 2 days posttreatment, indicating possible contamination during the sampling procedure.

In the 0- to 6-inch soil depth of the unvegetated plot, the degradate

N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine (CGA-62826) decreased from an average of 0.128 ppm (maximum 0.195 ppm) at day 0 posttreatment to 0.033 ppm at 2 days, increased to 0.091-0.099 ppm at 6-14 days, and was ≤0.023 ppm by 30 days (Table IX). At lower soil depths, CGA-62826 was detected at maximums of 0.203 ppm at 203 days posttreatment in the 6- to 12-inch depth, 0.266 ppm at 203 days in the 12- to 18-inch depth, 0.152 ppm at 126 days in the 18- to 24-inch depth, 0.081 ppm at 203 days in the 24- to 36-inch depth, and 0.047 ppm at 6 days in the 36- to 48-inch depth.

Vegetated plot: In an adjacent field plot of loamy sand soil that was treated with metalaxyl at 4.3 lb ai/A and planted to tobacco at 3 days posttreatment, metalaxyl dissipated with a registrant-calculated half-life of 39 days (r^2 = 0.82) from the 0- to 6-inch soil layer (Figure 2). In the 0- to 6-inch soil depth, metalaxyl decreased from an average of 2.913 ppm (maximum 3.280 ppm) at day 0 posttreatment to 0.941 ppm at 7 days; increased to 1.470 ppm at 12 days; then decreased to 0.220-0.248 ppm at 30-39 days, 0.087 ppm at 60 days, 0.028 ppm at 212 days, and <0.020 at 270-543 days (Tables I and X). At lower soil depths, metalaxyl was detected at maximums of 1.868 ppm at 3 days posttreatment in the 6- to 12-inch depth, 0.277 ppm at 39 days in the 12- to 18-inch depth, 0.120 ppm at 12 days in the 18- to 24-inch depth, 0.486 ppm at 3 days in the 24- to 36-inch depth, and 0.058 ppm at day 0 in the 36- to 48-inch depth (Table X). Metalaxyl was detected in the 12- to 18- and 36- to 48-inch depths at day 0 posttreatment and in the 24- to 36-inch depth at 3 days, indicating possible contamination during the sampling procedure.

In the 0- to 6-inch soil depth of the vegetated plot, CGA-62826 increased to an average of 0.124 ppm (maximum 0.238 ppm) at 12 days posttreatment, then decreased to 0.056 ppm at 30 days, 0.026 ppm at 60 days, and was ≤0.023 ppm by 73 days (Table X). At lower soil depths, CGA-62826 was detected at maximums of 0.104 ppm at 39 days posttreatment in the 6- to 12-inch depth, 0.178 ppm at 7 days in the 12- to 18-inch depth, 0.229 ppm at 212 days in the 18- to 24-inch depth, 1.118 ppm at 3 days in the 24- to 36-inch depth, and 0.023 ppm at 212 days in the 36- to 48-inch depth.

At the two field plots during the study (6/20/88-12/15/89), rainfall plus irrigation totaled 86.2 inches and air temperatures ranged from 14 to 107 F; soil temperature data were incomplete.

REVIEWERS' COMMENTS:

1. Although metalaxyl and its degradate CGA-62826 have been shown to leach to a depth of 36-48 inches in loamy sand and sandy loam soils in other terrestrial field dissipation studies (Studies 3 and 4, MRIDs 41765001 and 41809301), the patterns of leaching of metalaxyl and CGA-62826 in this study were confounded by an apparent problem with contamination during sampling.

   At the bareground plot, metalaxyl was detected in the 18-to 24- and 36- to 48-inch soil depths at day 0 posttreatment, in the 36- to 48-inch

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depth at 2 days, and in the 18- to 24- and 24- to 36-inch depths at 9 days, but was not detected at those depths at 14 days (Table IX). Similarly, CGA-62826 was detected in the 36- to 48-inch depth at 6, 9, and 14 days posttreatment, but was not detected in the upper 18- to 24- and 24- to 36-inch depths at the same sampling intervals. The bareground plot received 1.1 inches of rain at 1 day posttreatment, only 0.1 inches of rain from 2 to 14 days, and 4.0 inches of rain plus irrigation water between 15 and 30 days.

At the tobacco plot, metalaxyl was detected in the 6- to 12-, 12- to 18- and 36- to 48-inch depths at day 0 posttreatment, but was not detected below the 0- to 6-inch depth at 1 day; metalaxyl was also detected in the 24- to 36-inch depth at 3 days, but not in the 18- to 24-inch depth at the same sampling interval (Table X). Similarly, CGA-62826 was detected in the 6- to 12- and 12- to 18-inch depths at day 0 posttreatment, but was not detected in any soil layer at 1 day; CGA-62826 was also detected in the 24- to 36-inch depth at 3 days and 12- to 18-inch depth at 7 days, but was not detected in the soil layers directly above those depths at the same sampling intervals. The tobacco plot received 1.0 inch of rain at 2 days posttreatment, 0.2 inches at 7 days, 1.1 inches between 8 and 12 days, and 1.5 inches of rain plus irrigation water between 13 and 30 days. Metalaxyl was expected in the 6- to 12-inch soil depth at day 0 posttreatment, because the plots were disked to a depth of 8 inches immediately posttreatment.

2. Metalaxyl was detected in some soil samples collected from the treated plots prior to application, but it could not be determined if the site was contaminated prior to this study. The study author reported that there was no record of previous use of metalaxyl (Ridomil) at this site. At the bareground plot, metalaxyl was detected once at 0.025 ppm in the 6- to 12-inch soil depth, once at 0.023 ppm in the 12- to 18-inch depth, and twice at 0.049 and 0.128 ppm in the 36- to 48-inch depth in samples that were collected 23 days prior to treatment (Table IX). At the tobacco plot, metalaxyl was detected twice at 0.035 and 0.054 ppm in the 6- to 12-inch soil depth and once at 0.021 ppm in the 24- to 36-inch depth in samples that were collected at 13 days prior to treatment (Table X).

3. Adequate freezer storage stability data were not provided. In a storage stability experiment, loamy sand soil was fortified with metalaxyl and CGA-62826 at 0.5 ppm, then stored frozen for up to 6 months. After 3 and 6 months of storage, metalaxyl comprised 119-121% of the applied, and CGA-62826 comprised 89-123%, indicating that metalaxyl and CGA-62826 are stable in soil frozen for up to 6 months (Table XI). However, there were not enough storage sampling intervals or spiked soil samples at each interval for the results to be conclusive; only two soil samples were spiked for each storage interval. The study author reported that the 6-month stability experiment was adequate to cover the holding times for the samples in this study. However, using dates of extraction and analysis provided in Appendices 3 and 4, the reviewer determined that soil samples were stored up to approximately 11 months prior to extraction, then the soil extracts from the bareground plot were stored

up to an additional 7 months (207 days), and soil extracts from the tobacco plot were stored up to an additional 3 months (82 days) prior to analysis. Storage stability studies for metalaxyl and CGA-62826 must be conducted for the maximum length of time that soil samples were stored prior to extraction and analysis. In addition, the registrant must demonstrate that metalaxyl and CGA-62826 were stable in the soil extracts for the maximum length of time that the extracts were stored prior to analysis.

4. Concentrations of CGA-62826 in Tables II and V of the study text were calculated in terms of parent equivalents, whereas, the concentrations of CGA-62826 in Tables IX and X were not.

5. Recovery efficiencies from soil samples fortified at 0.025-1.00 ppm with metalaxyl ranged from 67 to 131% (mean 97.9 ± 12.7%) of the applied, and with CGA-62826 ranged from 53 to 135% (mean 94.2 ± 17.2%). It is preferred that recovery efficiencies be in the range of 70 to 120% of the applied. Although the recovery efficiencies in this study exceeded the 70 to 120% range, it appears that the majority of the recovery efficiencies were within that range. The author of the analytical reports presented mean recovery efficiencies for metalaxyl and CGA-62826 from fortified soil samples according to soil depth. There did not appear to be any significant differences in the mean recovery efficiencies based on soil depths. Therefore, the reviewer calculated overall mean recovery efficiencies for extracting metalaxyl and CGA-62826 from fortified soil samples using the data from Tables XII and XIII.

   At approximately 15 months posttreatment, three soil samples (50 g) were each fortified with metalaxyl or CGA-62826 at 0.1 ppm in the field, then analyzed after 8 months of storage; recoveries of metalaxyl ranged from 77 to 100% of the applied and CGA-62826 ranged from 88 to 101% (Table XIV). However, the field spike samples were shipped overnight via Federal Express, whereas, the field test samples were shipped via ACDS freezer truck. According to Protocol Deviation No. 8 (Appendix 1), soil samples collected within the first month after treatment were to be shipped via overnight express, but were mistakenly shipped via freezer truck. According to the Sample Shipping Summaries, it took <1 to 11 days to ship the soil samples from the field facility to the analytical laboratory. Therefore, the results from the field spike samples may not be relevant to the field test samples, because they were not handled similarly. According to the Field Spiking Instructions, four soil samples were spiked with metalaxyl and four samples were spiked with CGA-62826, but results were provided for only three out of the four field spike samples for each compound.

6. Petri dishes were used to determine the amount of spray solution that intercepted the soil. Fifteen 9.0-cm diameter glass Petri dishes were placed in each treated plot (five dishes per subplot) plus one dish in each untreated plot prior to application. Immediately posttreatment, the Petri dishes were collected, covered, sealed with parafilm, then frozen until shipped to the analytical laboratory for analysis. The

analytical laboratory reported that 0.775-3.214 mg (1.09-4.51 lb ai/A) metalaxyl was detected in the Petri dishes from the bareground plot and 0.325-1.240 mg (0.456-1.74 lb ai/A) metalaxyl was detected in the dishes from the tobacco plot (Tables VII and VIII). With an application rate of 4.28 lb ai/A to the bareground plot, an average of 58.4% (range 25.5 to 105.4%) of the theoretical was applied to the treated plot. With an application rate of 4.30 lb ai/A to the tobacco plot, an average of 20.7% (range 10.6 to 40.5%) of the theoretical was applied to the treated plot. According to the Sample Shipping Summaries, the Petri dishes from the bareground plot were shipped 1 day after collection and the shipping time was only 1 day, but the Petri dishes collected from the tobacco plot were shipped 4 days after collection and shipping took an additional 5 days; the length of time between arrival at the analytical laboratory and analysis of the petri dishes was not reported.

The application rate of 4.28-4.30 lb ai/A would be expected to result in approximately 2.14-2.15 ppm in the 0- to 6-inch soil layer; in the 0- to 6-inch soil depth at day 0 posttreatment, concentrations of metalaxyl ranged from 2.674 to 6.061 ppm in the bareground plot and from 2.377 to 3.280 ppm in the tobacco plot.

7. The spray solution was sampled from the tank following treatment to the bareground and tobacco plots, but the results from analysis of the sprayate samples were not reported.

8. The test soil collected in 1-foot increments to a depth of 4 feet was characterized by A&L Western Agricultural Laboratories as a loamy sand in the 0- to 12-inch depth and a sandy clay loam in the 12- to 24-, 24- to 36-, and 36- to 48-inch depths (Appendix 2); the study author referred to the soil as a Wagram loamy sand.

9. The slope to the field in the area of the test plots was 0-2%. The depth to the water table was 17 feet.

10. Soil temperatures were measured only on eight to nine selected sampling intervals during the 18-month study (June 1988 to December 1989); temperatures should have been recorded daily.

11. For the 3 years prior to this study, the bareground test site had been cropped to collards (1987), cabbage plants and cowpeas (1986), and sweet potatoes (1985); the site had been treated with Dipel (1986), malathion (1986), methomyl (1986), and carbaryl-malathion mix (1986). The tobacco test site was fallow in 1987, but cropped to cabbage plants in 1986 and sweet potatoes in 1985; the site had been treated with malathion (1986).

12. During the study, the bareground plot was mowed once (7/12/88) and lightly disked four times (7/18, 8/4, 8/11, and 10/3/88); the site also received one application of glyphosate (7/25/88). The tobacco plot was mowed on 1/19/89 to destroy the crop and on 9/5/89 for the grassy groundcover. The tobacco plot received one application of acephate

(7/16/88), two applications of glyphosate (7/25 and 8/3/88), and five applications of Dipel (8/5, 8/23, 9/15, 9/22, and 10/3/88).

13. Soil samples collected at 21 and 24 months posttreatment were not analyzed.

Metalaxyl Sha # 113501

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Pages 199 through 239 are not included.

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____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

✓ FIFRA registration data.

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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

DATA EVALUATION RECORD

STUDY 6

CHEM METALAXYL 164-2

FORMULATION--00--ACTIVE INGREDIENT

STUDY MRID 422598-03
Leech, G. and T. Wiepke. 1992. Aquatic dissipation of metalaxyl (Ridomil 2E) in a California rice paddy. Pan-Agricultural Laboratories, Inc. Study No. EF-90-326, Twin City Testing Corporation Study No. 31/90-CGA.1 and Ciba-Geigy Protocol No. 91/90. Performed by Pan-Agricultural Laboratories, Inc., Madera, CA and Twin City Testing Corporation, St. Paul, MN and submitted by Ciba-Geigy Corporation, Greensboro, NC. 272 pp.

DIRECT REVIEW TIME = 5

REVIEWED BY: Richard J. Mahler, Hydrologist
Environmental Chemistry Review Section 1, EFGWB

SIGNATURE: Richard J. Mahler

DATE: MAY 11 1993

APPROVED BY: Paul J. Mastradone, Chief
Environmental Chemistry Review Section 1, EFGWB

SIGNATURE: Paul J. Mastradone

DATE: MAY 11 1993

CONCLUSIONS:

Aquatic Field Dissipation

1. EFGWB concludes that this study is scientifically valid and provides supplemental information that shows metalaxyl to dissipate from rice paddy water with a calculated half-life of 20 days and from soil with a half-life of 24 days. The study is not acceptable because:

   Soil samples containing metalaxyl and its major degradate, CGA-62826, were stored frozen for up to 259 days before analysis; however, a storage stability experiment with soil was performed for only 105 days. Therefore, the registrant will have to provide data that shows metalaxyl and CGA-62826 are stable when stored frozen for up to 259 days.

METHODOLOGY:

The field study was conducted on an Alamo clay (fine, montmorillonitic, thermic, Typic Duraquolls, Table I) at Pan-Agricultural Laboratories, Inc, Madera, CA (Figure 2) during 1990-91. Metalaxyl was applied preflood at the rate of 0.50 lb ai/A to the soil of three experimental 0.1 acre (50 feet by 100 feet) rice paddies. Rice paddy water was sampled at the day of flooding (1 day after application), and at 1, 3, 7, 14, 21, 30, 62 and 92 days after application (DAA). Sampling of the soil/hydrosoil to a depth of 12 inches occurred on the same schedule as water, except no soil samples were collected at 21 DAA, and continued after draining the field at 122, 154, 178 and 259 DAA. An untreated control plot was sampled like the treated plots.

In order to verify the application rate, 50 ml samples were collected from two tank mixes for determination of metalaxyl. In addition, four glass petri plate 9-cm bottoms were placed in each of the treated paddies just prior to application. After application the petri plates were collected and analyzed for metalaxyl. The rice plots were a closed system and water was not circulated through or between treated plots. The water levels in the plots was maintained at a depth of about 4 to 6 inches by a float valve interfaced with a water meter.

All samples were kept frozen within a temperature range of -15 to 24 °F prior to shipping and analysis. In order to determine stability of metalaxyl and CGA-62826, during transport, control soil and well-water were fortified with a known concentration of each.

Residues of metalaxyl and CGA-62826 were extracted from the acidified water with methylene chloride:ethyl acetate and concentrated to dryness. The residue was transferred to a test tube using methylene chloride, evaporated to dryness and derivatized with BF_3-butanol reagent to convert the CGA-62826 into the butyl ester derivative (Figure 1). The derivatized CGA-62826 and unreacted metalaxyl were extracted into hexane, taken to dryness, dissolved in isooctane, and analyzed by GC with a nitrogen-phosphorous detector (NPD).

Residues of metalaxyl and CGA-62826 in soil were first extracted with methanol:water and then treated as above for water samples. The limit of quantitation for both analytes was 1 and 10 ppb in water and soil, respectively.

Concentration of metalaxyl in spray solutions was determined by dilution with isooctane and analysis by GC with NPD. Determination of metalaxyl residue in the petri dishes was performed by quantitative transfer with isooctane and analysis by GC with NPD.

Method validation was accomplished by fortifying water and soil prior to sample analysis. Water samples were fortified with 1, 5, 20, 100 and 500 g/l

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of metalaxyl and CGA-62826; while soil samples were fortified with 10, 50 and 500 ng/g. Parent and degradate were analyzed as noted above.
A storage stability experiment was established by spiking well water and control soil with metalaxyl or CGA 62826 and then analyzed at storage intervals of about 1, 2 and 3 months.

When appropriate, least squares regression analysis was applied to natural log (ln) transformed residue data over time in order to determine if decline in residues followed a 1st-order degradation rate. If linear correlation values were >0.7, a 1st-order degradation rate was assumed and a half-life ($t_{½}$) was calculated.

STUDY AUTHORS' DATA SUMMARY:

All results were corrected for procedural recoveries and percent moisture, where appropriate.

Application Verification:

Metalaxyl concentration in the top 3 inches of soil on the day of application averaged 347 ppb (Table III) which is 69% of the theoretical concentration of 500 ppb. Metalaxyl concentration in the two spray solution samples averaged 2.6 g/l which is 87% of the theoretical concentration of 3 g/l (Table VI). The petri plates averaged 314 g metalaxyl/plate or 88% of the theoretical concentration of 358 g/plate (Table VII). These data, along with the documented calibration, mixing and application (Appendix D), verify the application rate of 0.5 lb ai/A.

Freezer Stability:

Recovery of metalaxyl fortified-water after 34, 62 and 97 days of freezer storage averaged 86, 86 and 90%, respectively. At the same storage intervals, the recovery of CGA-62826 averaged 108, 87 and 105%, respectively (Table 11 from Appendix B).

Recovery of metalaxyl from fortified soil stored for 33, 61 and 105 days in a freezer averaged 83, 68 and 93%, respectively; while recovery of CGA-62826 for the same intervals averaged 117, 104 and 107%, respectively (Table 12 from Appendix B).

Recoveries of water samples fortified in the field, and shipped to the laboratory by overnight carrier or freezer truck averaged ≥90% (Table 7), soil samples fortified in the field averaged 84% (overnight carrier) and 104% (freezer truck) and recoveries of CGA-62826 averaged 107% (Table 8 from Appendix B).

The study author concludes that the data supports the stability of metalaxyl and CGA-62826 in water and soil during transport to the laboratory, and subsequent freezer storage for three months. All the water samples were extracted within 20 to 70 days of sampling. Soil samples were extracted within 62 to 259 days of sampling. The study authors report that an ongoing storage stability study will be submitted at a later date to provide details on soil samples stored longer than 3 months.

Metalaxyl Residues in Water:

The results of the paddy water sample analyses are shown in Table II. Means and total residues are present in Table IV. The maximum concentration of metalaxyl in water (68 ppb) occurred at 3 DAA. Decline was thereafter rapid, with concentrations below limit of quantitation (LOQ = 1 ppb) in two paddies and at 2.6 ppb in the third paddy just before draining by evaporation. The theoretical half-life ($t_{\frac{1}{2}}$) of metalaxyl in rice paddy water was 20 days (Figure 6 and 7, r=0.82). Peak concentration of CGA-62826, averaging 5.5 to 6.4 ppb occurred in water at 3, 21 and 30 DAA. Residues declined to an average of 2.9 ppb just before drainage.

Metalaxyl Residues in Soil:

The results of the soil sample analyses are shown in Table III. Means and total residues are presented in Table V. Generally, metalaxyl was not detected at or above the LOQ (10 ppb), below the top 3 inches of soil, with the exception of a few near LOQ detections in the 3-6 and 6-9 inches depth increments on the day of application, and then 1, 3, 7 and 14 DAA. (The study authors concluded from this that residues of metalaxyl below the top 3 inches on the day of application were the result of contamination). Decline of metalaxyl in the top 3 inches of soil was rapid, with a theoretical half-life of 24 days (Figure 6 and 8, r=0.85). Residues of CGA-62826 were detected below the top 3 inches, starting 14 DAA and throughout the 0-12 inch sampling depth by 92 DAA. Residues declined in all depth increments to essentially the LOQ by 122 to 154 DAA.

Conclusions:

The overall results of this study indicate that the dissipation of metalaxyl should be fairly rapid with a $t_{\frac{1}{2}}$ = <30 days in the water plus soil of water-seeded rice in California. Some apparent mobility of CGA-62826 in the soil occurred in the study; however, the concentration found below the top 6 inches generally remained near the LOQ of 10 ppb.

REVIEWER'S COMMENTS:

1. The study authors indicated that the storage stability study is continuing and will provide details on stability of soil samples stored longer than 3 months. This additional information is needed to indicate whether the pesticide and its degradates in the soil samples from the test plots, stored longer than 3 months, are degrading during handling and storage, and if so, whether it is possible to normalize the results to account for the amount of change during storage.

2. EFGWB notes that in the anaerobic metabolism study (MRID 104494) CGA-62826 was the only major metabolite found, besides CO_2; while, nonextractable residues were 8.4% of the applied.

Metalaxyl Shaugh # 113501

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Pages 245 through 251 are not included.

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____ Identity of product inert ingredients.

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____ Description of the product manufacturing process.

____ Description of quality control procedures.

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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

DATA EVALUATION RECORD

STUDY 7

CHEM METALAXYL 164-2

FORMULATION--00--ACTIVE INGREDIENT

STUDY MRID 422598-04
Biever, R. 1992. Ridomil 2E (metalaxyl): An aquatic dissipation study for water seeded rice in Memphis, Tennessee. SLI Report No. 91-11-4013, SLI Study No. 1781-0490-6242-330 and Ciba-Geigy Corporation Protocol No. 79-90. Unpublished report performed by Springborn Laboratories, Inc. Wareham, MA and Agricenter International, Inc. Memphis, TN and Submitted by Ciba-Geigy Corporation, Greensboro, NC. 173 pp.

DIRECT REVIEW TIME = 5

REVIEWED BY: Richard J. Mahler, Hydrologist
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DATE: MAY 11 1993

APPROVED BY: Paul J. Mastradone, Chief
Environmental Chemistry Review Section 1, EFGWB

SIGNATURE: Paul J. Mastradone

DATE: MAY 11 1993

CONCLUSIONS:

Aquatic Field Dissipation

1. EFGWB concludes that this study is scientifically valid and provides supplemental information that shows metalaxyl to dissipate from rice paddy water with a calculated half-life of 5 days and from soil with a half-life of 11 days. The study is not acceptable because:

    1. Soil samples containing metalaxyl and its major degradate, CGA-62826, were stored frozen for up to 436 days before analysis; however, a storage stability experiment with soil was performed for only 180 days. Therefore, the registrant will have to provide

data that shows metalaxyl and CGA-62826 are stable when stored frozen for up to 436 days.

EFGWB notes that water samples were stored frozen for up to 158 days before analysis; however, storage stability data was provide that shows metalaxyl and CGA-62826 to be stable for up to 190 days of storage in water.

2. The registrant did not provide characteristics of the water (pH, hardness, sediment load, etc.) used in the study.

METHODOLOGY:

The field study was conducted on a Falaya silt loam (Coarse-silty, mixed, acid, thermic Aeric Fluvaquents, Table I) at Agricenter International, Inc., Memphis, TN (Figure 2) during 1990-91. Metalaxyl was applied May 29, 1990 preflood at the rate of 0.58 lb ai/A to the soil of three experimental plots 50 by 150 ft. The plots were flooded on May 31, 1990 and rice was water seeded on June 1, 1990. The water source was a 5 acre reservoir (pH 7.5-8.0) used for fish culture and maintained with well water (pH 7.0). The water was drained from the plots on September 26, 1990, 120 days after application in keeping with normal rice cultural practices. Rice paddy water was sampled at the day of flooding (2 days after application), and at 3, 4, 7, 14, 30, 60, 90 and 120 days after application (DAA). Sampling of the soil/hydrosoil to a depth of 3 to about 10 inches occurred on the same schedule as water, except soil samples were collected at DAA, and continued after draining the field at 180 and 367 DAA. An untreated control plot was sampled like the treated plots.

In order to verify the application rate, a sample was collected from the tank mix for determination of metalaxyl. In addition, filter paper spray cards (27 in^2) were placed in each of the treated paddies just prior to application. After application the filter paper spray cards were collected and analyzed for metalaxyl. The rice plots were a closed system and water was not circulated through or between treated plots. The water level in the plots was maintained at a depth of about 4 to 6 inches by addition of water from a reservoir.

All samples were kept frozen prior to shipping and analysis. In order to determine stability of metalaxyl and CGA-62826 during transport, control soil and well-water were fortified with a known concentration of each.

Residues of metalaxyl and CGA-62826 in water were extracted using solid phase extraction (SPE) columns (C_{18}) activated with methanol prior to sample addition, and then dried and extracted with acetone. The residue was evaporated to dryness and derivatized with BF_3-butanol reagent to convert the CGA-62826 into the butyl ester derivative. The derivatized CGA-62826 and unreacted metalaxyl were extracted into hexane, taken to dryness, dissolved in isooctane, and analyzed by GC with a nitrogen-phosphorous detector (NPD).

Residues of metalaxyl and CGA-62826 in soil were first extracted with methanol:water and then treated as above for water samples. The limit of

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quantitation for both analytes was 1 and 10 ppb in water and soil, respectively.

Concentration of metalaxyl in spray solutions was determined by dilution with isooctane and analysis by GC with NPD. Determination of metalaxyl residue in the petri dishes was performed by quantitative transfer with isooctane and analysis by GC with NPD.

Method validation was accomplished by fortifying water and soil prior to sample analysis. Parent and degradate were analyzed as noted above.

A storage stability experiment was established by spiking control soil with metalaxyl or CGA 62826 and then analyzing at frozen storage intervals of about 0, 1, 2, 3, 6, 9 and 12 months.

Field fortified QC control samples were prepared, stored and analyzed at the same time as the treated samples. Procedural recovery samples were analyzed at the same time as the experimental samples.

When appropriate, least squares regression analysis was applied to natural log (ln) transformed residue data over time in order to determine if decline in residues followed a 1st-order degradation rate. If linear correlation values were >0.7, a 1st-order degradation rate was assumed and a half-life ($t_{½}$) was calculated.

Rainfall and temperature data for the study were obtained from the National Weather Service station located at the site and at the Memphis International Airport.

STUDY AUTHOR'S DATA SUMMARY:

On June 4, 1990, about 1 hour after water was added to the rice plots, the levee from treated plot 3 broke. The plot was completely drained and the break repaired and the plot refilled with water on June 4, 1990. The water from the treated plots did not contaminate the control plot or the other treated plots. The scheduled sampling continued on plot 3. In addition, the remaining composited water from treated plots 1 and 2 was combined to make an extra water sample identified as treated plot 3a. Two extra soil cores were collected from each zone sample in treated plots 1 and 2 which were composited to make an extra soil sample identified as treated plot 3a.

The study author noted in the "PROTOCOL DEVIATIONS" section that field fortified soil QC samples from 30 DAA were not analyzed because of the variable results from the other field fortified soil and water QC samples.

Procedural recovery samples for water and soil were considered acceptable if their recovery was within the range of 70-120% of the fortified concentration. The average recovery from the procedural recovery samples was used as a correction on measured concentration of test materials only when the average recovery was <100%.

Results of the water procedural recovery samples for metalaxyl are presented in Table 24 (99% ± 23%, N=20), and for CGA-62826 in Table 25 (89% ± 23%, N=20). Soil procedural recovery samples for metalaxyl are presented in Table 26 (93% ± 14%, and results for CGA-62826 are presented in Table 27 (88% ± 18%).

Recoveries of metalaxyl and CGA-62826 added to water and soil samples at the field site were variable (Table 11, 12, 13 and 14). The recoveries for metalaxyl and CGA-62826 in water ranged, respectively, from 65 to 107% and 69-129%; while recoveries for metalaxyl and CGA-62826 added to soil ranged, respectively, from 68 to 115% and 81 to 95%. The author stated that the range of recoveries should not be interpreted as being necessarily representative of the stability of both analytes during shipping by overnight transport and subsequent freezer storage at the lab before extraction. Problems with quantitatively transferring spike solution from glass ampules to control water and soil samples were noted during the field spiking process.

Mean percent recovery for metalaxyl (Table 7) and CGA-62826 (Table 8) fortified water stored for up to 190 days varied from 79-109% and 72 to 120%, respectively. Mean percent recovery for metalaxyl (Table 9) and CGA-62826 (Table 10) fortified soil stored for up to 198 days varied from 61-106% and 72 to 131%, respectively.

Mean percent recovery for metalaxyl fortified water and soil in the simulated transport experiment was 76% and 95%, respectively. Mean percent recovery for CGA-62826 fortified water and soil in the simulated transport experiment was 93% and 83%, respectively (Table 15).

Metalaxyl concentration in the top 3 inches of soil on the day of application averaged 794 ± 156 ug/kg (Table 34), or 150% of the theoretical expected concentration of 527 ug/kg. The filter papers averaged 813 ± 61 ug/paper, or 79% of the theoretical amount expected (1027 ug/filter paper, Table 5). Metalaxyl concentration in the tank mix sample was determined to be 1.44 g/l, which is 43% of the theoretical expected concentration of 3.36 g/l. The study author reports that the result from the tank mix was highly suspect, since metalaxyl recovered from the filter papers, and the concentration found in the soil on the day of application support the application at the intended rate.

The maximum concentration of metalaxyl in the rice paddy water, 150 ug/l, occurred on the day of flooding (2 DAA, Table 1). Decline was rapid after this time, with concentrations below the LOQ (1 ug/l) in all three replications by 60 DAA. The theoretical half-life of metalaxyl in the water was 5 days (r = -0.096, Figure 5). Peak concentrations of CGA-62826 (Table 1), in the water, 1.9 to 5.9 ug/l, also occurred on the day of flooding, and by 30 DAA the residues had declined to below the LOQ (1 ug/l). Residues remained below the LOQ on 60, 90 and 120 DAA except for a detection of 1.86 ug/l in plot 1 at 120 DAA.

Residues of metalaxyl and CGA-62826 were found throughout the 0-9 inch soil sampling depth by 7 DAA (Table 2). Dissipation of metalaxyl in the top 3 inches of soil was rapid, with a half-life of 11 days (r=-0.91, Figure 6). Parent and metabolite soil residues declined to below the LOQ (10 ug/kg) by 90

DAA. Residues remained below the LOQ on 120, 181 and 367 DAA except for a reported result from plot 3a which was slightly above the LOQ on 120 DAA (15.2 ug/kg).

REVIEWER'S COMMENTS:

1. The study authors indicated that the storage stability study is continuing and will provide details on stability of soil samples stored longer than 3 months. This additional information is needed to indicate whether the pesticide and its degradates in the soil samples from the test plots, stored longer than 6 months, are degrading during handling and storage, and if so, whether it is possible to normalize the results to account for the amount of change during storage.

2. Characteristics of the test water, including pH and dissolved oxygen content, were not reported. These characteristics are needed to demonstrate that the physical, chemical and biological parameters of the pond water are within normal ranges.

Metalaxyl Sha # 113501

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Pages 288 through 318 are not included.

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____ Identity of product impurities.

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____ Description of quality control procedures.

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____ The product confidential statement of formula.

____ Information about a pending registration action.

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DATA EVALUATION RECORD

STUDY 8

CHEM	METALAXYL	165-1

FORMULATION--00--ACTIVE INGREDIENT

STUDY MRID 421965-01
McFarland, J. 1992. Uptake and metabolism of Metalaxyl in greenhouse rotational crops following target tobacco grown in soil treated with [phenyl-^{14}C]-metalaxyl. Laboratory Project ID ABR-91084. Unpublished study performed and submitted by Ciba-Geigy Corporation, Greensboro, NC. 272 pp.

DIRECT REVIEW TIME = 5

REVIEWED BY: Richard J. Mahler, Hydrologist
Environmental Chemistry Review Section 1, EFGWB

SIGNATURE: Richard J. Mahler

DATE: [illegible] MAY 1993

APPROVED BY: Paul J. Mastradone, Chief
Environmental Chemistry Review Section 1, EFGWB

SIGNATURE: Paul J Mastradone

DATE: [illegible] 1993

CONCLUSIONS:

Confined Accumulation in Rotational Crops

1. EFGWB concludes that this study provides acceptable data that shows metalaxyl residues are present in rotational crops (wheat, sugar beets, leaf lettuce and soybeans) planted 232 days (≈7.5 months) after treatment.

2. EFGWB notes that tolerances for residues of parent metalaxyl and all metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxy methyl-6-methyl)-*N*-(methoxyacetyl)-alanine methylester are established for more than 80 agricultural commodities (see 40 CFR §§ 180.408, 185.4000 and 186.4000). Eight of the 21 metalaxyl degradates identified

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in the rotational crops contain the moieties for which tolerances are established.

The other 13 residues, based on a preliminary cursory review by Tox Branch/HED[1], do not appear to be toxicologically significant. However, EFGWB defers to Toxicology Branch/HED for the final determination of the toxicological significance of the residues identified in the confined study that are not included in the established tolerances.

3. EFGWB notes that the concentrations of parent metalaxyl and metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxy methyl-6-methyl)-*N*-(methoxyacetyl)-alanine methylester residues in the rotational crops do not exceed the tolerances for residues as listed in 40 CFR §§ 180.408, 185.4000 and 186.4000.

METHODOLOGY:

Approximately 13 kg of a Georgia sandy soil (soil pH: water-5.3. buffer-6.5; 2.3% organic matter; 5.38 meq/100 g CEC; 90% sand, 2% clay 8% silt; 6.17% field moisture @ 1/3 bar; 1.33 g/cc bulk density) were placed into each of 28 plastic pails. Twenty pails were amended with an additional 2 kg of [phenyl-^{14}C]-metalaxyl treated soil distributed evenly on top of the 13 kg of untreated soil. All pails contained a total of 15 kg of soil with a depth of 8 inches. On 9/13/89, 3 or 4 Coker 319 tobacco seedlings (41 days old) were transplanted into each pail. The mature tobacco was harvested on 4/27/90 which was 226 days after soil treatment.

James spring wheat, Giant Western 4189 sugar beets, Royal Oak leaf lettuce and Corsoy soybean seeds were planted into the pails on 5/3/90, which was 232 days after soil treatment in the same pails used for growing the tobacco. There were 5 treated and 2 control pails for each crop.

The treated and untreated control plants were separately housed in 10′ x 10′ temperature controlled greenhouse cubicles. Temperature and % relative humidity were continuously monitored throughout the test period. The average low temperatures were 70 and 72 °F and 86 and 87 °F in the treated and control cubicles, respectively, throughout the growing periods. The relative humidity ranged from 25 to 100% during the study. Overhead artificial lighting was used to supplement the natural sunlight and to extend the photoperiod to approximately 14 hours. The crops received scheduled nutrient and pesticide application as needed.

Crop maintenance and major actions, including plant and soil sampling, taken during the course of the study are listed in Table IA. Soil samples were taken with a Hoffler coring tool. The soils were collected from the treated and control soils on the day of treatment, at 34, 170 days and at maturity of the target tobacco crop (226 days after treatment); and at the time of planting and at mature harvest of the rotational crops. The soil samples were

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[1]Personal communication with John Whalan on 5/6/93.

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divided in 0-3", 3-6" and 6-8" segments. All samples were frozen immediately after collection at -20 °C and stored prior to analysis.

Soil moisture was determined by the difference in weight before and after drying about 2 g soil using a Max 50 moisture analyzer.

Triplicate aliquots (≈2 g) of soil samples and quadruplicate (≈0.2 g) of plant samples were combusted in a Harvey Oxidizer. Combustion efficiencies were obtained using control plant or soil samples fortified with known quantities of ^{14}-C-mannitol. Radioassays were performed by liquid scintillation using Oxosol^{14}-C scintillation cocktail.

Normal phase one-dimensional (1D) or two-dimensional (2D) thinlayer chromatography (TLC) separations on a stationary phase of silica gel were performed on 20 x 20 cm precoated 250 m silica gel plates using 5 mobile phases. Radioactive zones were detected using Ambis Radioanalytic Imaging System or Beta Emission Radio Thin Layer Analyzer and were recorded on film. Quantitation of the radioactive zones was conducted by the Ambis Radioanalytic Imaging System. Results were normalized to 100% recovery.

Reversed phase 2D-TLC separations were performed on 20 x 20 cm precoated 250 m reversed phase F plates in saturated chambers using 2 mobile phases.

Twenty two HPLC solvent systems were used in the characterization, isolation and identification of metabolites in the rotational study. Quantitation of radioactive metabolites separate by HPLC was achieved by collecting 0.5 minute fractions and assaying for radioactivity after the addition of 5 ml of Ready-Safe scintillation cocktail.

The flow diagram for the general procedures used to extract and characterize metalaxyl metabolites in soil samples is shown in Figure 2; while Figures 4-9 show the flow diagrams for the procedures used to characterize metalaxyl metabolites in the rotational crops.

DATA SUMMARY:

Concentration of metalaxyl and CGA-62826 at the time of planting the target tobacco crop were 4.21 and 0.051 ppm, respectively. Residues in the 0-3" soil depth at the time of the rotational crop planting (Tables IV and VI) were 1.05 ppm and the major extractable residues were metalaxyl (0.18 ppm) and CGA-62826 (0.10 ppm); while in the 6-8" depth the concentrations were 0.089 ppm and 0.084 ppm , respectively, for metalaxyl and CGA-62826. Concentration of metalaxyl and CGA-62826 in the 0-3" depth at the soybean harvest were, respectively, 0.093 and 0.066 ppm.

Total radioactive residues (TRR) in the rotational crops at maturity (Table X) were 0.275 ppm (0.009 ppm parent metalaxyl, 0.015 CGA-62826, Table XV) in sugar beet roots, 0.564 ppm (0.134 ppm parent, <0.008 ppm CGA-62826, Table XVI) in lettuce, 7.171 ppm (0.007 ppm parent, 0.05 ppm CGA-62826, Table XVII) in spring wheat stalks and 3.612 ppm (concentration of parent and CGA-62826 not quantified) in soybean stalks. Total radioactive residues in mature soybeans and wheat grain were 0.398 and 0.593 ppm, respectively.

The identification of the residues was determined for lettuce, wheat and sugar beets (Tables XII to XXII). A total of 79% of the TRR in mature spring wheat stalks, 91% in the 50% mature lettuce and 57 % TRR in beet roots was characterized and/or identified.

Seven intact glucose conjugates were isolated from the rotational crops and identified by mass spectral analyses. One conjugate was also analyzed by NMR. Other metabolites were identified by analysis of enzyme/hydrolysis products, cochromatography with standards, comparison to standards and/or cochromatography and comparison to metabolites isolated from animals.

The metabolism of [phenyl-^{14}C-metalaxyl which resulted in the identification of 14 metabolites and 9 glucose conjugates of metalaxyl in the rotational crops is summarized in Table XXII. A comprehensive pathway of the metabolism of metalaxyl in rotational crops is presented in Figure 62. The chemical names and structures are presented in Figure 1.

REVIEWER'S COMMENTS:

1. In this confined accumulation study, soil and plant tissue samples were frozen immediately after collection and placed into storage. Generally, a storage stability test needs to be performed in order to determine whether metalaxyl residues in the samples degraded during handling and storage, and if so, whether it is possible to normalize the results to account for the amount of change during storage.

   No data was presented relating to the freezer stability of the rotational crops. However, data from studies submitted to Chemistry Support Branch I/HED (memo dated 12/18/91 from Lascola to PM-21, PP#0F3893, CBTS #8898, DP Barcode D171050) indicates that metalaxyl residues; in plant material stored for up to 12 months, are generally stable; or the data show a limited decline and a correction factor can be used to normalize the data.

   A previously submitted soil freezer storage stability study (MRID 40985401) was reviewed May 14, 1990 (See DER for Study 5, EFGWB # 90-0350) showed that metalaxyl and residues in soil were stable when stored frozen for up to 7 months.

2. EFGWB notes that only the 0-3" and 6-8" soil samples at the rotational crop planting and at the mature crop harvest were extracted and analyzed for residues. Apparently, the study author did not extract and/or analyze the 3-6" soil depths sampled.

Metalaxyl Sha # 113501

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____ The product confidential statement of formula.

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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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The following studies were reviewed:

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Guy, S.O. 1988a. Field dissipation study on Ridomil 5G for terrestrial uses on bareground in Hollandale, MN. Laboratory Study Number 1641-87-71-07-15B-01. Unpublished study performed by Landis Associates, Inc., Valdosta, GA, and submitted by Ciba-Geigy Corporation, Greensboro, NC. (MRID 40985401)

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McFarland, J. 1992. Uptake and metabolism of Metalaxyl in greenhouse rotational crops following target tobacco grown in soil treated with [phenyl-^{14}C]-metalaxyl. Laboratory Project ID ABR-91084. Unpublished study performed and submitted by Ciba-Geigy Corporation, Greensboro, NC. 272 pp. (MRID 421965-01)

Vithala, R. 1992. Anaerobic aquatic metabolism of ^{14}C-metalaxyl. Laboratory Project ID 005/001/007/89. Unpublished study performed by Center for Hazardous Materials Research, Pittsburgh, PA and submitted by Ciba-Geigy Corporation, Greensboro, NC. 229 pp. (MRID 422598-01)

Vithala, R. 1991. Aerobic aquatic metabolism of ^{14}C-metalaxyl. Laboratory Project ID 005/002/008/89. Unpublished study performed by Center for Hazardous Materials Research, Pittsburgh, PA and submitted by Ciba-Geigy Corporation, Greensboro, NC. 130 pp. (MRID 422598-01)

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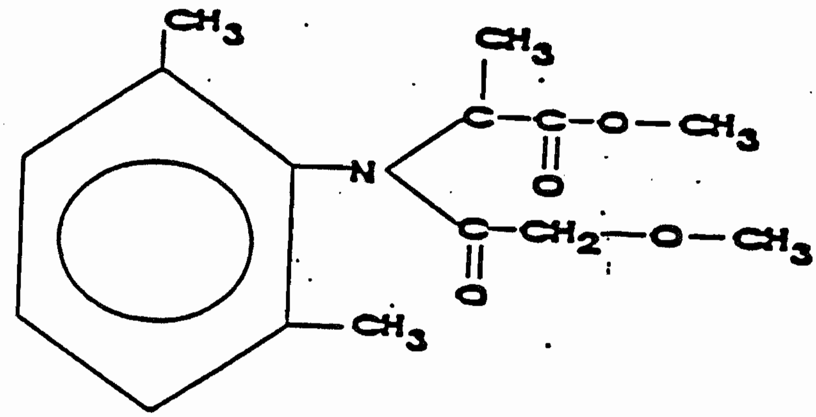
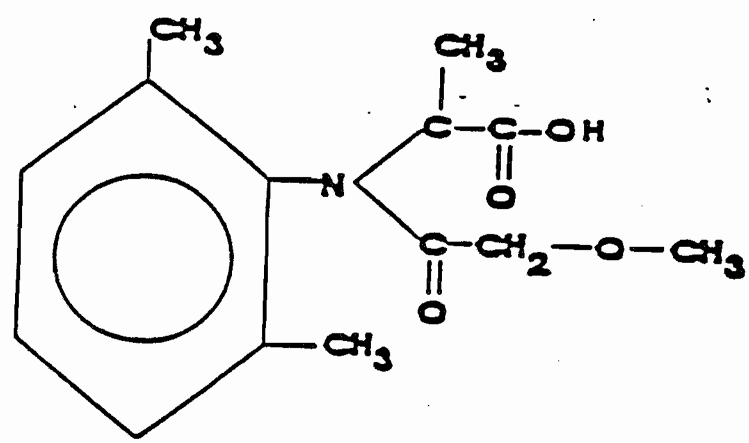
APPENDIX

METALAXYL AND ITS DEGRADATE



Methyl N-(2-methoxyacetyl)-N-(2,6-xylyl)-L-alaninate (IUPAC)

(Metalaxyl; CGA-48988)



N-(2,6-Dimethylphenyl)-N-(methoxyacetyl)-L-alanine

(CGA-62826)