DATA EVALUATION RECORD

STUDY 4

CHEM 113501 | Metalaxyl | §164-1

FORMULATION--12--EMULSIFIABLE CONCENTRATE (EC)

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 Unpublished study performed by Pan-Agricultural Laboratories, Inc., Madera, CA, and ChemAlysis, Inc., Laurel, MD, and submitted by Ciba-Geigy Corporation, Greensboro, NC.

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CONCLUSIONS:

Field Dissipation - Terrestrial

1. EFGWB concludes that metalaxyl dissipated with a half-life of 50 days from the upper 6 inches of plots of sandy loam soil planted to young citrus in California following the last of three applications (3-month intervals) of metalaxyl (Ridomil 2E, 2 lb/gallon EC) at 4.4 lb ai/A (13.2 lb ai/A total).

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

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

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

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

METHODOLOGY:

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

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

DATA SUMMARY:

Metalaxyl dissipated with a registrant-calculated half-life of 50 days from the upper 6 inches of plots of sandy loam soil planted to young citrus in California following the last of three applications (3-month intervals) of metalaxyl (Ridomil 2E, 2 lb/gallon EC) at 4.4 lb ai/A/application (13.2 lb ai/A total) between May and November, 1988. In the 0- to 6-inch soil depth, metalaxyl increased from an average of 0.719-1.096 ppm at 0-1 days after the third application to an average of 2.066 ppm (maximum 2.216 ppm) at 14 days, then decreased to 1.016 ppm at 28 days, 0.385 ppm at 3 months, and 0.103 ppm at 6 months; metalaxyl was not detected (<0.02 ppm) at 9-18 months (Table I). Downward movement of metalaxyl resulted in maximum concentrations of 0.451 ppm at 28 days after the second application in the 6- to 12-inch depth, 0.212 ppm at 3 days after the third application in the 12- to 18-inch depth, 0.057 ppm at 2 months after the third application in the 18- to 24-inch depth, 0.155 ppm at 14 days after the first application in the 24- to 36-inch depth, and 0.021 ppm at 14 days after the first application in the 36- to 48-inch depth (Tables II-VI).

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

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

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

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

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

REVIEWERS' COMMENTS:

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

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

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

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

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

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

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

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

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

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

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

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

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

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