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

JUL 9 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Metalaxyl Registration Standard (FRSTR)

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Enclosed find the EAB Phase II document for Metalaxyl. All studies previously reviewed were reviewed again for this FRSTR Standard. Several categories accepted as satisfying EAB Data Requirements under the previous standard are no longer acceptable for current guideline requirements (See tables). In addition, the ground water issue has not yet been adequately resolved (see attached review) and further monitoring studies will be required.

METALAXYL

REGISTRATION STANDARD

(FRSTR)

Final Report

Metalaxyl is a fungicide sold as Ridomil, Subdue, Apron and Proturf. It is also sold as a combination with mancozeb, chlorothalonil, pentachloronitrobenzene and triadimefon. It is formulated as G, P/T, WP, EC and FLC. It is used on tobacco, ornamentals, turf, citrus, fruit, nonbearing nursery stock, seed treatment, vegetables and peanuts. Metalaxyl is applied to soil or foliage. Application rates range from 0.135 - 8.0 lb ai/acre. Multiple applications (varying with use) are approved.

The 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 EAB guidelines. Studies for three data categories that were previously accepted were found to be inadequate. In addition, the ground water issue has not yet been adequately resolved (see attached review) and further monitoring studies will be required. No PIMS information is available.

EXECUTIVE SUMMARY - Previously reviewed studies re-reviewed for current EAB guidelines.

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

Metalaxyl was also found to be stable to photodegradation on soil. A silty loam soil was fortified with ^{14}C-Metalaxyl to 10 ppm and exposed to xenon arc lamp with IR and UV filters which simulated the spectrum of natural sunlight but at twice the intensity. The results indicated no difference between the degradation of the irradiated sample and the control sample (residues degraded at a rate comparable to the aerobic metabolism study).

The aerobic soil metabolism halflife of metalaxyl was determined to be about 40 days. The only major degradate was CGA-62826 identified as N-(2,6-dimethylphenyl)-N-(2'methoxyacetyl)~~a~~niline. This in turn breaks down to non-extractable material and CO_2. CGA-62826 accumulates to 53.6% of the applied at 66 days and thereafter degrades to 23% of the applied at 360 days. A polar fraction is found between 6 and 12 months at levels of 3.7-4.8% of the applied. At 12 months, metalaxyl parent accounts for less than 2% of the applied and nonextractable residues account for 38.3% of the applied.

The aerobic soil degraded parent metalaxyl to 60% of the applied at 31 days, afterwhich anaerobic conditions were established. At 66 days, the parent declined to 49.4% and at 89 days it had declined to 32.5%. The major degradation product was CGA-62826 which accumulated to 52.4% of the applied at 89 days (the last sample of the experiment). CO_2 was not a major degradation pathway and non-extractables did not exceed 10% of the applied.

Both metabolism studies used a clay loam soil (83.8% sand, 7.3% silt, 8.9% clay, 2.2% OM, CEC 11.3 meq/100 g, pH 6.5) and was fortified with ring-labeled ^{14}C-metalaxyl at 10 ppm. For anaerobic studies, the treated soil was aged for 30 days and then brought to anaerobic conditions. The temperature was kept at 25 C.

Parent ^{14}C-metalaxyl leached rapidly in sand soils with up to 92% of the radioactivity recovered in the leachate. In the sandy clay loam, the majority of the radioactivity was recovered in the 6-12 cm soil layers with less than 0.4% in the leachate. In the silt loam soil, the majority of the radioactivity was recovered in the 16-24 cm soil layers

with 0.6% recovered in the leachate. Soil column leaching was studied with metalaxyl 50WP containing 1% radiolabeled parent applied at 5 kg ai/ha (4.5 lb ai/A). Over a two day period, 200 mm of water was applied to the tops of the 30 cm soil columns. Four columns were used containing sand, sand, silt loam and sandy clay loam soils.

In aged leaching experiments, 79.2% of the applied radioactivity was found in the leachate and 16.1% remained in the soil in the sand soil column. Of the activity found in the leachate, 56% was parent, 31% was CGA-62826, 1% was an unknown polar degradate and 12% was unaccounted for. In the silt loam soil, 48.7% was in the leachate and 34.9% remained in the soil. Of the activity found in the leachate, 70% was parent, 18% was CGA-62826, 1% was the unknown polar metabolite and 11% was unaccounted for. In this experiment, phenyl-labeled ^{14}C-metalaxyl was added to sand and silt loam soils and aged for 30 days. Aliquots of these soils were then placed on 28 cm soil columns. One-half inch of water was then added to the columns daily for 45 days.

Adsorption/Desorption studies using ^{14}C-metalaxyl demonstrated Kads (ug adsorbed per g of soil) values of 0.43, 0.48, 0.87 and 1.40 for sand, sand, silt loam, and sandy clay loam soils. The soils were the same as those used in the soil column leaching studies.

Volatilization experiments demonstrated that less than 0.5% of the applied metalaxyl would be lost due to volatilization. The volatilization rate is directly proportional to the initial soil concentration of metalaxyl, the soil temperature, and the air flow rate across the soil surface. It is inversely proportional to greater soil adsorption capacities. These experiments utilized both unlabeled and labeled ^{14}C-metalaxyl.

The field dissipation half-life of metalaxyl was shown to be about 2 weeks. CGA-62826 was the major degradation product, peaking during the first month at about 20% of the initial activity and then declining to 0.5% of the applied at 1 year. Nonextractable activity increased to about 25% of the initial dose in the first 3-4 months and then declined to half of that level at one year. Two additional minor degradates were less than 1% of the applied. Radioactivity not accounted for was presumably lost to $^{14}CO_2$ production and/or leaching beyond the sampling depth (30 cm). In this study, ring labeled ^{14}C-metalaxyl was applied at an equivalent rate of 3.65 lb ai/A using the 50WP formulation. The Swiss plot (65.8% sand, 17.3% silt, 16.9% clay, 2.5% OM, and pH 6.9) was sampled at 0, 33, 54, 81, 103 and 355 days post-application.

Fish accumulation was found not to exceed 7X when exposed to metalaxyl at 1 ppm in water. Residues were found to accumulate in the non-edible portions over the edible portions in a ratio range of 4:1 to 15:1. Residues declined rapidly during depuration. The low levels of accumulation did not permit identification of the residues. In this study, bluegill fish were exposed to ^{14}C-metalaxyl at a level of 1 ppm in a continuous flow system for 29 days.

A separate fish accumulation study using catfish showed accumulation of 1X and rapid depuration.

Rotational crop uptake was studied using ^{14}C-metalaxyl. Crops were planted from 33 weeks to 36 weeks after the last of six applications at 0.4 lb ai/acre at 14-day intervals.

Lettuce total ^{14}C-residues reached a peak of 0.11 ppm during the early growth periods of sampling and declined to 0.06 ppm at 9 weeks of growth. These levels were found in the whole plant (Fischer, Cassidy 1978; 0082).

Spring oats total ^{14}C-residues reached a peak of 0.33 ppm during the early periods of sampling and declined to 0.21 ppm at 11 weeks of growth. These were whole plant residues (Fischer, Cassidy, 1979).

Corn did not take up ^{14}C-residues in excess of 0.06 ppm in any plant part during growth through maturity (Fischer, Cassidy).

Soybeans did take up ^{14}C-residues of 0.2 - 0.8 ppm (calculated) as parent compound (Hamilton, Fischer, Cassidy, 1979).

Sugarbeets did take up ^{14}C-residues at levels of 0.16 ppm at 6 weeks growth, but this level dropped to 0.02 ppm at 20 weeks and will probably be even lower at maturity (Hamilton, Fischer, Cassidy, 1979).

Rotational crop uptake (Ciba-Geigy Corp., 1979; 0129) was studied using unlabeled metalaxyl applied at 0.5 to 1.0 lb. ai/acre six times weekly to potatoes or a single 3 - 6 lb application to tobacco. It is not known if residues available for pick up by rotational crops will be different due to a single large application or six weekly small applications.

Winter wheat planted in rotation to potatoes did pick up residues even when the wheat is planted 13 1/2 months (early forage '78) after the last treatment:

Crop	Treatment to sampling	Total Residue, ppm	
		0.5 lb ai/A	1.0 lb ai/A
Early Forage '77	68	1.0	1.5
Spring Forage	287	0.27	0.61
straw	336	0.56	1.10
grain	336	0.19	0.44
Early Forage '78	448	0.09	0.09

Field corn planted in rotation to potatoes treated at 1.0 lb. ai/A accumulated 0.2 ppm residues at 5 weeks growth and less than 0.05 ppm at 9 weeks. The rotation interval was 10 months.

Sugarbeets planted in rotation to potatoes 10 months after treatment. Results indicate accumulatation in forage and less than 0.05 ppm in roots:

Crop	Treatment to sampling	Total Residue, ppm	
		0.5 lb ai/A	1.0 lb ai/A
Early Forage	326	0.21	0.73
Late Forage	414	0.08	0.33
Roots	414	<0.05	<0.05

Soybeans planted 10 months after treatment accumulated 0.83 ppm (0.5 lb. application) or 2.7 ppm (1.0 lb. application) total residues in the forage. The treatment to sampling interval was 326 days.

Soybeans were planted 13 months after a single application at either 3 or 6 lb. ai/A of metalaxyl to tobacco. Harvest was at either 1 1/2 or 5 months growth.

Crop	Treatment to sampling	Total Residue, ppm	
		3.0 lb ai/A	6.0 lb ai/A
Forage	437	0.45	1.3
Fodder	539	0.15	0.54
Beans	539	0.05	0.14

Soybeans were planted 13 1/2 months after a single application at either 3 or 6 lb ai/A of metalaxyl to tobacco and harvested at 2 and 4 1/2 months growth.

Crop	Treatment to sampling	Total Residue, ppm	
		3.0 lb ai/A	6.0 lb ai/A
Forage	481	0.29	0.25
Fodder	552	1.4	0.40
Grain	552	0.35	0.49

Corn was planted 12 months after a single application at either 3.0 or 6.0 lb. ai/A to tobacco and harvested at 2 and 5 months of growth.

Crop	Treatment to sampling	Total Residue, ppm	
		3.0 lb ai/A	6.0 lb ai/A
Silage	430	<0.05	0.06
Fodder	526	<0.05	<0.05
Grain	526	<0.05	<0.05

Sweet potatoes were planted 13 months after a single application of metalaxyl at either 3.0 or 6.0 lb. ai/A to tobacco and were harvested at 3 and 6 months growth.

Crop	Treatment to sampling	Total Residue, ppm	
		3.0 lb ai/A	6.0 lb ai/A
Early foliage	481	0.12	0.06
Roots	569	<0.05	<0.05
Tops	569	<0.05	<0.05

The rotational crop data demonstrate 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 to 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 potatoe foliage). Sweet potatoe roots, corn grain, and sugarbeet roots had less than 0.05 ppm residues, however the method sensitivity needs to be about 0.02 ppm. Until adequate data are received, a 12 month rotational crop interval should be imposed for all crops for which tolerances have not been established.

RECOMMENDATIONS

The following data are required (EPA Data Requirements for Registering Pesticides) where indicated to fully assess the environmental fate of metalaxyl:

Hydrolysis studies: This requirement is satisfied; no data are required. (00104493)

Photodegradation studies on soil: This requirement is satisfied; no data are required. (00100456)

Photodegradation studies in water: This requirement is not satisfied because the submitted study (00100457) did not use a light source that adequately simulated natural sunlight. All data are required.

Photodegradation studies in air: No data were submitted; however, no data are required based on the use pattern of metalaxyl.

Aerobic soil metabolism studies: This requirement is satisfied; no data are required. (104494)

Anaerobic soil metabolism studies: This requirement is satisfied; no data are required. (104494)

Anaerobic aquatic metabolism studies: No data were submitted; however, no data are required based on the use pattern of metalaxyl.

Aerobic aquatic metabolism studies: No data were submitted; however, no data are required based on the use pattern of metalaxyl.

Leaching and adsorption/desorption studies: This requirement is satisfied; no data are required. (00100464, 00100465, 00100466)

Laboratory volatility studies: This requirement is satisfied; no data are required. (00100455)

Field volatility studies: No data were submitted; however, based on the low laboratory volatility and on the use pattern of metalaxyl, no data are required.

Terrestrial field dissipation studies: This requirement is not satisfied by the submitted data (00100459) because the field leaching characteristics of metalaxyl were not adequately addressed. Residues were found in the lowest soil layers and it is unknown what residues may have leached to deeper levels. All data are required.

Aquatic field dissipation studies: No data were submitted; however, no data are required based on the use pattern of metalaxyl.

Forestry dissipation studies: No data were submitted; however, no data are required based on the use pattern of metalaxyl.

Dissipation studies for combination products and tank mix uses: No data were submitted; however, no data are required because data requirements for combination products and tank mix uses are currently not being imposed for this standard.

Long-term field dissipation studies: No data were submitted, no data are required based on the rapid dissipation of metalaxyl in field soils.

Confined accumulation studies on rotational crops: No data were submitted; however, all data are required. The ^{14}C-labeled studies that were submitted are not considered confined because of the large unconfined area of application and because the studies did not specifically identify parent and degradate residues. These studies were classified as field studies. Confined studies should include a confined area of application and specifically identify individual residues.

Field accumulation studies on rotational crops: This requirement is not satisfied because the submitted studies (00104376, 00104381, 00104382, 00104383, 00104384, 00104385) did not demonstrate rotational intervals at which accumulation did not occur. Method sensitivity should be about 20 ppb for residues identified in a confined study. Tolerances must be established when significant residues are detected at 12 months.

Accumulation studies on irrigated crops: No data were submitted; however, no data are required based on the use pattern of metalaxyl.

Laboratory studies on pesticide accumulation in fish: This requirement is satisfied; no data are required. (00100468, 00100470)

Field accumulation studies on aquatic nontarget organisms: No data were submitted; however, no data are required based on the use pattern of metalaxyl.

Reentry studies: No data were submitted; however, no data are required based on the moderate toxicity of metalaxyl.

Protective clothing: This will be addressed in the label improvement program.

Spray drift: These studies are not required based on the

moderate toxicity of metalaxyl.

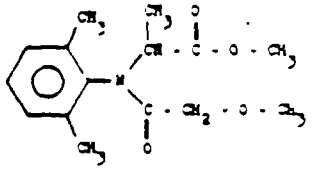
Ground water monitoring and laboratory leaching studies: The data submitted on ground water monitoring (see attached review) are inadequate. The results of the studies indicate that some parent residues reached ground water. The laboratory adsorption/desorption studies indicate that parent compound can readily leach in sand, silt loam and sandy clay loam soils. In the laboratory column leaching study, parent plus the CGA-62826 degradate leached in sand and silt loam soils. Also, both parent and CGA-62826 were shown to be sufficiently persistent in laboratory studies to have potential to reach ground water. New monitoring studies that conform to current study requirements will be needed. Notification of the type of studies and sites will be made within 90 days of issuance of this Standard.

Ground Water Advisory: Residues of metalaxyl can seep or leach through soil and can contaminate ground water which may be used as drinking water. Users are advised not to apply metalaxyl where the water table (ground water) is close to the surface and where the soils are very permeable, i.e., well-drained soils such as loamy sands. Your local agricultural agencies can provide further information on the type of soil in your area and the location of ground water.

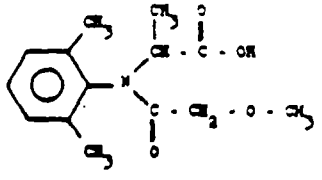
Label Restrictions:

Based on currently available data, it is recommended that crops other than those with established tolerances be restricted from being planted in metalaxyl treated soils for a period of 12 months after application.

APPENDIX



CGA 48988, N-(2,6-dimethylphenyl)-N-(2'-methoxyacetyl)-alanine methylester



CGA [illegible], N-(2,6-dimethylphenyl)-N-(2'methoxyacetyl)-alanine

00104376 Ballantine, L. (1979) Rotational Crop Data Submitted in Support of Conditional Registration for Ridomil (Metalaxyl) Use on Tobacco: Report No. ABR-79099. (Unpublished study received Oct 31, 1979 under 100-607; submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:241243-A)

00104493 Burkhard, N. (1976) Hydrolysis of CGA-48988 under Laboratory Conditions: Project Report 26/76. (Unpublished study received Jul 13, 1978 under 100-EX-62; prepared by Ciba-Geigy, Ltd., Switz., submitted by Ciba-Geigy Corp., Greensboro, NC; CDL: 234438-C)

00100455 Burkhard, N. (1977) Volatilization of CGA-48988 from Soil under Laboratory Conditions: Project Report 29/77. (Unpublished study received Apr 26, 1979 under 100-600; prepared by Ciba-Geigy, Ltd., Switzerland, submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:238231-D)

00100456 Burkhard, N. (1978) Photolysis of CGA-48988 (Ridomil) on Soil Surfaces under Artificial Sunlight Conditions: Project Report 09/78. (Unpublished study received Apr 26, 1979 under 100-600; prepared by Ciba-Geigy, Ltd., Switzerland, submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:238231-E)

00100457 Burkhard, N. (1979) Photolysis of CGA-48988 (Ridomil) in Aqueous Solution under Artificial Sunlight Conditions: Project Report 12/79. (Unpublished study received Apr 26, 1979 under 100-600; prepared by Ciba-Geigy, Ltd., Switzerland, submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:238231-F)

00100459 Ellgehausen, H. (1977) Distribution and Degradation of CGA 48 988 (Ridomil) in a Field Soil: Project Report 55/77. (Unpublished study received Apr 26, 1979 under 100-600; prepared by Ciba-Geigy, Ltd., Switzerland, submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:238231-H)

00104494 Ellgehausen, H. (1977) Distribution of the Non-extractable Radioactivity between Different Soil Organic Matter Fractions of a Field Soil Treated with 14C-labeled CGA 48988 (Addendum to Project Report 55/77): Project Report 56/77. (Unpublished study received Jul 13, 1978 under 100-EX-62; prepared by Ciba-Geigy, Ltd., Switz., submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:234438-G)

00104381 Fischer, W.; Cassidy, J. (1978) Uptake and Characterization of [Phenyl]-14C-CGA-48988 and Its Soil Metabolites in Rotation Lettuce, M6-69-8PR, 8SR: Report No. ABR-78078. (Unpublished study received Oct 31, 1979 under 100-607; submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:241243-G)

00104382 Fischer, W.; Cassidy, J. (1979) Uptake and Characterization of [Phenyl]-14C-CGA-48988 and Its Soil Metabolites in Field Rotation Spring Oats, M6-69-4PR, 4SR: Report No. ABR-79002. (Unpublished study received Oct 31, 1979 under 100-607; submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:241243-H)

00104383 Fischer, W.; Cassidy, J. (1979) Uptake and Characterization of ♦Phenyl|-14C-CGA-48988 and Its Soil Metabolites in Field Rotation Corn, M6-69-6PR, 6SR: Report No. ABR-79004. (Unpublished study received Oct 31, 1979 under 100-607; submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:241243-I)

00100464 Guth, J. (1976) Leaching Model Study with the Fungicide CGA-48988 in Four Standard Soils: Project Report 30/76. (Unpublished study received Apr 26, 1979 under 100-600; prepared by Ciba-Geigy, Ltd., Switzerland, submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:238232-A)

00100465 Guth, J. (1978) Leaching Characteristics of Aged 14C-CGA 48988 (Ridomil) Residues in Two Standard Soils: Project Report 33/78. (Unpublished study received Apr 26, 1979 under 100-600; prepared by Ciba-Geigy, Ltd., Switzerland, submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:238232-B)

00100466 Guth, J. (1978) Adsorption and Desorption of CGA 48988 (Ridomil) in Various Soil Types: Project Report 35/78. (Unpublished study received Apr 26, 1979 under 100-600; prepared by Ciba-Geigy, Ltd., Switzerland, submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:238232-C)

00104384 Hamilton, T.; Fischer, W.; Cassidy, J. (1979) Uptake and Characterization of ♦Phenyl|-14C-CGA-48988 and Its Soil Metabolites in Field Rotation Soybeans, M6-69-7PR, 7SR: Report No. ABR-79003. (Unpublished study received Oct 31, 1979 under 100-607; submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:241243-K)

00104385 Hamilton, T.; Fischer, W.; Cassidy, J. (1979) Uptake and Characterization of ♦Phenyl|-14C-CGA-48988 and Its Soil Metabolites in Field Rotation Sugar Beets, M6-69-5PR, 5SR: Report No. ABR-79005. (Unpublished study received Oct 31, 1979 under 100-607; submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:241243-L)

00100470 Ladd, S.; Enos, J. (1979) Kinetics of ♦Phenyl|-14C-CGA in a Model Aquatic Ecosystem: Report #BW-79-2-401. (Unpublished study received Apr 26, 1979 under 100-600; prepared by EG & G, Bionomics, submitted by Ciba-Geigy Corp., Greensboro, NC; CDL: 238232-G)

00100468 Ladd, S.; Wilson, W. (1979) Accumulation and Elimination of 14C-residues by Bluegill Sunfish ... Exposed to 0-14C-CGA-48988: Report #BW-78-10-328. (Unpublished study received Apr 26, 1979 under 100-600; prepared by EG & G, Bionomics; submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:238232-E)

TABLE A
GENERIC DATA REQUIREMENTS FOR METALAXYL

Data Requirement	Composition[1/]	Use Pattern[2/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframes for Data Submission[3/]
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B	Yes	00104493	No
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,B	No		Yes
161-3 - On soil	TGAI or PAIRA	A	Yes	00100456	No
161-4 - In Air	TGAI or PAIRA		No		No[4/]
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	Yes	104494	No
162-2 - Anaerobic Soil	TGAI or PAIRA	A	Yes	104494	No
162-3 - Anaerobic Aquatic	TGAI or PAIRA		No		No[4/]
162-4 - Aerobic Aquatic	TGAI or PAIRA		No		No[4/]
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B	Yes	00100464 00100465 00100466	No
163-2 - Volatility (Lab)	TEP	A	Yes	00100455	No
163-3 - Volatility (Field)	TEP	A	No		No[4/]

TABLE A
GENERIC DATA REQUIREMENTS FOR METALAXYL

Data Requirement	Composition[1/]	Use Pattern[2/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframes for Data Submission[3/]
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,B	No		Yes[3/]
164-2 - Aquatic (Sediment)	TEP		No		No[4/]
164-3 - Forestry	TEP		No		No[4/]
164-4 - Combination and Tank Mixes	TEP		No		No[5/]
164-5 - Soil, Long-term	TEP	A	No		No[6/]
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes[3/]
165-2 - Rotational Crops (Field)	TEP	A	Partially	00104376 00104381 00104382 00104383 00104384 00104385	Yes[7/]
165-3 - Irrigated Crops	TEP		No		No[4/]
165-4 - In Fish	TGAI or PAIRA	A,B	Yes	00100468 00100470	No
165-5 - In Aquatic Nontarget Organisms	TEP		No		No[4/]

TABLE A
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Data Requirement	Composition[1/]	Use Pattern[2/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframes for Data Submission[3/]
158.142 Spray Drift					
202-1 - Drift Field Evaluation	TEP	A,B	No		No[8/]
201-1 - Droplet Size Spectrum	TEP	A,B	No		No[8/]
Monitoring Studies					
Ground Water Monitoring Studies			No		Yes[9/]

TABLE A
GENERIC DATA REQUIREMENTS FOR METALAXYL

FOOTNOTES:

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframes, which begin on the date of the Guidance Document (see front cover for this date).

4/ Not required based on the use pattern of metalaxyl.

5/ Tank mix data requirements are not being imposed by this standard.

6/ Soil long term study is not required because of the rapid dissipation rate of metalaxyl.

7/ Data are required based on data showing (unidentified) residues to accumulate.

8/ Data are not required based on the moderate toxicity of metalaxyl.

9/ Notification of types of studies and sites will be made within 90 days of issuance of this standard. The time limit for submission of the studies will be indicated at that time.

TABLE A
GENERIC DATA REQUIREMENTS FOR METALAXYL

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Da Be Submitted Under FIFRA § 3(c)(2)(B) Time frames for I Submission[3]
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	AB	No		No
132-1 - Soil Dissipation	TEP	AB	No		No
133-3 - Dermal Exposure	TEP	AB	No		Conditional[4]
133-4 - Inhalation Exposure	TEP	AB	No		Conditional[4]

1. TEP = Typical end-use product
2. The use patterns are coded as follows: A=Terrestrial Food Crop; B=Terrestrial Non-Food Crop; C=Aquatic Food Crop; D=Aquatic Non-Food; E=Greenhouse Food Crop; F=Greenhouse Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3. Data must be submitted no later than _____.
4. Human-exposure monitoring data may be submitted at the Registrant's option. If Dermal Exposure data are submitted Inhalation Exposure data must also be submitted

7. CONCLUSIONS:

Groundwater monitoring wells in all three locations were inadequately described. Florida results 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. Still, 2 of 67 samples showed positive results, 3.1 (confirmed at 3.3) and 4.7 ppb. (also confirmed). For North Carolina and Oregon results, two years of approximately monthly samples from three wells at each location show no positive results, supporting the hypothesis that metalaxyl may not be traversing off-site at this locations. Still, wells were inadequately described (see Discussion Section), and water table depths described at 40-140 ft in Oregon are at the far end of a definition of "shallow" water tables.

Surface water monitoring in the Sacramento River, California, showed seasonal concentrations of metalaxyl in two of three years of bi-monthly sampling. 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. 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, with a range of 0.25-0.43 ppb.

Samples from tap water which obtained water from the Sacramento River showed no positive residues in three years of sampling.

Surface and ground water monitoring results from these studies are included as attachments to this review.

8. RECOMMENDATIONS:

In the future, evaluation of ground water studies should begin with an evaluation of well selection. If a complete well description is unavailable, then no conclusions or hypothesis can be generated from the data. Important information that must be available include: depth of water table, depth of well screen (and length of well screen, if possible), and proximity to field using the pesticide. Also, some discussion on history of pesticide use on the field and gradient of water table (i.e., direction of ground water flow) with respect to the field and the well is desirable.

Attachments 1 and 2, referenced by CIBA-GEIGY in their report which described in more detail the Florida and Oregon well sites, were not included with this submission and should be obtained from the registrant.

Results of these studies should be retained in EAB files for future reference. High positive results in one well in Florida

used for chemigation illustrate the possibility of high residues remaining in irrigation wells following chemigation.

9. BACKGROUND:

This data was voluntarily submitted in December of 1985 for no specific purpose except, as put by Karen Stumpf of CIBA-GEIGY in the cover letter with these submissions, "These data are submitted to provide the Agency with additional data on the presence of agricultural chemicals in ground and surface water."

10. DISCUSSION

Three wells located on the property of Southern Citrus Nurseries, Inc. in Dundee, Florida, were sampled between 1983 and 1985. A fourth well, in Avon City, was monitored in 1984 and 1985. Information on precisely where the water was being extracted (i.e., well screen depth) was not available. Information provided for the three wells in the Southern Citrus Nurseries include: well depth: 660 - 852 ft, casing depth: 203-231 ft, and static water level: 105-146 ft. For the fourth well in Florida, information provided was that the water table is shallow, 40-50 feet, and that the well depth is 438 ft. It is assumed that the casing depth is the depth to which water samples are extracted for the first three wells, but there is no analagous assumption for the fourth well.

Of 67 samples extracted from the four wells in the three years of study, only 2 showed positive results: 3.1 and 4.7 ppb. Both results were verified. This low frequency of positive results is not unexpected, given the depth of water table, >100 feet, and the depth of water extraction, >200 feet. In another extensive monitoring study of deep wells in Florida in which 800 samples were extracted from approximately 400 deep wells in search of a different leaching pesticide, no positive results were found. The hydrogeology of Florida is such that shallow unconfined aquifers above confined aquifers receive the leaching pesticides, and rural shallow wells tapping the surficial aquifers are the most sensitive. None of the wells sampled for metalaxyl in this monitoring program can be considered rural, shallow wells.

The location of these two sites is above the Floridan Aquifer, the principal aquifer of Florida. In most locations, the Floridan is confined and deep. However, the two sites are, in fact, located in areas of recharge to the Floridan where there isn't any known clay confining layer restricting flow from the surface to the Floridan Aquifer (this information is from a map entitled, "Areas of Natural Recharge to the Floridan Aquifer in Florida", by J.W. Stewart, prepared by USGS, Map Series 98, Tallahassee, Florida). From this perspective, the choice of sites was very appropriate. Still, the monitoring in Florida did not examine the more hydrogeologically sensitive scenario (leaching to shallow surficial

aquifers), and the conclusion on p. 6 of the ground water submission, "Ridomil is not expected to cause adverse effects through movement to the ground water under normal agricultural use conditions" is not warranted for the Florida monitoring.

One well showed unusually high readings of 29-226 ppb Metalaxyl. This was found to be the result of sampling from the injection port of the irrigation well used for chemigation. When sampling through the coolant line of the same well, there were no positive results. The most important use of this data may be to illustrate the possible contamination of well water when chemigation is practiced.

The North Carolina wells were inadequately described. Distance from a treated field was noted at 100-200 feet. However, description of the three wells was inadequate: "The wells are primarily used for irrigation, and the estimated depth of water table in the three wells is 40-50 ft." Water tables do not exist in wells. The water level in the well is roughly equivalent to the depth of the water table if the well is tapping an unconfined aquifer. However, the water level in the well can be much higher than the depth of the water table if the well is tapping a confined aquifer, and artesian pressure forces water up the well. Without more precise information on the three wells, there is no valid conclusion or hypothesis concerning leaching of metalaxyl that can be generated from the North Carolina negative results.

The Oregon well sites were apparently directly on the hops fields in which Metalaxyl was applied for same three years of sampling, 1983-1985 (and not before 1983). However, again, there was no information of well screen depth, but rather estimated water table depth, which was 40-50 ft for one well, 60 ft for another well, and 120-140 ft for the third well. Without knowing precisely where the water samples were extracted, one cannot say that the metalaxyl did not reach the aquifer - only that the metalaxyl did not reach the well screen.

Finally, there was a few minor points of sloppiness in the reporting of data by CIBA-GEIGY, including:

1) Dundee is not in Highlands County, Florida, but rather in Polk County, Florida.

2) The cover letter to these reports inaccurately states, "Results show no detectable residues of metalaxyl at the screening levels of 0.25-1.0 ppb during the entire monitoring period, from May, 1983 - May, 1985". In fact, there were 2 positives of 67 samples in the Florida ground water sampling that were not due to sampling of the chemigation injection port.

3) The "Results and Discussion" section of the report made mention of only one of these two positive results, and the "Conclusions" section, like the cover letter, claimed that there were "no detectable residues of metalaxyl at the screening levels of 0.25-1.0 ppb". The summary table lists the second positive

result, and the raw data accompanying the report lists this second positive, as well as it's confirmation.

The surface water sampling was conducted in the Sacramento River, one mile from the confluence with the San Joaquin River. Sampling occurred between January, 1983, and July, 1985 in both the river near the river bank where the water was flowing, and out of a tap whose water originated from the river. The tap water never showed positive results. Samples from the Sacramento River did not show positives the first year of sampling, but positives regularly showed up in the spring, summer, and fall months of the next two years of sampling. In the second year, between March and September, 14 samples were taken, 8 were positive with a range of 0.97 to 3.5 ppb and a mean of 1.6 ppb. In the third year, 10 samples were extracted between March and July, 5 were positive with a range of 0.25 to 0.43 and a mean of 0.32 ppb (method sensitivity of 0.25 ppb). It can be concluded that in two of three years of sampling, metalaxyl appeared in surface waters during the spring and summer, most likely a result of surface runoff. Degradation and/or removal of the residues occurred by the time Sacremento River water appeared in the tap.

Page 25 is not included in this copy.

Pages _____ through _____ are not included in this copy.

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.

__X_ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

___ Internal deliberative information.

_____ Attorney-Client work product.

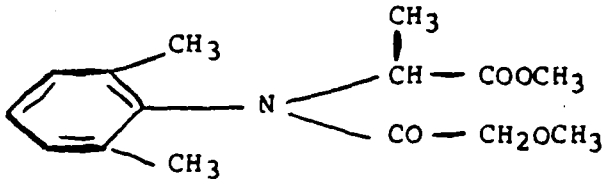
_____ Claimed Confidential by submitter upon submission to the Agency.

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.

EVALUATION OF GROUND AND SURFACE WATER MONITORING STUDIES FOR METALAXYL

1. CHEMICAL:

Chemical name: N-(2,6-Dimethylphenyl)-N-(methoxyacetyl)-alanine methyl ester
Common name: Ridomil
Structure:



2. TEST MATERIAL:

not applicable

3. STUDY/ACTION TYPE:

Evaluation of ground and surface water monitoring studies conducted by Ciba-Geigy on Metalaxyl between 1983 and 1985.

4. STUDY IDENTIFICATION:

Title: Ridomil Groundwater Monitoring Study Results During 1983 and 1984 (Accession No: 260857)
Summary of Metalaxyl Surface Water Monitoring for 1983-1985 (Accession No: 260856)
Author: K. Balu (groundwater)
R. H. Ross and K. Balu (surface water)
Submitted by: Ciba-Geigy Corporation
Agricultural Division
P.O. Box 18300
Greensboro, NC 27419
Issue Date: Dec. 12, 1985
Identifying No: 100-601

5. REVIEWED BY:

Matthew N. Lorber, Agricultural Engineer Matthew Lorber Date 9/30/86
Environmental Processes and Guidelines Section/EAB/HED

6. APPROVED BY:

Carolyn K. Offutt, Chief Carolyn K. Offutt Date 9/30/86
Environmental Processes and Guidelines Section/EAB/HED

Page _____ is not included in this copy.

Pages __27__ through __38__ are not included in this copy.

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.

__X__ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

__ _ __ Internal deliberative information.

_____ Attorney-Client work product.

_____ Claimed Confidential by submitter upon submission to the Agency.

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.

Book ec/RCB

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUL 1 - 1987

MEMORANDUM

SUBJECT: Metalaxyl Registration Standard - Addendum #1
FDA Monitoring Data

FROM: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Amy Rispin
Science Integration Staff
Hazard Evaluation Division (TS-769)

and

L. Rossi
Product Manager Team # 21
Registration Division (TS-767)

Attached is addendum #1 to the metalaxyl Registration Standard which was completed by Residue Chemistry Branch on 6/22/87. This addendum was produced in-house by R. Perfetti.

This addendum refers to information on the results of monitoring of domestic and imported foods and feeds and total diet studies conducted by the Food and Drug Administration. This addendum is to be added to the Residue Chemistry chapter of the metalaxyl Registration Standard under "Regulatory Incidents".

This addendum contains no confidential information.

If you need additional information please advise.

Attachment (2 pages)

cc: A. Barton/HED
R. Gardner/TOX
L. Rossi/HFB/RD
E. Eldredge/PMSD/ISB
S. Simko/EAB
W. Boodee/RCB
R. Perfetti/RCB
SIS
Subject File
Reading File
Metalaxyl Registration Standard File
P. Lombardo/FDA
M. Cordle/FSIS, USDA

Metalaxyl Registration Standard
Residue Chemistry Chapter - Addendum #1

Regulatory Incidents

Information supplied to the Residue Chemistry Branch by the Food and Drug Administration indicates that four domestic surveillance samples of Romaine lettuce were found to contain residues of metalaxyl at the following levels; 1.2, 0.6, 0.1, and 0.15 ppm. These four positive samples were observed out of 2120 domestic and 173 imported surveillance and 16 domestic and 9 imported compliance samples of Romaine lettuce analyzed during the period FY-78 to FY-87 (to date). No other positive findings were found for metalaxyl residues in other commodities during the period in question. A total of 25,149 samples were analyzed.

Total Diet Study samples collected from April, 1982 to April, 1986 were not analyzed using methodology known to be capable of determining metalaxyl.

13544

R112620

Chemical:	**Metalaxyl**
PC Code:	**113501**
HED File Code	***11100 Other Chemistry Documents***
Memo Date:	**07/09/1987**
File ID:	**00000000**
Accession Number:	**412-05-0100**

HED Records Reference Center
08/19/2005