3-11-2002

DATA EVALUATION RECORD

STUDY 10

CHEM 120603 Tetraconazole §164-1
CAS No. 112281-77-3
FORMULATION–15–SOLUBLE CONCENTRATE

STUDY ID 44865405

Hattermann, D. R. 1994. Terrestrial field dissipation of tetraconazole applied to bare ground in California and Georgia. Landis Study/Protocol No. 38023D003. Unpublished study performed by Landis International, Inc., Valdosta, GA; and submitted by SIPCAM AGRO USA, Inc., Roswell, GA.

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CONCLUSIONS

Field Dissipation - Terrestrial

1. This study is scientifically valid and provides supplemental information that tetraconazole ([2-(2,4-dichlorophenyl)-3-(1H-1,2,4-triazol-1-yl)propyl 1,1,2,2-tetrafluoroethyl ether]; Eminent 125 SL; 124.4 g ai/L) broadcast once at a nominal rate of 1.50 lbs a.i./A onto a plot of loamy sand soil in Sunsweet, GA, and a plot of sandy loam soil in Tulare County, CA, dissipated very slowly with extrapolated EFED-calculated, first order linear, half-

lives of 91 (r^2 = 0.62; nonlinear $t_{1/2}$ = 90 weeks and r^2 = 0.59) and 222 (r^2 = 0.18; nonlinear $t_{1/2}$ = 198 weeks and r^2 = 0.22) weeks, respectively. At the Georgia site, tetraconazole averaged 0.34 ppm at 0 days, ranged from 0.34 to 0.18 ppm between 3 and 360 days with no clear pattern of decline, and averaged 0.17 and 0.16 ppm at 483 and 540 days, respectively. At the California site, tetraconazole averaged 0.30 ppm at 0 days and ranged from 0.29 to 0.15 ppm between 3 and 540 days with no clear pattern of decline. Tetraconazole was <0.01 ppm at depths below 6 inches. The spray drift (petri dish) samples on both sites contained residues less than limits of quantitation (LOQ), 0.01 ppm. Tetraconazole was not detected in the soil prior to treatment, and was not detected in the control plot at any sampling interval. Precipitation plus irrigation was approximately 110% of the 30-year mean annual precipitation. The soil was analyzed only for tetraconazole.

2. This study does not meet Subdivision N Guidelines for the fulfillment of EPA data requirements on terrestrial field dissipation for the following reasons:

   A. Mean recoveries of the parent from the application monitoring dishes were low (CA: 52-74% ; GA: 53-60%; see Deficiencies/Deviations 2);

   B. Only single tetraconazole application was tested;

   E. Pan evaporation data were not provided;

   F. Degradates were not studied; and

   G. Some soils samples were not frozen but were cool or at ambient temperatures upon arrival to the laboratory (see Deficiencies/Deviations 6).

3. There were alternative terrestrial field dissipation studies conducted in Germany (MRID 44865406) and Italy (MRID 4486540) which raised an issue of different tetraconazole formulations being less persistent. Tetraconazole applied as the Eminent 40EW formulation (Emulsifiable Concentrate, 40 g a.i./L), at the rate of at 0.120 kg a.i./ha, onto bare ground in Salerano sul Lambro, Italy (MRID 44865404) dissipated with a linear half-life of 128 days (r^2 = 0.86; nonlinear $t_{1/2}$ = 41 days and r^2 = 0.71). Tetraconazole applied as M 14360 10 EC formulation (10.86% a.i.), at the rate of 0.128 kg a.i./ha, onto bare ground in four German sites dissipated with the first order overall linear half-lives ranging from 182 to 800 (an extrapolated value) days. Although, the studies were considered, they were not accepted for the purpose of tetraconazole risk assessment, as a part of Eminent 125SL registration process, because different liquid formulation of the product, the soil type, climate, and site variables contributed to high uncertainty of the studies' results.
4. No further information is needed on the terrestrial field dissipation study of tetraconazole at the present time. However, if any of tetraconazole degradate was of the human health

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or/and ecotoxicological concern, additional terrestrial field dissipation data for the degradate may be required.

MATERIALS AND METHODS

Tetraconazole [2-(2,4-dichlorophenyl)-3-(1H-1,2,4-triazol-1-yl)propyl 1,1,2,2-tetrafluoroethyl ether; Eminent 125 SL; 124.4 g a.i./L; Lot BPL-013; pp. 46, 51] was broadcast once at a nominal application rate of 1.50 lbs a.i./A onto unvegetated plots located in Georgia and California. In Sunsweet, Georgia, three replicate plots (each 19 x 85 feet; slope 1-2%) consisting of loamy sand soil (83.6-85.6% sand, 8.0-10.0% silt, 4.4-6.4% clay, 0.43% organic matter, pH 5.6-5.8, CEC 1.08-2.52 meq/100 g; Table III, p. 32) were treated on July 15, 1996 (pp. 14-15). The three plots were separated by 20-30 foot buffer zones. In Tulare County, California, one plot (3,800 sq. ft, slope <0.5%) consisting of loam soil (51.2% sand, 41.2% silt, 7.6% clay, 1.14% organic matter, pH 8.4, CEC 6.66 meq/100 g; Table IV, p. 33) was treated on May 15, 1996; the plot was treated in a single pass and divided into three end-to-end subplots with no buffers between them. At both sites, applications were made using a tractor-mounted hydraulic boom, and an untreated plot located approximately 150 feet upwind and upslope from the treated plots served as a control. To confirm the application rate, five soil-filled petri dishes placed in each subplot immediately prior to each application (p. 16). Immediately following each application, the dishes were sealed and shipped frozen to the analytical laboratory.

A five-year plot history indicated that no related compounds were previously applied to the test plots (Appendix I, II, pp. 47-48, 52). The plots were irrigated to maintain 110% of the 30-year monthly precipitation average. Environmental data were collected on-site and at weather stations located up to 19.7 miles away (p. 15; Appendix II, p. 51). Pan evaporation data were not reported.

Soil samples were collected from the Georgia site prior to treatment and at 0, 3, 14, 30, 120, 190, 240, 360, 483, and 540 days posttreatment (Table V, pp. 34-35). The 0 day samples were collected several hours following application and subsequent to irrigation. Samples were collected from the California site prior to treatment, immediately following treatment, and 3, 14, 30, 120, 181, 257, 439, 481, 540 days posttreatment (Table VI, pp. 36-37). At each sampling interval, five soil samples (two sets of five at 0 days) were randomly collected from each treated subplot using a hydraulic soil probe equipped with an acetate liner (15 cores total; p. 18). The 0- to 6-inch core (2-inch diameter) was removed first, leaving behind a metal sheath. A smaller diameter probe (0.87-1.5 inches) was then inserted through the metal sheath to collect soil in a single continuous core to a depth of 36 inches. One set of the 0 day samples was divided into 0- to 3 and 3- to 6-inch segments; the other set remained as a 0- to 6-inch segment. The deeper soil cores were divided into 6- to 12-, 12- to 18-, 18- to 24-, and 24- to 36-inch segments. Samples were stored frozen at the field facility until being shipped frozen to the analytical laboratory. The soil samples were stored frozen for up to 931 days prior to analysis (p. 27).

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The 0- to 3-, 0- to 6, 6- to 12-, and 12- to 18-inch segments were analyzed for tetraconazole (p. 73). The soils were homogenized, and subsamples (50 g) were shaken with acetone (45 minutes), then centrifuged. The supernatants were filtered through glass wool, mixed with additional acetone, and again shaken (50 minutes). The mixture was centrifuged and filtered through the glass wool, and the filtrate was collected and extracted as described. Following the third filtration, the glass wool was rinsed with acetone. The filtrate and rinse were combined and concentrated by rotary evaporation (35°C) to approximately 30 mL. The concentrate was combined with water (80 mL) in a separatory funnel, mixed with sodium chloride and methylene chloride, and shaken. The process was repeated twice. Each time, the organic phase was removed and filtered through sodium sulfate. The combined organic phase extracts were concentrated by rotary evaporation and dissolved in 2 mL of hexane:acetone (9:1, v:v; p. 71). The extracts were cleaned-up by passing through a pre-conditioned alumina column with a sodium sulfate bed. The column was eluted with hexane:acetone (9:1, v:v) followed by hexane:acetone (1:1, v:v), and the eluate was discarded. The column was then eluted with hexane:acetone (9:1, v:v) and the eluate was collected, concentrated by rotary evaporation, and reconstituted with ethyl acetate. Duplicate aliquots were analyzed for tetraconazole by GC operated according to the following conditions (pp. 74-76):

Sample date	Day 0 to 32 days posttreatment	32 days posttreatment to December 15, 1997	December 15, 1997-study completion
Instrument	HP 5890	HP 5890 Series II	HP 6890
Detector	Electron capture		
Column	SPB-1 capillary, 30 m x 530 µm, 1.5 µm film	DB-608 capillary column, 15 m x 530 µm, 0.83 µm film	
Injector temperature	260°C	200°C	
Oven temperature	230°C, isocratic	70°C for 1.5 minutes, ramp 30°C/minute to 200°C, hold for 2 minutes, ramp 50°C/minute to 250°C, hold 5 minutes	
Carrier gas	Nitrogen, 10 mL/minute	Helium, 8 mL/minute	
Detector make-up gas	Nitrogen, 50 mL/minute	Nitrogen, 45 mL/minute	
Injection volume	1-2 µL	0.5 µL	
Quantitation limit	0.01 ppm		

In a method validation study, soil samples were fortified with tetraconazole at 0.10, 10.0, and 15.0 ppm (Georgia only) and 0.01, 1.0, 1.0, and 15.0 ppm (California plots; Appendix III, Tables 1, 2, p. 86). Mean recoveries (across all fortifications) were 94 ± 9.5% and 130 ± 13.0% (1 of 4 samples outside 70-120%) for the Georgia and California plots, respectively.

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To determine concurrent recoveries, soil samples were fortified with tetraconazole at 0.01, 0.10, 0.5, 1.0, 10.0, and 15.0 ppm (Appendix III, Table 3, p. 87-88). Mean recovery (across all fortifications) of the parent was 96 ± 8.7% (range of 79 to 119%).

To confirm the application rate, the soil in petri dishes was composited by subplot and extracted as described; the extracts were analyzed by GC (SPB-1 capillary column) equipped with a ECD (Appendix III, p. 74). Mean recoveries of the parent from the application monitoring dishes were 52-74% of the applied for the California plots and 53-60% of the applied for the Georgia plots (p. 25; Tables 29, 30, pp. 115-116).

To confirm the adequacy of handling and shipping, field spikes were prepared. Tetraconazole-free samples were treated with tetraconazole at 0.10, 1.00, or 10.00 ppm, stored frozen, and shipped to the analytical laboratory with concurrently collected field samples. Samples were transported and stored (up to 917 days) in the same manner as the test samples. Data indicated that the parent was stable for up to 917 days. Mean recoveries (across all sampling intervals) of the parent were 85-119% with the exception of 76 and 79% at 125 and 369 days frozen storage (Appendix III, Table 36, pp. 122-123). Mean recovery from concurrent fortifications was 88-100%.

RESULTS/DISCUSSION

Tetraconazole [2-(2,4-dichlorophenyl)-3-(1H-1,2,4-triazol-1-yl)propyl 1,1,2,2-tetrafluoroethyl ether; Eminent 125 SL; 124.4 g a.i./L], broadcast once at a nominal application rate of 1.5 lbs a.i./A onto a plot of loamy sand soil in Sunsweet, GA, and a plot of sandy loam soil in Tulare County, CA, dissipated with observed half-lives of >360 and >540 days, respectively. Respective EFED-calculated half-lives were 633 days ($r^2 = 0.62$) and 1556 days ($r^2 = 0.18$). However, the half-lives are of questionable validity because of the very low r^2 values and because they were extrapolated beyond the scope of the observed data. Soil samples were not analyzed for degradates of tetraconazole.

Georgia loamy sand: Tetraconazole was 0.30-0.36 ppm in the 0- to 6-inch depth at 0.34 ppm at 0 days, which was several hours after application and subsequent to irrigation (Table 28, p. 114). Tetraconazole ranged from 0.12 to 0.44 ppm between 3 to 360 days (0.18-0.34 ppm average) with no pattern of decline, and was 0.13-0.20 ppm at 483 and 540 days (0.17 and 0.16 ppm average, respectively). Tetraconazole was <0.01 ppm at depths below 6 inches (Tables 16-26, pp. 102-112). Tetraconazole was not detected in the soil prior to treatment, and was not detected in the control plot at any sampling interval (Table V, p. 34). Precipitation plus irrigation was approximately 110% of the 30-year mean annual precipitation, and totaled approximately 4.2 inches during the first 2 weeks of the study, 63 inches during the first year, and 106 inches during the entire study period (Table I, p. 30)

(5)

California sandy loam: Tetraconazole was 0.28-0.31 ppm in the 0- to 6-inch depth immediately following treatment, and ranged from 0.07 to 0.37 ppm (0.15-0.29 ppm average) with no clear pattern of decline between 3 and 540 days (Table 27, p. 113). Tetraconazole was <0.01 ppm at depths below 6 inches (Tables 5-15, pp. 90-101). Tetraconazole was not detected in the soil prior to treatment, and was not detected in the control plot at any sampling interval (Table VI, p. 35). Precipitation plus irrigation was approximately 110% of the 30-year mean annual precipitation, and totaled approximately 3.4 inches during the first 2 weeks of the study, 50 inches during the first year, and 70 inches during the entire study period (Table II, p. 31)

DEFICIENCIES/DEVIATIONS

1. The study author stated that the targeted application rate of 1.50 lbs a.i./A was "more than twice the total maximum anticipated seasonal rate for agricultural uses" (p. 12). According to the registrant-submitted proposed label, the maximum seasonal usage is the curative treatment on turfgrass, 1.36 lb a.i./acre, applied via ground and aerial spray, three times in 14-day intervals (4.08 ai lb/acre per year). The proposed treatment rate for peanuts is 0.20 lb a.i./acre applied four times per season in 14-day intervals (0.8 ai lb/acre per year) and for sugarbeets 0.101 lb a.i./acre applied no more than six times in 14-day intervals.

2. Mean recoveries of the parent from the application monitoring dishes were 52-74% of the applied for the California plots and 53-60% of the applied for the Georgia plots (p. 25; Tables 29, 30, pp. 115-116). The study author attributed the difference between theoretical and observed application rates to photolysis (p. 28). Although soil photolysis appears to be the major route of tetraconazole dissipation, it is unlikely that photolysis alone would result in these low recoveries. Photolysis data indicate that tetrazonazole present in the fresh, aerobically active, soil samples exposed to sunlight degraded with a half-life of 106 days (MRID 44367004). Aerobic soil metabolism study showed that tetraconazole is metabolically stable in soil (MRID 4436700[illegible]. A further explanation of the low recovery data is required.

3. The spray deposition samples were picked up immediately following the application while the soil cores at the California site were collected minutes or hours later (with no irrigation between the application and sampling).

4. Pan evaporation data were not reported. Such data are necessary to determine water balances and to assess whether sufficient moisture was present to facilitate leaching of the test substance.

5. The soil was analyzed only for tetraconazole; the patterns of formation and decline of degradates of tetraconazole were not addressed.

6. Some soil samples were not frozen but were cool or at ambient temperatures when they arrived at the analytical laboratory. These included the petri dish samples from the California plots. The study author suggested that the lack of continuous frozen storage did not impact the study since no degradation of tetraconazole at field temperatures was observed over short periods of time.

7. At the California site, the plots were not true replicates, but rather subdivisions of a larger plot treated in a single pass of the sprayer. In Georgia, the plots were true replicates separated by 20- to 30-foot buffer zones.

8. The depth to water table was not reported for either site. Since tetraconazole was not detected below a depth of 6 inches, this omission has no impact on the interpretation of the study results.

9. The soil series names were not reported.

ATTACHMENT 1
Data Critical to the Study Interpretation

THE FOLLOWING ATTACHMENT IS NOT AVAILABLE ELECTRONICALLY
SEE THE FILE COPY

TABLE I. SUMMARY OF NATURAL PRECIPITATION AND IRRIGATION COMBINED COMPARED TO 30-YEAR PRECIPITATION AVERAGES (1967-1996) FOR THE TETRACONAZOLE FIELD DISSIPATION SITE ON BARE GROUND IN GEORGIA

DATE	MONTHLY IRRIGATION (IN.)	MONTHLY NATURAL PRECIP. (IN.)	TOTAL MONTHLY IRRIGATION AND PRECIP. (IN.)	30-YEAR MONTHLY AVERAGE PRECIP. (IN.)	110% OF 30-YEAR MONTHLY AVERAGE (IN.)
July 1996[1]	3.36	0.84	4.20	2.40	2.64
August 1996	2.01	5.83	7.84	4.82	5.30
September 1996	1.63	3.86	5.49	3.02	3.32
October 1996	0.00	3.33	3.33	2.15	2.37
November 1996	1.88	1.02	2.90	2.92	3.21
December 1996	0.00	3.74	3.74	3.79	4.17
January 1997	0.60	4.80	5.40	4.90	5.39
February 1997	0.00	7.13	7.13	4.65	5.12
March 1997	3.49	1.94	5.43	4.80	5.28
April 1997	3.38	4.06	7.44	3.78	4.16
May 1997	3.13	1.90	5.03	4.04	4.44
June 1997	4.06	1.44	5.50	4.26	4.69
July 1997	3.70	2.90	6.60	4.66	5.13
August 1997	3.11	1.54	4.65	4.82	5.30
September 1997	1.62	5.37	6.99	3.02	3.32
October 1997	0.96	8.61	9.57	2.15	2.37
November 1997	0.00	8.29	8.29	2.92	3.21
December 1997	0.00	6.31	6.31	3.79	4.17
January 1998[1]	0.00	0.02	0.02	0.95	1.04

[1] Includes data (irrigation and precipitation) from the period of July 15, 1996 (study initiation date) until July 31, 1996, and from January 1, 1998 until January 6, 1998 (date 540-day samples were collected) except for the 30-year monthly average precipitation and 110% of the 30-year monthly average which are for the entire months.

9

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Dissipation of Tetraconazole MRID#44865405

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Pages 9 through 35 are not included.

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____ Identity of product impurities.

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