5-11-93

DATA EVALUATION RECORD

STUDY 7

CHEM	METALAXYL	164-2

FORMULATION--00--ACTIVE INGREDIENT

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 Unpublished report performed by Springborn Laboratories, Inc. Wareham, MA and Agricenter International, Inc. Memphis, TN and Submitted by Ciba-Geigy Corporation,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

DIRECT REVIEW TIME = 5

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

SIGNATURE: Richard J. Mahler

DATE: MAY 11 1993

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

SIGNATURE: Paul J. Mastradone

DATE: MAY 11 1993

CONCLUSIONS:

Aquatic Field Dissipation

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

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

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

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

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

METHODOLOGY:

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

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

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

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

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

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

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

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

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

When appropriate, least squares regression analysis was applied to natural log (ln) transformed residue data over time in order to determine if decline in residues followed a 1st-order degradation rate. If linear correlation values were >0.7, a 1st-order degradation rate was assumed and a half-life ($t_{1/2}$) was calculated.

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

STUDY AUTHOR'S DATA SUMMARY:

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

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

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

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

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

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

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

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

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

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

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

REVIEWER'S COMMENTS:

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

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

RIN-3498-95

METALAXYL 113501

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