Shaughnessy No.: 113501

Date Out of EFGWB: MAY 14 1990

TO: Susan Lewis
Product Manager #21
Registration Division (H7505C)

FROM: Paul Mastradone, Chief
Environmental Chemistry Review Section #1
Environmental Fate and Ground Water Branch

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

Attached please find the EFGWB review of:

Reg./File # : 100-601, 100-607, 100-629, 100-628, 8F-3695, 8H-5569, 100-627, 9F-3698

Chemical Name : Metalaxyl

Product Type : Systemic Fungicide

Product Name : Ridomil 2E, Ridomil MZ58, Ridomil 5G

Company Name : CIBA-GEIGY

Purpose : New use on alfalfa, root and tuber vegetable crop groupings, and carrots. Rotation to barley and oats. Review general correspondence, fate and ground water monitoring studies. Review lab audit findings.

Date Received : 2/28/89

Action Code: 305, 400
230, 330
354

Date Completed : 5/14/90

EFGWB No. : 90-0311-12
~~89~~ 90-0411-15
~~89~~ 90-509
90-350
90788-789
90-0519

Total Reviewing Time (decimal days): 10.0

Deferrals to :

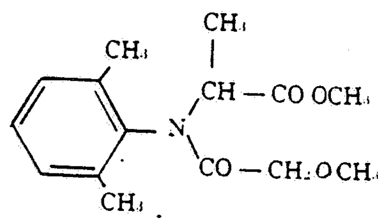
_____ Ecological Effects Branch, EFED
_____ Science Integration & Policy Staff, EFED
_____ Non-Dietary Exposure Branch, HED
XX Dietary Exposure Branch, HED
_____ Toxicology Branch, HED

1.0 CHEMICAL:

Common Name: Metalaxyl

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

Chemical Structure:



Chemical/physical properties:

molecular weight: 279.34
melting point: 71-72°C
solubility: 0.7%
vapor pressure: 2.2×10^{-6} Torr at 20°C

2.0 TEST MATERIAL: Not applicable

3.0 STUDY/ACTION TYPE:

3.1 Review amendments submitted by Ciba-Geigy requesting new uses of metalaxyl on alfalfa (100-607), root and tuber crop groupings (100-607 and carrots (100-629).

3.2 Review requests for a 14 day interval when rotating to barley (100-607) and oats (100-607).

3.3 Review requests for establishing tolerances for alfalfa, root and tuber vegetable crop groupings, barley and oats.

3.4 Review general correspondence from the registrant related to design of experiments to determine build-up potential of metalaxyl.

3.5 Review four field dissipation studies and one storage stability study submitted by the registrant.

3.6 Review ground water monitoring study.

3.7 Review lab audit findings.

4.0 STUDY IDENTIFICATION:

4.1 Three letters from Ciba-Geigy dated 9/22/89, 9/28/89 and 10/30/89 related to new uses, rotational crops and tolerances. (No MRID #)

4.2 General correspondence related to design of experimentation to determine build-up of potential of metalaxyl when used at the maximum rate over a period of several years (Letters from Henry Jacoby to CIBA-GEIGY dated November 25, 1985; Karen Stumpf to Henry Jacoby dated April 2, 1986; EAB review of "Proposal to determine metalaxyl residue carryover" dated August 28, 1986; and Karen Stumpf to Susan Lewis dated March 14, 1989; and memorandum from F. B. Suhre to Susan Lewis dated December 5, 1989). (No MRID #)

4.3 The following environmental fate studies were submitted for review, including four field dissipation and one freezer storage stability (included in the 1st study listed below):

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

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. (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. (40985404)

4.4 Ridomil Groundwater Monitoring Projects. Summary report - June 18, 1981. Report Number EIR-81007. Submitted by W. B. Nixon. Issued by Larry G. Ballantine. Prepared for Safety Evaluations

Department, Agricultural Division, Ciba-Geigy Corporation, Greensboro, NC. (No MRID or Accession Number)

4.5 GLP Inspection/Study Audit Report: Request for Regulatory Review. Memo from David L. Dull, Director LDIAD to Ferial Bishop, Chief, RSB dated January 22, 1990.

5.0 REVIEWED BY:

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

Signature: Richard J Mahler

Date: MAY 14 1990

6.0 APPROVED BY:

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

Signature: Paul J Mastradone

Date: MAY 14 1990

7.0 CONCLUSION:

7.1 NEW USES:

This appears to be a relatively minor projected increase (see BACKGROUND SECTION 9.1 discussion below).

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. The company has been requested to carry out additional monitoring studies. 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 proposed Ground Water Restricted Use Rule.

As indicated in the BACKGROUND Section 9.1, below, these new uses are projected to increase sales by around [redacted] and may significantly increase metalaxyl residues in ground water.

COMMERCIAL/FINANCIAL INFORMATION IS NOT INCLUDED

Registration division should keep this in mind during the decision making process.

7.2 ROTATION:

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 (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 allow a 14 day interval for barley and oats. Since the registrant has requested rotational crop tolerances through Dietary exposure Branch on barley and oats, EFGWB has no scientific objection to allowing the proposed rotational interval for barley and oats when the tolerances are granted.

7.3 TOLERANCES:

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

7.4 GENERAL CORRESPONDENCE:

This package was sent to EFGWB for informational purposes only. This is old correspondence which appears to be a progress report on the multicropping project with metalaxyl.

7.5 ENVIRONMENTAL FATE DATA SUBMITTED BY REGISTRANT:

At the present time, none of the four submitted field dissipation studies satisfy the data requirements for Field Dissipation For Terrestrial Uses for the following reasons:

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. An avocado crop application rate varies with the diameter of the tree canopy and can be as high as 16 lb ai/A (total permissible application of 48 lb ai/A/year).

EFGWB would like to review and have acceptable data from field dissipation studies from representative areas where the highest total application rates (i.e. 12 and 48 lb ai/A/year) are used before the field dissipation studies can satisfy the data requirements. EFGWB suggests that the registrant use representative areas in California and Florida where citrus and avocados are grown, since these are the two crops that have the highest label rates, and are generally grown in soils in which pesticides are susceptable to leaching.

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. Studies 1 and 2 related to field dissipation (See attached DERs) are scientifically valid, and may partially satisfy the data requirements if there is satisfactory resolution of the storage stability problems. 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. Studies 3 and 4 related to field dissipation (See attached DERs) 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).

7.6 GROUND WATER MONITORING STUDY:

EFGWB cannot make a complete review of this groundwater monitoring study because it is only a partial submission of the complete study. EFGWB would like the complete study summary to review.

7.7 ENVIRONMENTAL FATE REQUIREMENTS:

The following environmental fate data requirements are fulfilled:

Hydrolysis--161-1

Photolysis on soil--161-3

Aerobic soil metabolism-162-1

Anaerobic soil metabolism--162-2

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:

Field dissipation for terrestrial uses--164-1

Confined accumulation in rotational crops--165-1

Ground water monitoring and laboratory leaching studies--166-1

The following environmental fate data requirements are not required because of use pattern:

Photolysis in air--161-4

Anaerobic aquatic metabolism--162-3

Aerobic aquatic metabolism--162-4

Field volatility--163-3
Aquatic field dissipation--164-2

Forestry dissipation--164-3

Accumulation in irrigated crops--165-3

Field accumulation in aquatic non-target crops--165-5

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

The following environmental fate data is not required because of the rapid dissipation in field soils:

Long-term field dissipation--164-5

7.8 ENVIRONMENTAL FATE ASSESSMENT:

Based on a review of all studies submitted, both acceptable and unacceptable, the following 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 photolized 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.

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 parent was detected in leachate of unaged 30 cm long soil columns of sandy soils, while approximately 44 and 34% of parent was detected in the leachate of aged soil columns of a sand and silty loam soil, respectively.

Under field conditions, the fate of metalaxyl is soil is similar to that under lab conditions except for the shorter half-life of two weeks under field conditions. The major soil degradation product formed 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. Confined studies are needed to identify all residues of concern plus field tests to determine the need for additional inadvertent tolerances.

Ground water monitoring studies were determined to be inadequate. The results from a Florida test site do not address the issue of metalaxyl leaching to shallow first-encountered aquifers, but rather the possibility of leaching to deep aquifers at >200 feet. Of the 67 samples extracted, two showed positive results of 3.1 and 4.7 ppb. In addition, on test sites located in North Carolina and Oregon, two years of approximately monthly sampling from three wells at each location showed no positive results, supporting the hypothesis that metalaxyl may not be traversing off-site at these locations. However, wells were not adequately described, and water table depths described at 40 to 140 feet in Orgon are at the far end of the definition of "shallow" water tables.

Surface water monitoring in the Sacramento River, California, showed seasonal (seasonal, in this context, refers to spring, summer and fall when runoff typically transports residues of pesticide from the treated field to the surface water) concentrations of metalaxyl in two of the three years of bi-monthly sampling. In one year, 61% of seasonal samples were positive with a range of 0.97 to 3.5 ppb, while in the other year of positive results, 50% of seasonal samples showed positive (range of 0.25 to 0.43 ppb). Samples from tap water obtained from the Sacramento River showed no positive residues in three years of sampling. In conclusion, surface and ground water monitoring results from these studies were considered inconclusive and additional monitoring data are required.

7.9 REVIEW LAB AUDIT FINDINGS:

EFGWB has not received the study, to which this lab audit refers, for review. Until the study is reviewed, EFGWB cannot make reach any conclusions as to the impact of the GLP findings on the study. Registration Division should retain this report and send it along with the subject study when it submitted by the registrant. EFGWB notes that a cursory review of the report indicates that the GLP deficiencies noted by the inspector would probably have little if any effect on our conclusions about the study.

8.0 RECOMMENDATIONS:

8.1 NEW USES:

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.

In a note from Holden to Fiol dated May 25, 1989, EFGWB raised for consideration the following issue:

> Based on a brief review of existing monitoring data, metalaxyl is reaching ground water at low levels (a few ppb) in some tobacco growing areas. Metalaxyl is not known to be toxicologically significant at these levels. Because the goal of the Agricultural Chemicals in Ground Water Strategy is to minimize the contamination of ground water by agricultural chemicals, we should evaluate the significance of detections of low-level metalaxyl residues in ground water in light of the Strategy.

8.2 ROTATION:

Although not acceptable under present EFGWB guidelines, a review of submitted confined rotational crop data indicate, in some cases, the persistence of metalaxyl residues beyond 12 months in rotational crops. Since a crop rotation restriction beyond 12 months can no longer be imposed, a tolerance for the subject crops should be established through the Dietary Exposure Branch.

8.3 TOLERANCES:

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

8.4 GENERAL CORRESPONDENCE:

Since the registrant has indicated (see BACKGROUND SECTION 9.4 below) that the complete report will be submitted to the Agency within two months no further action is needed at this time on these submissions.

8.5 ENVIRONMENTAL FATE DATA SUBMITTED BY REGISTRANT:

Inform the registrant of the points indentified in the field dissipation 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 attached individual Data Evaluation Records (DER).

8.6 GROUND WATER MONITORING STUDY:

EFGWB would like to have a summary of the complete study and will provide a complete review with Data Evaluation Record when received.

8.7 REVIEW LAB AUDIT FINDINGS:

Registration Division should inform OCM that EFGWB's regulatory review of the GLP Inspection/Study Audit will be delayed until the completed study is sent for review.

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.

9.1 NEW USES:

Ciba-Geigy has pending new use permits for alfalfa, root and tuber crop grouping and carrots. According to the company these new uses (along with new uses on strawberries, blueberries, stone fruits, walnuts, almonds, and sugar beets) were projected (meeting 5/24/89) to increase current market sales by around [redacted]

COMMERCIAL/FINANCIAL INFORMATION IS NOT INCLUDED

Results of field and laboratory leaching studies indicate that both the parent and the primary degradate (CGA-62826) can leach in sand, silt-loam, and sandy-clay-loam soils (Metalaxyl Registration Standard [FRSTR], September 1988). However, results of tests indicate that metalaxyl is not oncogenic, mutagenic, or teratogenic, and that acute toxicity is low (memo: Barbehenn to Rossi, 7/17/87).

Previously, reports of metalaxyl residues in ground water have been submitted and reviewed by the Ground-Water Section of EFGWB. In their reviews, EFGWB requested more detailed information about the reports (EAB # 70774, 8/5/87; EAB # 80334, 2/4/88; and EAB # 80588, 4/12/88). These requests for information were reiterated in EAB review # 80054 (5/31/88), and in a note from Eiden to Fiol (6/17/88), stating that this missing information must be submitted to EPA before an accurate evaluation of the leaching potential of metalaxyl can be made. The ground-water monitoring protocol submitted to EFGWB for review (5/4/89) does not contain this information, nor does it contain any new data that would provide supplemental information to assist in this evaluation.

9.2 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.

9.3 TOLERANCES:

CIBA-GEIGY is requesting to establish tolerances for the combined residues of metalaxyl and its metabolites in or on oat commodities, alfalfa, root and tuber vegetable crop groupings and barley.

9.4 GENERAL CORRESPONDENCE:

When tolerances for metalaxyl were established in November 1985, concern was raised by EPA that the potential carryover of residues from year to year could lead to residues of metalaxyl and its metabolites in excess of the established tolerances. Therefore, EPA requested that the registrant develop data that addresses what the build-up potential would be for residues of concern.

The registrant submitted these plans to EPA in a letter dated April 12, 1986. EFGWB approved the proposed metalaxyl double-cropping residue program in a review dated August 28, 1986. In a progress report from Karen Stumpf to Susan Lewis dated March 14, 1989, the registrant reported that most of the first year samples had been analyzed and work was beginning on the second year samples. The registrant projected a submission date for the complete study, including the second year of sampling to be January 1990.

Recent telephone conversation (March 26 and April 3, 1990) between EFGWB and the registrant indicated that the complete report would probably be finished and submitted to the Agency within two months.

9.5 ENVIRONMENTAL FATE DATA SUBMITTED BY REGISTRANT:

Registration Division has requested EFGWB review of 4 field dissipation studies and a freezer storage stability study submitted to support application for sugar beets, legume vegetables, tomatoes, head lettuce and spinach.

9.6 GROUND WATER MONITORING STUDY:

CIBA-GEIGY submitted this summary report pursuant to a telephone conversation between Henry Jacoby, EFGWB and Richard Feulner, CIBA-GEIGY (see attached letter from Richard Feulner dated May 31, 1989).

9.7 REVIEW LAB AUDIT FINDINGS:

Registration Division has requested EFGWB review lab audit findings on an ongoing field dissipation study.

10.0 DISCUSSION OF INDIVIDUAL STUDIES:

See attached reviews of the field dissipation and storage stability studies in the Data Evaluation Records.

11.0 COMPLETION OF ONE-LINER:

Not applicable

12.0 CBI APPENDIX:

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

DATA EVALUATION RECORD

STUDY 1

CHEM 113501 Metalaxyl §164-1

FORMULATION--5G-GRANULAR

STUDY ID 40985403
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.

DIRECT REVIEW TIME = 8

REVIEWED BY: J. Harlin TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
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APPROVED BY: R. Mahler
TITLE: Hydrologist
ORG: EFGWB/EFED/OPP
TEL: 557-5734

SIGNATURE: Richard J. Mahler MAY 14 1990

CONCLUSIONS:

Field Dissipation - Terrestrial--164-1

1. This study is scientifically valid but does not meet Subdivision N guidelines for the following reason:

   an adequate freezer storage stability study was not submitted to demonstrate that metalaxyl and its degradates are stable in frozen soil stored for the longest period of time that soil samples were stored frozen prior to analysis.

2. The study can only partially satisfy the data requirements because the highest rate recommended on the product label

for any crop was not used (although the highest recommended rate for tomatoes was used in this study). Citrus and avocado crops have permissible application rates of up to 4.0 and 16 lb ai/A, respectively .

2. In order for this study to be considered partially in fulfillment of the data requirements, the registrant must submit further details of the storage stability study (see Study 5 for details of what is needed before any conclusions can be reached in regards to the freezer storage stability of metalaxyl).

3. EFGWB notes that pan evaporation exceeded precipitation plus irrigation during the length of the study. Therefore, it is not unexpected that little leaching of metalaxyl occurred below the 0-6" soil depth sampled, since it is probable that little water leached below this depth either.

4. EFGWB concludes that metalaxyl, at 3 lb ai/A, probably dissipated with a half-life of 36 days in unvegetated sandy loam soil in Madera, California, that was treated with a 5% G formulation. The degradate N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine (CGA-62826) accumulated to a maximum 0.25 ppm at 30 days. Metalaxyl and CGA-62826 did not appear to leach below the 0- to 6-inch soil depth during the study.

METHODOLOGY:

Metalaxyl (Ridomil 5% G, Ciba-Geigy Corporation) was applied as a broadcast application at 3 lb ai/A to unvegetated plots of sandy loam soil (68% sand, 23% silt, 9% clay, 0.9% organic matter, pH 6.3, CEC 4.4 meq/100 g) located near Madera, California, on July 1, 1987. The study author stated that 3 lb ai/A is the maximum registered application rate for metalaxyl. Application was made by sprinkling metalaxyl, contained in a glass jar with a perforated lid, over the subplot areas three times to obtain a uniform distribution. The treated plot consisted of three subplots (each 15 x 75 feet) that were separated by untreated buffer zones (10-foot wide). An untreated plot located upwind and at least 200 feet away from the treated plot served as the control. Prior to treatment, the test plots were disked to a depth of 6 inches and raked smooth. The depth to the water table was ≈90 feet and there was no subsurface drainage in place. The field plots were flat with no measurable slope. Soil cores were collected from the 0- to 6- and 6- to 48-inch depths separately in order to avoid contamination of soil cores at lower depths. Soil cores (1-inch diameter) taken from the upper 6 inches of soil at intervals through 30 days posttreatment were collected using

a can excavation technique to avoid contamination of soil cores at the lower depths; soil samples taken from the 6-to 48-inch depth were collected using a 2-inch wide zero-contamination probe with no excavation. Soil cores were collected from the untreated and treated plot 7 days before treatment, 1 hour after treatment, and at 1, 7, 14, 30, 61, 91, 126, 190, 274, and 336 days posttreatment. The soil cores were frozen at -20 ± 5 F, then sectioned into 6-inch segments. The samples were then stored frozen at -25 to -10 F for up to 1 year and 19 days prior to analysis.
The soil samples were analyzed for metalaxyl and its degradate N-(2,6-dimethylphenyl)-N-(methyoxyacetyl)alanine (CGA-62826) using Ciba-Geigy Method AG-323, as presented in Figure 2. Soil subsamples (50 g) were shaken with 50% aqueous methanol for 90 minutes, then centrifuged and filtered. The extract was adjusted to pH 10 with 12 N sodium hydroxide and partitioned three times with methylene chloride. The methylene chloride phases were combined, filtered through a cotton plug and sodium sulfate, and evaporated to dryness on a rotary evaporator. The resulting residues were redissolved in hexane and filtered (if cleanup was necessary) on a basic alumina column. The eluate was dried and redissolved in isooctane, then analyzed for metalaxyl using GC with nitrogen-phosphorus detection. The aqueous phases resulting from the original partitioning were combined and acidified to pH 3 with 1 N hydrochloric acid. The acidic solution was partitioned three times with methylene chloride and the methylene chloride phases were combined, filtered, and dried on a rotary evaporator. The resulting residues were redissolved in methanol and reacted with diazomethane for 20 minutes. The solution was dried under a stream of nitrogen and redissolved in hexane, dried and redissolved in isooctane, and analyzed by GC as described previously. Average recovery efficiencies from soil samples fortified (0.05 or 0.10 ppm) with either metalaxyl or CGA-62826 ranged from 70 to 127% and 70 to 135%, respectively. Recoveries from field soil samples fortified (0.1 ppm) with metalaxyl or CGA-62826 were 69-81% and 71-93%, respectively. The detection limit was 0.05 ppm for both metalaxyl and CGA-62826.

DATA SUMMARY:

Metalaxyl (5% G), at 3 lb ai/A, dissipated with a calculated half-life of 36 days in the 0- to 6-inch depth of unvegetated plots of sandy loam soil located near Madera, California, that were treated on July 1, 1987. In the upper 6 inches of the treated plot, metalaxyl was 1.01-1.26 ppm (average 1.10 ppm) immediately posttreatment, 0.55-1.04 ppm (average 0.83 ppm) at 30 days, 0.14-0.20 (average 0.19 ppm) at 61 days, and was not detected (≤0.05 ppm) by 190 days posttreatment (Table I). In the 6- to 12-inch depth, metalaxyl was ≤0.05 ppm except at 61 days posttreatment, at which time it was 0.050, 0.051, and 0.102 ppm in the three subplots (Table II). Metalaxyl was <0.05 ppm (detection limit) in the 12- to 18-, 18- to 24-, 24- to 36-, and 36- to 48-inch depths at all sampling intervals (Tables III-VI).

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

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

increased from an average 0.09 ppm immediately posttreatment to 0.25 ppm at 30 days, then decreased to 0.14 ppm at 61 days and ≤0.05 ppm by 126 days (Table VII). CGA-62826 was detected at 61 days in the 6- to 12- and 12- to 18-inch depths at 0.11 and 0.06 ppm, respectively, and at 61 days in the 6- to 12-inch depth at 0.06 ppm (Tables VIII and IX). The degradate was not detected at sampling depths greater than 18 inches (Tables X-XII).

During the study, precipitation plus irrigation totaled 5.46 inches by the first 30 days posttreatment, 16.60 inches by 61 days, and 44.21 inches by 330 days. Air temperatures ranged from 24 to 107 °F and soil temperatures (2-inch depth) ranged from 32 to 118 °F during the study period.

REVIEWERS COMMENTS:

1. The storage stability data provided by the registrant were inadequate to determine that metalaxyl and its degradates are stable in soil when stored frozen for 1 year and 19 days, the longest period of time that soil samples in this study were stored frozen prior to analysis. The frozen soil storage stability study (Study 5, STUDY ID 40985401-B) submitted with these field dissipation studies was conducted for only 7 months and has many unanswered details that need to be addressed.

   In the present study, soil samples taken at all sampling depths were stored for periods longer than the established 7-month storage stability. Maximum storage intervals for samples taken at each depth were as follows: 377 days at 0- to 6-inches (345 days from sampling to extraction and 32 days from extraction to analysis); 313 days at 6- to 12-inches (309 days from sampling to extraction and 4 days from extraction to analysis); 302 days at 12- to 18-inches (299 days from sampling to extraction and 3 days from extraction to analysis); 251 days at 18- to 24-inches (239 days from sampling to extraction and 12 days from extraction to analysis); 1 year and 52 days at 24- to 36-inches (1 year and 19 days from sampling to extraction and 33 days from extraction to analysis); and, 1 year and 26 days at 36- to 48-inches (1 year and 9 days from sampling to extraction and 17 days from extraction to analysis).

Although the longest period of time that the soil samples were stored frozen prior to analysis was 1 year and 19 days, EFGWB concludes that a freezer storage stability study conducted for at least 1 year in order determine that metalaxyl and its degradates are stable in frozen soil will suffice.

2. Metalaxyl concentrations were somewhat variable in soil samples taken at the 0- to 6-inch depth at intervals up to 30 days posttreatment. This variability may have been due to the use of a granular formulation and the inherent difficulty in obtaining a uniform distribution when applying granules to field plots.

3. The degradate, CGA-62826, was detected in the 6- to 12-inch depth at 61 and 91 days posttreatment (average values 0.11 and 0.06 ppm, respectively) and in the 12- to 18-inch depth at 61 days (average 0.06 ppm), but was not detected at these depths at any other sampling intervals. The study author stated that these concentrations were most likely due to contamination caused by the inherent difficulties involved in taking soil cores at the lower sampling depths.

4. Although of minor impact, the field test data, including meteorological data, were incomplete. Air temperature data were not provided for the last 3 study days (May 27-29, 1988), and soil temperature data were not provided for July 1-14, 1987, October 21 and 29-31, 1987, November 1-12, 1987, and May 27-29, 1988.

5. The residue values reported by the study author were expressed on a dry weight basis and were corrected for procedural recovery.

6. A method validation study was conducted prior to sample analyses to determine the adequacy of the analytical method. Soil samples taken at the 0- to 6- and 12- to 18-inch depths of silt loam soil were fortified with either metalaxyl or CGA-62826 at 0.05, 0.20, or 2.0 ppm. The average recoveries for metalaxyl were 111 ± 18% for soil samples taken at the 0- to 6-inch depth and 95 ± 6% for soil samples taken at the 12- to 18-inch depth. The average recoveries for CGA-62826 were 113 ± 12% and 106 ± 11% at the 0- to 6-and 12- to 18-inch depths, respectively.

7. An additional experiment to determine the distribution of the test substance in the field plots was conducted by spraying petri dishes with the 5% G formulation at 3 lb ai/A. Only one of the four dishes exhibited a distribution rate (110%) near the theoretical value; the distribution rate of the three remaining dishes was unacceptably low (8-39%). The study author suggested that these poor recoveries may have been due to loss of granules from the petri dishes during processing and shipment, and to uneven field distribution of the granules onto the small area of the petri dishes.

8. No crops were grown on the test site and no pesticides were applied during the three years prior to the initiation of the study. During the study, paraquat was applied at 1.5 pints/A on July 17, 1987; and glyphosate was applied at 4 pints/A on August 21, February 24, and March 28, 1987, and at 3 pints/A on September 10, 1987.

Metalaxyl Sha # 113501

Page _____ is not included in this copy.

Pages 21 through 37 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.

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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 2

CHEM 113501 Metalaxyl §164-1

FORMULATION--5G-GRANULAR

STUDY ID 40985404
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.

DIRECT REVIEW TIME = 8

REVIEWED BY: J. Harlin TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
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APPROVED BY: R. Mahler
TITLE: Hydrologist
ORG: EFGWB/EFED/OPP
TEL: 557-5734
SIGNATURE: Richard J. Mahler MAY 14 1990

CONCLUSIONS:

Field Dissipation - Terrestrial--164-1

1. This study is scientifically valid but does not meet Subdivision N guidelines for the following reasons

   An adequate freezer storage stability study was not submitted with sufficient details to demonstrate that metalaxyl and its degradates are stable in frozen soil stored for the longest period of time that soil samples were stored frozen prior to analysis.

2. The study can only partially satisfy the data requirements because the highest rate recommended on the product label for any crop was not used (although the highest recommended

rate for tomatoes was used in this study). Citrus and avocado crops have permissible application rates of up to 4.0 and 16 lb ai/A, respectively . Multiple applications allow a total of 12 and 48 lb ai/A/year, respectively for the two crops. EFGWB is requesting addition field dissipation studies to address the higher application rates of metalaxyl.

3. In order for this study to be considered partially in fulfillment of the data requirements, the registrant must submit further details of the storage stability study (see Study 5 for details of what is needed before any conclusions can be reached in regards to the freezer storage stability of metalaxyl).

4. The registrant should provide more details related to normal cultural practices for tomatoes grown near Madera, California (these should include, but not be limited to: typical planting dates, fertilization and cultivation practices, irrigation schedules, sprinkler application rates and runoff when irrigating, harvest dates, etc.). This will allow EFGWB to ascertain if the study was conducted under typical growth conditions for the crop.

   EFGWB would also, like to know the condition of the tomato crop before the hail damage, in order to verify that an adequate amount of water was applied to the test crop.

5. EFGWB concludes that metalaxyl, at 3 lb ai/A, probably dissipated with a half-life of 27 days in sandy loam soil planted to tomatoes in Madera, California, that was treated with a 5% G formulation. N-(2,6-dimethylphenyl)-N-(methoxy-acetyl)alanine (CGA-62826) accumulated to a maximum 0.91 ppm at 30 days. Metalaxyl and CGA-62826 did not appear to leach below the 0- to 6-inch soil depth during the study.

4. EFGWB notes that pan evaporation exceeded precipitation plus irrigation during the length of the study. Therefore, it is not unexpected that little leaching of metalaxyl occurred below the 0-6" soil depth sampled, since it is probable that little water leached below this depth either.

METHODOLOGY:

Metalaxyl (Ridomil 5% G, Ciba-Geigy Corporation) was applied as a broadcast application at 3 lb ai/A to field plots of sandy loam soil (68% sand, 23% silt, 9% clay, 0.9% organic matter, pH 6.3, CEC 4.4 meq/100 g) planted to tomatoes near Madera, California, on July 1, 1987. The study author stated that 3 lb ai/A is the maximum registered application rate for metalaxyl. Application was made by sprinkling metalaxyl, contained in a glass jar with a perforated lid, over the subplot areas three times to obtain a uniform distribution. The treated plot consisted of three subplots (each 15 x 75 feet) that were separated by untreated buffer zones (10-foot wide). An untreated plot located upwind and at least 200 feet away from the treated plot served as the control. Prior to treatment, the test plots were disked to a depth of 6 inches and raked smooth. The depth to the water table was ≈90 feet and there was no subsurface drainage in place. The field plots were flat with no measurable slope. Soil cores were collected from the 0- to 6- and 6- to 48-inch depths separately in order to avoid contamination of soil cores at lower depths. Soil cores (1-inch diameter) taken from the upper 6 inches of soil were collected using a can excavation technique; soil cores taken from the 6- to 48-inch depth were collected using a 2-inch wide zero-contamination probe with no excavation. Soil samples were collected from the untreated and treated plot 7 days prior to treatment, 1 hour after treatment, and at 1, 7, 14, 30, 61, 91, 126, 190, 274, and 336 days posttreatment. The soil cores were frozen at -20 ± 5 F, then sectioned into 6-inch-thick segments. The samples were then stored frozen at -25 to -10 F for up to 1 year and 19 days prior to analysis.

The soil samples were analyzed for metalaxyl and its degradate N-(2,6-dimethylphenyl)-N-(methyoxyacetyl)alanine (CGA-62826) using Ciba-Geigy Method AG-323, as presented in Figure 2. Soil subsamples (50 g) were shaken with 50% aqueous methanol for 90 minutes, then centrifuged and filtered. The extract was adjusted to pH 10 with 12 N sodium hydroxide and partitioned three times with methylene chloride. The methylene chloride phases were combined, filtered through a cotton plug and sodium sulfate, and evaporated to dryness on a rotary evaporator. The resulting residues were redissolved in hexane and filtered (if cleanup was necessary) on a basic alumina column. The eluate was dried and redissolved in isooctane, then analyzed for metalaxyl using GC with nitrogen-phosphorus detection. The aqueous phases resulting from the original partitioning were combined and acidified to pH 3 with 1 N hydrochloric acid. The acidic solution was partitioned three times with methylene chloride and the methylene chloride phases were combined, filtered, and dried on a rotary evaporator. The resulting residues were redissolved in methanol and reacted with diazomethane for 20 minutes. The solution was dried under a stream of nitrogen and redissolved in hexane, dried and redissolved in isooctane, and analyzed by GC as described previously. Average recovery efficiencies from soil samples fortified (0.05 or 0.10 ppm) with either metalaxyl or CGA-62826 ranged from 70 to 127% and 70 to 135%, respectively. Recoveries from field soil samples fortified (0.1 ppm) with metalaxyl or CGA-62826 were 69-81% and 71-

93%, respectively. The detection limit was 0.05 ppm for both metalaxyl and CGA-62826.

DATA SUMMARY:

Metalaxyl (Ridomil 5% G), at 3 lb ai/A, dissipated with a calculated half-life of 27 days in the 0- to 6-inch depth of plots of sandy loam soil planted to tomatoes near Madera, California, that were treated on July 1, 1987. In the upper 6 inches of the plots, metalaxyl was 0.82-1.13 ppm (average 1.00 ppm) immediately posttreatment, 0.46-1.11 ppm (average 0.68 ppm) at 30 days, 0.25-0.33 (average 0.28 ppm) at 61 days, and was not detected (≤0.05 ppm) by 126 days post-treatment (Table I). In the 6- to 12-inch depth, metalaxyl was detected only at 1 and 61 days posttreatment, at 0.20 and 0.12 ppm, respectively (Table II). Metalaxyl was not detected in the 12- to 18-, 18-to 24-, 24- to 36-, and 36- to 48-inch depths at any sampling interval (Tables III-VI).

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

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

increased from an average 0.09 ppm immediately posttreatment, to 0.91 ppm at 30 days, then decreased to 0.23 ppm at 61 days, 0.08 ppm at 126 days, and ≤0.05 ppm by 190 days posttreatment (Table VII). CGA-62826 was detected at 61 days posttreatment at an average 0.08 ppm in the 6- to 12-inch depth; and at 126 days at 0.06, 0.14, and 0.10 ppm in the 12- to 18-, 18- to 24-,and 24- to 36-inch depth), respectively (Tables VIII-XI). It was not detected in the 36- to 48-inch soil depth at any interval (Table XII).

During the study, precipitation plus irrigation totaled 5.46 inches by the first 30 days, 16.60 inches by 61 days, and 44.21 inches by 330 days. Air temperatures ranged from 24 to 107 ^{o}F and soil temperatures (0- to 2-inch depth) ranged from 32 to 118 ^{o}F during the study period.

REVIEWERS COMMENTS:

1. The storage stability data provided by the registrant were inadequate to determine that metalaxyl and its degradates are stable in soil when stored frozen for 1 year and 19 days, the longest period of time that soil samples in this study were stored frozen prior to analysis. The frozen soil storage stability study (Study 5, STUDY ID 40985401-B) submitted with these field dissipation studies was conducted for only 7 months and has many unanswered details that need to be addressed.

In the present study, soil samples taken at all sampling depths except the 0- to 6-inch depth were stored for periods longer than the established 7-month storage stability. Maximum storage intervals for samples taken at each depth were as follows: 196 days at 0- to 6-inches (180 days from sampling to extraction and 16 days from extraction to analysis); 330 days at 6- to 12-inches (312 days from sampling to extraction and 18 days from extraction to analysis); 322 days at 12- to 18-inches (extraction and analysis on the same day); 290 days at 18- to 24-inches (287 days from sampling to extraction and 3 days from extraction to analysis); 1 year and 34 days at 24- to 36-inches (1 year and 19 days from sampling to extraction and 15 days from extraction to analysis); and, 321 days at 36- to 48-inches (319 days from sampling to extraction and 2 days from extraction to analysis).

Although the longest period of time that the soil samples were stored frozen prior to analysis was 1 year and 19 days, EFGWB concludes that a freezer storage stability study conducted for at least 1 year in order determine that metalaxyl and its degradates are stable in frozen soil will suffice.

2. Metalaxyl concentrations were variable in soil samples taken at the 0- to 6-inch depth at intervals through 30 days posttreatment. This variability was most apparent in two of the three replicates in which maximum concentrations occurred at 14 days (1.14 ppm) or 30 days (1.11 ppm), whereas in the remaining replicate, metalaxyl concentrations showed a relatively steady decline, with the maximum concentration occurring at 1 day posttreatment (1.48 ppm; Table I). The variability may have been due to the inherent difficulty of obtaining a uniform distribution when applying a granular formulation on the field plots. However, the method of sampling (a 3 inch diameter by 4 inch deep can placed into the soil and then the top six inches of soil was excavated and placed into the sample bag) used during the first 30 days should have precluded this variability.

3. The degradate, CGA-62826, was detected in the 6- to 12-inch depth at 61 days posttreatment and in the 12- to 18-, 18- to 24-, and 24- to 36-inch depths at 126 days posttreatment, but was not detected at these depths at any other sampling intervals. The study author stated that these concentrations were most likely due to slight contamination caused by the inherent difficulties involved in taking soil cores at the lower sampling depths.

4. Although of minor impact, the field test data, including meteorological data, were incomplete. Air temperature data were not provided for the last 3 study days (May 27-29,

1988), and soil temperature data were not provided for July 1-14, 1987, October 21 and 29-31, 1987, November 1-12, 1987, and May 27-29, 1988.

5. The residue values reported by the study author were expressed on a dry weight basis and were corrected for procedural recovery.

6. The tomato crop planted on June 30, 1987, was poor due to hot weather during emergence. A replanting was made on August 4 and 7, 1987, to improve the original stand. This second crop was destroyed by a hailstorm on October 28, 1987; however, it was stated that the storm did not effect the results of the study since most growers would have harvested the remaining crop by this date. The plots were rototilled to a depth of ≈5 inches on December 2, 1987, to simulate grower practices. The question remains if enough water was supplied for the growth needs of the crop. If sufficient water was not applied this would probably render this study not unlike the bare-ground study. Therefore, the data requirement would not be satisfied since Subdivision N Guidelines suggest that a cropped soil be used for a field dissipation study.

   The registrant should provide more details related to normal cultural practices for tomatoes grown near Madera, California. This will allow EFGWB to ascertain if the study was conducted under typical growth conditions for the crop.

7. A method validation study was conducted prior to sample analyses to determine the adequacy of the analytical method. Soil samples taken at the 0- to 6- and 12- to 18-inch depths were fortified with either metalaxyl or CGA-62826 at 0.05, 0.20, or 2.0 ppm. The average recoveries for metalaxyl were 111 ± 18% for soil samples taken at the 0- to 6-inch depth and 95 ± 6% for soil samples taken at the 12- to 18-inch depth. The average recoveries for CGA-62826 were 113 ± 12% and 106 ± 11% at the 0- to 6-and 12- to 18-inch depths, respectively.

8. An additional experiment to determine the distribution of the test substance in the field plots was conducted by spraying petri dishes with the 5% G formulation at 3 lb ai/A. Only one of the four dishes exhibited a distribution rate (95%) near the theoretical value; the distribution rate of the three remaining dishes was unacceptably low (0-46%). The study author suggested that these poor recoveries may have been due to loss of granules from the petri dishes during processing and shipment, and to uneven field distribution of the granules onto the small area of the petri dishes.

9. No crops were grown on the test site and no pesticides were applied during the three years prior to the initiation of the study. During the study, paraquat was applied at 1.5 pints/A on July 17, 1987; and glyphosate was applied at 4 pints/A on August 21, February 24, and March 28, 1987, and at 3 pints/A on September 10, 1987.

Metalaxyl Sha # 113501

Page_____ is not included in this copy.

Pages 45 through 61 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.

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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 3

CHEM 113501 | Metalaxyl | §164-1

FORMULATION--5G--GRANULAR

STUDY ID 40985401-A
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 Agri-Growth Research, Inc., Hollandale, MN, and Tegeris Laboratories, Inc., Laurel, MD; prepared by Landis Associates, Inc., Valdosta, GA; and submitted by Ciba-Geigy Corporation, Greensboro, NC.

DIRECT REVIEW TIME = 10

REVIEWED BY: J. Harlin TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
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APPROVED BY: R. Mahler
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ORG: EFGWB/EFED/OPP
TEL: 557-5734

SIGNATURE: R. J. Mahler MAY 14 1990

CONCLUSIONS:

Field Dissipation - Terrestrial--164-1

1. This study cannot be used to fulfill data requirements.

2. These data are considered to be of uncertain value and should not be used to predict the environmental behavior of metalaxyl and its degradates.

3. This study is unacceptable for the following reasons:

   1. The data were too variable to accurately assess the dissipation of metalaxyl on soil.

2. The concentration of metalaxyl in the treated soil immediately posttreatment failed to confirm the theoretical application rate of 3 lb ai/A; and

3. An adequate freezer storage stability study was not submitted to demonstrate that metalaxyl and its degradates are stable in frozen soil stored for the longest period of time that soil samples were stored frozen prior to analysis (see Study 5 for details of what is needed before any conclusions can be reached in regards to the freezer storage stability of metalaxyl).

4. Since the data were too variable to accurately assess the dissipation rate of metalaxyl on soil, the problems with this study cannot be resolved with the submission of additional data. A new study must be conducted.

METHODOLOGY:

Metalaxyl (Ridomil 5% G, Ciba-Geigy Corporation) was applied as a broadcast application at 3 lb ai/A to unvegetated plots of silt loam soil (40% sand, 42% silt, 18% clay, 3.6% organic matter, pH 7.9, CEC 17.1 meq/100 g) located in Hollandale, Minnesota, on July 17, 1987. The study author stated that 3 lb ai/A is the maximum registered application rate for metalaxyl. Application was made using a trailer-mounted pneumatic application system. The treated plot consisted of three subplots (each 12 x 80 feet) that were separated by untreated buffer zones (10-foot wide). An untreated plot located at least 275 feet upslope and upwind from the treated plots served as the control. The slope of the field was 5% and the depth to the water table was 3-5 feet. A subsurface tile drainage system was in place at the test site. Prior to treatment, the test plots were disked and cultivated. Roundup (glyphosate) was applied for weed control at a rate of 1.5 qt/A on July 15, 1987. Soil cores were collected from the 0- to 6- and 6- to 48-inch depths separately in order to avoid contamination of soil cores at lower depths. Soil cores (1-inch diameter) taken from the upper 6 inches of soil were collected using a stainless steel probe fitted with acetate liners; soil cores (2-inch diameter) taken from the 6- to 48-inch depth were collected using a hydraulic probe fitted with an acetate liner. Soil samples were collected from the untreated and treated plot 2 days before treatment, 1 hour after treatment, and at 1, 10, 14, 31, 67, 95, 122, 278, and 364 days posttreatment. The soil cores were frozen at 0 ± 10 F, then sectioned into 6-inch segments. The samples were then stored frozen at -15 ± 5 C for a maximum of 1 year prior to analysis.

The soil samples were analyzed for metalaxyl and its degradate N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine (CGA-62826) using Ciba-Geigy Method AG-323, as presented in Figure 2. Soil subsamples (50 g) were shaken with 50% aqueous methanol for 90 minutes, then centrifuged and filtered. The extract was adjusted to pH 10 with 12 N sodium hydroxide and partitioned three times with methylene chloride. The methylene chloride phases were combined, filtered through a cotton plug and sodium sulfate, and evaporated to dryness on a rotary evaporator. The resulting residues were redissolved in hexane and filtered (if cleanup was necessary) on a basic alumina column. The eluate was dried and redissolved in isooctane, then analyzed for metalaxyl using GC with nitrogen-phosphorus detection. The aqueous phases resulting from the original partitioning were combined and acidified to pH 3 with 1 N hydrochloric acid. The acidic solution was partitioned three times with methylene chloride and the methylene chloride phases were combined, filtered, and dried on a rotary evaporator. The resulting residues were redissolved in methanol and reacted with diazomethane for 20 minutes. The solution was dried under a stream of nitrogen and redissolved in hexane, dried and redissolved in isooctane, and analyzed by GC as described previously. Average recovery efficiencies from soil samples fortified (0.1 ppm) with either metalaxyl or CGA-62826 were 78 and 95%, respectively. Average recoveries from field soil samples fortified (0.05 or 0.10 ppm) with metalaxyl or CGA-62826 were 80.9-97.8% and 89.5-103.4%, respectively (Table 12). The detection limit was 0.05 ppm for both metalaxyl and CGA-62826.

DATA SUMMARY:

Metalaxyl (5% G), at 3 lb ai/A, dissipated with a calculated half-life of 148 days in the 0- to 6-inch depth of unvegetated plots of silt loam soil located in Hollandale, Minnesota, that were treated on July 17, 1987. In the upper 6 inches of the treated plot, concentrations of metalaxyl were variable; metalaxyl was 0.60-1.14 ppm (triplicate samples; average 0.81 ppm) at 0 days, 0.69-1.60 ppm (average 1.05 ppm) at 14 days, 0.10-0.13 ppm (average 0.11 ppm) at 67 days, 0.56-0.84 ppm (average 0.68 ppm) at 122 days, and <0.05 (detection limit)-0.16 ppm (average 0.09 ppm) at 364 days posttreatment (Table 14). In the 6- to 12-inch depth, metalaxyl was <0.05 ppm at 0-14 days, <0.05-0.09 ppm (average 0.05 ppm) at 31 days, <0.05-0.12 ppm (average 0.07 ppm) at 67 days, and was detected in single samples at 0.12 ppm on day 95, 0.06 ppm on day 122 days, and 0.12 ppm on day 364; Table 16). Metalaxyl was <0.05 ppm in the 12- to 18-, 18- to 24-, 24- to 36-, and 36-to 48-inch depths at all sampling intervals (Tables 18, 20, 22, and 24).

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

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

was not detected until 67 days posttreatment, at which time it was 0.14-0.20 ppm (average 0.16 ppm); thereafter, the degradate was 0.09-0.32 ppm (average 0.18 ppm) at 95 days and decreased to <0.05-0.13 ppm (average 0.07 ppm) at 364 days posttreatment (Table 15). In the 6- to 12-inch depth, CGA-62826 was <0.05 ppm at all sampling intervals, except for single samples taken at 67 days (0.05 ppm), 95 days (0.08 ppm), and 364 days posttreatment (0.06 ppm; Table 17). The degradate was not detected at sampling depths greater than 12 inches (Tables 19, 21, and 23).

During the study, precipitation plus irrigation totaled 6.85 inches during the first 31 days posttreatment, 13.20 inches by 95 days, 21.41 inches by 278 days, and 31.44 inches by 364 days. Air temperatures ranged from -27 to 96 °F, and soil temperatures (2-inch depth) ranged from 9 to 84 °F during the study period.

REVIEWERS COMMENTS:

1. Data were too variable to accurately assess the field dissipation of metalaxyl in soil. In the upper 6 inches of the treated plot, average concentrations of metalaxyl increased from 0.81 ppm immediately posttreatment to 1.05 ppm at 14 days, decreased to 0.11 ppm at 67 days, increased to 0.68 ppm at 122 days, and decreased to 0.09 ppm at 364 days posttreatment (Table 14). The degradate CGA-62826 was not detected in the upper 6 inches of soil until 67 days posttreatment, and was highly variable at later sampling intervals through 364 days posttreatment; average concentrations were 0.16 ppm at 67 days, 0.18 ppm at 95 days, and 0.07 ppm at 364 days posttreatment (Table 15). The variability in concentrations of metalaxyl and CGA-62826 in the 0- to 6-inch soil depth may have been due in part to the difficulty of obtaining a uniform distribution when applying granules to field plots.

2. The initial concentration of metalaxyl in the 0- to 6-inch depth of the treated soil (0.81 ppm) was significantly less than the 1.5 ppm that would be expected from an application of 3 lb ai/A. That the lower-than-expected concentration in the soil resulted from an incomplete application was supported by an additional experiment conducted by the study author. Five petri dishes were placed in each subplot prior to treatment in order to determine the distribution of the granular metalaxyl in the field plots. The concentration of

metalaxyl in the dishes was only 55.4% of the theoretical application rate of 3 lb ai/A (Table 10).

3. The storage stability data provided by the registrant were inadequate to determine that metalaxyl and its degradates are stable in soil when stored frozen for 1 year, the longest period of time that soil samples in this study were stored frozen prior to analysis. The frozen soil storage stability (Study 5, STUDY ID 40985401-B) submitted with these field dissipation studies was conducted for only 210 days (7 months).

   In the present study, soil samples taken at all sampling depths except the 6- to 12-inch depth were stored for periods longer than the established 7-month storage stability. Maximum storage intervals for samples taken at each depth were as follows: 262 days at 0- to 6-inches (230 days from sampling to extraction and 32 days from extraction to analysis); 204 days at 6- to 12-inches (196 days from sampling to extraction and 8 days from extraction to analysis); 325 days at 12- to 18-inches (324 days from sampling to extraction and 1 day from extraction to analysis); 321 days at 18- to 24-inches (312 days from sampling to extraction and 9 days from extraction to analysis); 1 year and 41 days at 24- to 36-inches (1 year from sampling to extraction and 41 days from extraction to analysis); and, 302 days at 36- to 48-inches (300 days from sampling to extraction and 2 days from extraction to analysis). Therefore, a freezer storage stability study must be conducted in order to determine that metalaxyl and its degradates are stable in soil frozen for 1 year prior to extraction, which was the longest period of time that the soil samples were stored frozen prior to analysis.

4. It was stated that during the course of the experiment, the soil in the 0- to 6-inch depth was frozen approximately 30% of the time; therefore, degradation of metalaxyl in the Minnesota soil is expected to be slow. Due to excessive precipitation or frozen ground, some of the proposed soil sampling intervals specified in the protocol had to be changed to later dates.

5. The residue values reported by the study author were expressed on a dry weight basis and were corrected for procedural recovery.

6. The soil temperature data were obtained from the Southern Experiment Station located in Waseca, Minnesota, at least 10 miles from the test site. It is preferred that meteorological data be measured at the test site, since temperatures and rainfall can vary between sites in close proximity.

7. A method validation study was conducted prior to sample analyses to determine the adequacy of the analytical method. Soil samples taken at the 0- to 6- and 12- to 18-inch depths were fortified with either metalaxyl or CGA-62826 at 0.05, 0.20 or 2.0 ppm. The average recoveries for metalaxyl were 83 ± 13% for soil samples taken at the 0- to 6-inch depth and 79 ± 11% for soil samples taken at the 12- to 18-inch depth. The average recoveries for CGA-62826 were 102 ± 18% and 109 ± 11% at the 0- to 6- and 12- to 18-inch depths, respectively.

8. Soybeans were grown in 1984 and 1986 and corn was grown in 1985 in the test plot area. No metalaxyl was applied to the test area during the three years prior to the initiation of the study. In 1984, the test area was treated with Lasso (2.5 lb ai/A), Amiben (2.0 lb ai/A), and Sencor (0.33 lb ai/A). During 1985, the herbicides Lasso and Bladex were applied to the test plot area at 3.0 and 2.0 lb ai/A, respectively. In 1986, Basalin and Sencor were applied at 1.0 and 0.375 lb ai/A, respectively.

Metalaxyl Sha # 113501

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DATA EVALUATION RECORD

STUDY 4

CHEM 113501 Metalaxyl §164-1

FORMULATION--5G--GRANULAR

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

DIRECT REVIEW TIME = 10

REVIEWED BY: J. Harlin TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

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SIGNATURE: R.J. Mahler MAY 14 1990

CONCLUSIONS:

Field Dissipation - Terrestrial--164-1

1. This study cannot be used to fulfill data requirements.

2. These data are considered to be of uncertain value and should not be used to predict the environmental behavior of metalaxyl and its degradates.

3. This study is unacceptable for the following reasons:

    1. The data were too variable to accurately assess the dissipation of metalaxyl in soil.

2. The concentration of metalaxyl in the treated soil immediately posttreatment failed to confirm the theoretical application rate of 3 lb ai/A; and

3. An adequate freezer storage stability study was not submitted to demonstrate that metalaxyl and its degradates are stable in frozen soil stored for the longest period of time that soil samples were stored frozen prior to analysis (see Study 5 for details of what is needed before any conclusions can be reached in regards to the freezer storage stability of metalaxyl).

4. Since the data were too variable to accurately assess the dissipation rate of metalaxyl in soil, the problems with this study cannot be resolved with the submission of additional data. A new study must be conducted.

METHODOLOGY:

Metalaxyl (Ridomil 5% G, Ciba-Geigy Corporation) was applied as a broadcast application at 3 lb ai/A to field plots of silt loam soil (40% sand, 42% silt, 18% clay, 3.6% organic matter, pH 7.9, CEC 17.1 meq/100 g) planted to tomatoes located in Hollandale, Minnesota, on July 17, 1987. The study author stated that 3 lb ai/A is the maximum registered application rate for metalaxyl. Application was made using a trailer-mounted pneumatic application system.

The treated plot consisted of three subplots (each 12 x 80 feet) that were separated by untreated buffer zones (10-foot wide). An untreated plot located at least 275 feet upslope and upwind from the treated plot served as the control. The slope of the field was 5% and the depth to the water table was 3-5 feet. A subsurface tile drainage system was in place at the test site. Prior to treatment, the test plots were disked and cultivated. Roundup (glyphosate) was applied for weed control at a rate of 1.5 qt/A on June 15, 1988.

Soil cores were collected from the 0- to 6- and 6- to 48-inch depths separately in order to avoid contamination of soil cores at lower depths. Soil cores (1-inch diameter) taken from the upper 6 inches of soil were collected using a stainless steel probe fitted with acetate liners; soil cores (2-inch diameter) taken from the 6- to 48-inch depth were collected using a hydraulic probe fitted with an acetate liner. Soil samples were collected from the untreated and treated plots 2 days before treatment, 1 hour after treatment, and at 1, 10, 14, 31, 67, 95, 122, 278, and 364 days posttreatment. The soil cores were frozen at 0 ± 10 °F, then sectioned into 6-inch segments. The samples were then stored frozen at -15 ± 5 °C for up to 1 year prior to analysis.

The soil samples were analyzed for metalaxyl and its degradate N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine (CGA-62826) using Ciba-Geigy Method AG-323, as summarized in Figure 2. Soil subsamples (50 g) were shaken with 50% aqueous methanol for 90 minutes, centrifuged and filtered. The extract was adjusted to pH 10 with 12 N sodium hydroxide and partitioned three times with methylene chloride. The methylene chloride phases were combined, filtered through a cotton plug and sodium sulfate, and evaporated to dryness on a rotary evaporator. The resulting residues were redissolved in hexane and filtered (if cleanup was necessary) on a basic alumina column. The eluate was dried and redissolved in isooctane, then analyzed for metalaxyl using GC with nitrogen-phosphorus detection.

The aqueous phases resulting from the original partitioning were combined and acidified to pH 3 with 1 N hydrochloric acid. The acidic solution was partitioned three times with methylene chloride and the methylene chloride phases were combined, filtered, and dried on a rotary evaporator. The resulting residues were redissolved in methanol and reacted with diazomethane for 20 minutes. The solution was dried under a stream of nitrogen and redissolved in hexane, dried and redissolved in isooctane, and analyzed by GC as described previously. Average recovery efficiencies from soil samples fortified (0.1 ppm) with either metalaxyl or CGA-62826 were 78 and 95%, respectively. Average recoveries from field soil samples fortified (0.05 or 0.10 ppm) with metalaxyl or CGA-62826 were 79.6-99.6% and 88.3-104%, respectively (Table 12). The detection limit was 0.05 ppm for both metalaxyl and CGA-62826.

DATA SUMMARY:

Metalaxyl (5% G), applied at 3 lb ai/A, was variable in the 0- to 6-inch depth of plots of silt loam soil planted to tomatoes in Hollandale, Minnesota, that were treated on July 17, 1987. In the upper 6 inches of the treated plot, metalaxyl was 0.60-1.01 ppm (triplicate samples; average 0.84 ppm) at 0 days, decreased to 0.17-0.53 ppm (average 0.36 ppm) at 1 day, increased to 0.56-1.22 ppm (average 0.95 ppm) at 10 days, decreased to <0.05 (detection limit)-0.38 ppm (average 0.24 ppm) at 67 days, then increased to 0.23-0.39 ppm (average 0.31 ppm) at 364 days posttreatment (Table 14). In the 6- to 12-inch depth, metalaxyl was not detected at any sampling interval, except in two soil samples taken at 364 days posttreatment that bore residues of 0.05 and 0.07 ppm (Table 16). Metalaxyl was not detected in the 12- to 18-, 18- to 24-, 24- to 36-, and 36-to 48-inch depths at all sampling intervals (Tables 18, 20, 22, and 24).

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

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

was not detected until 67 days posttreatment, at which time two soil samples bore 0.16 ppm (Table 15). The concentration of CGA-62826 was highly variable at later sampling intervals; CGA-26826 was 0.05-0.25 ppm (average 0.12 ppm) at 95 days, <0.05-0.14 ppm (average 0.08 ppm) at 122 days, 0.15-0.19 ppm (average 0.16 ppm) at 278 days, and 0.18-0.23 ppm (average 0.20 ppm) at 364 days posttreatment. The degradate was not detected in the 6- to 12- and 12- to 18-inch depths until 364 days posttreatment, at which time concentrations were 0.07-0.13 ppm (average 0.09 ppm) and 0.05-0.31 ppm (average 0.15 ppm), respectively (Tables 17 and 19). CGA-62826 was not detected at sampling depths greater than 18 inches (Tables 21 and 23).

During the study, precipitation plus irrigation totaled 6.85 inches during the first 31 days, 11.51 inches by 67 days, 13.20 inches by 95 days, 21.41 inches by 278 days, and 31.44 inches by 364 days. Air temperatures ranged from -27 to 96 °F, and soil temperatures (2-inch depth) ranged from 9 to 84 °F during the study period.

COMMENTS:

1. Data were too variable to accurately assess the field dissipation of metalaxyl in soil. In the upper 6 inches of the treated plot, average concentrations of metalaxyl decreased from 0.84 ppm immediately posttreatment to 0.36 ppm at 1 day, increased to 0.95 ppm at 10 days, decreased to 0.24 ppm at 67 days, and then increased to 0.31 ppm at 364 days posttreatment (Table 14). The degradate CGA-62826 was not detected in the upper 6 inches of soil until 67 days posttreatment, and was highly variable at later sampling intervals through 364 days posttreatment (Table 15). The variability in concentrations of metalaxyl and CGA-62826 may have been due in part to the difficulty of obtaining a uniform distribution when applying granules to field plots.

2. The initial concentration of metalaxyl in the 0- to 6-inch depth of the treated soil (0.84 ppm) was significantly less than the 1.5 ppm that would be expected from an application of 3 lb ai/A. That the lower-than-expected concentration in the soil resulted from an incomplete application rather than interception by vegetation was supported by an additional experiment conducted by the study author. Five petri dishes were placed in each subplot prior to treatment in order to determine the distribution of the granular metalaxyl in the

field plots. The concentration of metalaxyl in the dishes was only 55.4% of the theoretical application rate of 3 lb ai/A (Table 10).

3. The storage stability data provided by the registrant were inadequate to determine that metalaxyl and its degradates are stable in soil when stored frozen for 1 year, the longest period of time that soil samples in this study were stored frozen prior to analysis. The frozen soil storage stability (Study 5, STUDY ID 40985401-B) submitted with these field dissipation studies was conducted for only 210 days (7 months).

   In the present study, soil samples taken at all sampling depths except the 6- to 12-inch depth were stored for periods longer than the established 7-month storage stability. Maximum storage intervals for samples taken at each depth were as follows: 244 days at 0- to 6-inches (223 days from sampling to extraction and 21 days from extraction to analysis); 191 days at 6- to 12-inches (190 days from sampling to extraction and 1 day from extraction to analysis); 274 days at 12- to 18-inches (271 days from sampling to extraction and 3 days from extraction to analysis); 222 days at 18- to 24-inches (189 days from sampling to extraction and 33 days from extraction to analysis); 1 year and 36 days at 24- to 36-inches (1 year from sampling to extraction and 36 days from extraction to analysis); and, 301 days at 36- to 48-inches (300 days from sampling to extraction and 1 day from extraction to analysis). Therefore, a freezer storage stability study must be conducted in order to determine that metalaxyl and its degradates are stable in soil frozen for 1 year prior to extraction, which was the longest period of time that the soil samples were stored frozen prior to analysis.

4. CGA-62826 was detected in the 6- to 12- and 12- to 18-inch depths at 364 days posttreatment only. The study author suggested that the degradate may have moved into these lower horizons as a direct result of the 4.82 inches of rainfall plus irrigation water that the plots received from July 8-12, 1988, 3 days prior to the final sampling interval (364 days posttreatment).

5. It was stated that during the course of the experiment, the soil in the 0- to 6-inch depth was frozen approximately 30% of the time; therefore, degradation of metalaxyl in the Minnesota soil is expected to be slow. Due to excessive precipitation or frozen ground, some of the proposed soil sampling intervals specified in the protocol had to be changed to later dates.

6. The residue values reported by the study author were expressed on a dry weight basis and were corrected for procedural recovery.

7. The study author estimated the half-life of metalaxyl to be 296.2 days ($r = 0.567$), but stated that this estimation is not expected to be accurate due to the low r value.

8. The soil temperature data were obtained from the Southern Experiment Station located in Waseca, Minnesota, at least 10 miles from the test site. It is preferred that meteorological data be measured at the test site, since temperatures and rainfall can vary between sites in close proximity.

9. A method validation study was conducted prior to sample analyses to determine the adequacy of the analytical method. Soil samples taken at the 0- to 6- and 12- to 18-inch depths were fortified with either metalaxyl or CGA-62826 at 0.05, 0.20 or 2.0 ppm. The average recoveries for metalaxyl were 83 ± 13% for soil samples taken at the 0- to 6-inch depth and 79 ± 11% for soil samples taken at the 12- to 18-inch depth. The average recoveries for CGA-62826 were 102 ± 18% and 109 ± 11% at the 0- to 6- and 12- to 18-inch depths, respectively.

10. Soybeans were grown in 1984 and 1985 and corn was grown in 1985 in the test plot area. No metalaxyl was applied to the test area during the three years prior to the initiation of the study. In 1984, the test area was treated with Lasso (2.5 lb ai/A), Amiben (2.0 lb ai/A), and Sencor (0.33 lb ai/A). During 1985, the herbicides Lasso and Bladex were applied to the test plot area at 3.0 and 2.0 lb ai/A, respectively. In 1986, Basalin and Sencor were applied at 1.0 and 0.375 lb ai/A, respectively.

Metalaxyl Sha # 113501

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DATA EVALUATION RECORD

STUDY 5

CHEM 113501 Metalaxyl §164-1

FORMULATION--5G-GRANULAR

STUDY ID 40985401
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.

DIRECT REVIEW TIME = 10

REVIEWED BY: J. Harlin TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

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SIGNATURE: R. J. Mahler MAY 14 1990

CONCLUSIONS:

Freezer Storage Stability - Ancillary Study

1. Freezer storage stability studies are not specifically required by Subdivision N guidelines.

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

3. Other points that need to be addressed include metalaxyl and soil characterization (see REVIEWERS COMMENTS for details).

METHODOLOGY:

Samples (50 g) of soil (uncharacterized) taken from the upper 6-inch soil depth were placed into screw cap jars and treated at 0.5 ppm with solutions of either metalaxyl (-uncharacterized) or CGA-62826. After the solvent (unspecified) was allowed to evaporate, the jars were capped and stored frozen at -15 ± 5°C for 0, 3, or 7 months.

The frozen soil samples, along with freshly treated controls, were analyzed using Ciba-Geigy Method AG-323, as described in the field dissipation experiment. After the soil was transferred to the centrifuge bottle, the jar was rinsed three times with 50% aqueous methanol into the centrifuge bottle and analyzed as described previously. The residue levels were corrected for procedural recoveries (<100%), which were determined by analyzing a freshly fortified soil sample at 0.5 ppm at each sampling interval.

DATA SUMMARY:

The recovery of metalaxyl from fortified soil (uncharacterized) treated with either metalaxyl (uncharacterized) or its degradate, CGA-62826 at 0.5 ppm and stored frozen for up to 7 months at -15°C ranged from 81 to 107% and 104 to 123%, respectively (Tables 5 and 9). No definitive relationship could be established between recoveries of metalaxyl and length of frozen storage, due to an anomaly noted in the 7-month soil sample; recoveries were lowest at 3 months and highest at 0 days. Recoveries from frozen soil that was treated with CGA-62826 appeared to be related to length of frozen storage; the lowest recovery was measured at 7 months and the highest at 0 days.

REVIEWERS COMMENTS:

1. The metalaxyl was not characterized; the purity of the test substance was not reported and it was not specified whether the metalaxyl was radiolabeled.

2. The soil was not adequately characterized; it was only stated that the soil samples were taken from the 0- to 6-inch soil depth.

3. The study author stated that at the 7-month sampling interval, an anomaly was observed for the freshly fortified sample containing metalaxyl and could not be used in correcting the value of the old spikes; a set of contingency samples was used instead. EFGWB would like more details as to what transpired at the 7-month sampling interval.

4. The study author stated that sampling intervals were at 0 day, and at 3, 6, 9 and 12 months following frozen storage; however, no data were provided for the 9- and 12-month sampling intervals, and the 6-month sampling interval was changed to a 7-month sampling interval. EFGWB would like to see all the data related to freezer storage stability.

5. The field dissipation portion of this study is unacceptable because the data were too variable to accurately assess the dissipation of metalaxyl on soil. In the 0- to 6-inch depth of silt loam soil treated with a 5% G formulation at 3 lb ai/A, metalaxyl concentrations were highly variable in all three replicates, with no clear pattern of decline. In two of these replicates, maximum concentrations of metalaxyl (0.86 and 0.84 ppm) occurred at either 14 or 122 days posttreatment. In addition, the measured initial application rate (1.66 lb ai/A) was only 55.4% of the theoretical application rate of 3 lb ai/A, and its variability indicates that the applications were not even.

Metalaxyl Sha # 113501

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