DATA EVALUATION RECORD

STUDY 10

CHEM 128847 Difenoconozole §163-1
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STUDY ID 42245138
Spare, W. C. 1986. Leaching characteristics of aged CGA-169374. Laboratory Project No.: 1243. Unpublished study performed by Agrisearch Incorporated, Frederick, MD; and submitted by CIBA-GEIGY Corporation, Greensboro, NC.

DIRECT REVIEW TIME = 40 Hours

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CONCLUSIONS

Mobility - Leaching & Adsorption/Desorption

1. This study is not scientifically valid and does not provide useful information on the soil mobility (aged column leaching) of difenoconozole in loam soil. The experimental method was inadequate because the soil columns were leached with deionized, distilled water, and because the leaching required 26 days to complete.

   It is noted that this study was not conducted in accordance with Good Laboratory Practices (GLP) as specified in 40 CFR 160. The study was conducted in accordance with the EPA GLP Standards in place at the time of the study.

2. This study does not meet Subdivision N Guidelines for the fulfillment of EPA data requirements on soil mobility (column leaching) for the following reasons:

   (i) soil columns were leached with deionized, distilled water rather than the required 0.01-0.02 *N* $CaCl_2$; and

   (ii) a constant head of water was not maintained on the soil columns.

3. The soil mobility (aged column leaching) of radiolabeled [Δ-^{14}C]difenoconozole, applied at a nominal rate of 10 ppm and aged (30 days) in loam soil adjusted to 75% of 0.33 bar soil moisture content and incubated in darkness at 25 ± 1 °C, was studied in loam soil columns which were leached with deionized, distilled water over a period of 26 days. However, the results were questionable due to the leaching of the soils with deionized, distilled water rather than 0.01-0.02 *N* $CaCl_2$ solution.

   Following the soil aging period (30 days), the parent was present at 95.6% of the applied radioactivity (reviewer-calculated mean). Based on LSC analysis, most of the [^{14}C]residues retained in the soil column following leaching remained in the 0- to 1-inch depth (90.0% of the applied radioactivity). Residues were also detected in the 1- to 2-inch (0.43%), 2- to 3-inch (0.39%; two of three replicates; reviewer-calculated mean), 8- to 9-inch (0.27%; one of three replicates), 10- to 11-inch (0.34%; one of three replicates), and 11- to 12-inch (0.35%; two of three replicates; reviewer-calculated mean) depths. Of the aged (30 days) pesticide applied to the loam soil column, the parent accounted for 94.7% of the recovered radioactivity in the 0- to 1-inch depth (reviewer-calculated mean); residues detected in depths below 0- to 1-inch were not characterized. Nonextractable [^{14}C]residues accounted for 17.6% of the applied radioactivity in the 0- to 1-inch depth. Total [^{14}C]residues in the leachate were 0.48% of the applied radioactivity.

METHODOLOGY

A subsample (50 g) of air-dried, sieved (2 mm) loam soil (collected from Bay City, TX; p. 9) was treated with radiolabeled [Δ-^{14}C]difenoconozole {CGA-169374; 1-(2-[4-(4-chlorophenoxy)-2-chlorophenyl-(4-methyl-1,3-dioxolan-2-yl)-methyl])-1H-1,2,4-triazole; radiochemical purity 96.8%, specific activity 19.7 μCi/mg; p. 10; Figure 1, p. 22), dissolved in acetone, at a nominal application rate of 10 ppm (p. 10). The treated soil was aerobically incubated in darkness at 25 ± 1 °C for 30 days; soil moisture was maintained at 75% of 0.33 bar moisture content. Following the aging period, soil samples were analyzed for the parent. Soil samples were extracted by sonication with methanol:water (9:1, v:v) and filtered, and the extracts were analyzed by TLC on silica gel plates developed two times with acetonitrile and by TLC developed with toluene:acetone (75:25, v:v) followed by acetonitrile (Tables 1, 2, pp. 16, 17). The post-extracted soil samples were analyzed by LSC following combustion (p. 10).

To determine pesticide mobility, PVC columns (3-in. i.d.) were packed to depth of 12 inches with untreated, sieved (2 mm) loam soil (p. 11; Figure 2, p. 23). To support the bottom of the column, each column was fitted with an aluminum wire screen and glass fiber filter paper. To equilibrate the soil columns, soils were saturated with water (from the bottom to the top of the column). The aged, treated soil (approximately 10 g) was added to the top of each soil column (p. 10); three columns were utilized. The treated layer was covered with a subsample (10 g) of untreated soil, and the soil surfaces were covered with glass fiber filter paper and glass wool. The columns were leached with approximately 2317 mL (50.8 cm) of deionized, distilled water over a period of 26 days (p. 11; Table 3, p. 18); 116 mL (2.5 cm; 1 inch) of water was added to the column on each of 20 days (see Comment #3), and the leachate was collected following each one-inch addition of water. Following leaching, the columns were divided into twelve one-inch sections and homogenized.

Following leaching, duplicate aliquots of the leachate collected from each soil column were analyzed for total radioactivity by LSC (p. 11); the limit of detection was 0.0003 ppm (Appendix C, p. 52). [^{14}C]Residues in the leachate (≤0.48% of the applied radioactivity; Table 3, p. 18) were not characterized.

Duplicate soil subsamples from each soil section were analyzed for total radioactivity following combustion (p. 11); the limit of detection was 0.001 ppm (Appendix C, p. 49). The 0- to 1-inch soil section from each soil column was extracted twice by sonication with methanol:water (90:10, v:v) and filtered (p. 12). The extracts were combined and duplicate aliquots were analyzed by LSC. The extracts were concentrated by rotary evaporation and analyzed by TLC on silica gel plates developed twice with acetonitrile and by TLC developed with toluene:acetone (75:25, v:v) followed by acetonitrile (Table 6, p. 21). Subsamples of the post-extracted soil were analyzed by LSC following combustion.

DATA SUMMARY

The soil mobility (aged column leaching) of radiolabeled [Δ-^{14}C]difenoconozole (radiochemical purity 96.8%), applied at a nominal rate of 10 ppm and aged (30 days) in loam soil adjusted to 75% of 0.33 bar soil moisture content and incubated in darkness at 25 ± 1 °C, was studied in loam soil columns which were leached with deionized, distilled water over a period of 26 days. However, the results were questionable due to the leaching of the soils with deionized, distilled water rather than 0.01-0.02 *N* $CaCl_2$ solution.

Following the soil aging period (30 days), the parent was present at 95.6% of the applied radioactivity (reviewer-calculated mean from data in Table 2, p. 17). Unidentified [^{14}C]residues (designated as "unknown") were 1.8% (reviewer-calculated mean) of the applied radioactivity. Uncharacterized origin material was 1.9% (reviewer-calculated mean) of the applied radioactivity. Uncharacterized radioactivity (designated as "remainder") was 0.6% (reviewer-calculated mean) of the applied radioactivity. Nonextractable [^{14}C]residues accounted for 9.9% of the applied radioactivity (Table 1, p. 16).

Based on LSC analysis, most of the [^{14}C]residues retained in the soil column following leaching remained in the 0- to 1-inch depth (90.0% of the applied radioactivity; Table 4, p. 19). Residues were also detected in the 1- to 2-inch (0.43% of the applied), 2- to 3-inch (0.39% of the applied; two of three replicates; reviewer-calculated mean), 8- to 9-inch (0.27% of the applied; one of three replicates), 10- to 11-inch (0.34% of the applied; one of three replicates), and 11- to 12-inch (0.35% of the applied; two of three replicates; reviewer-calculated mean) depths. Of the aged (30 days) pesticide applied to the loam soil column, the parent accounted for 94.7% of the recovered radioactivity in the 0- to 1-inch depth following leaching (reviewer-calculated mean from data in Table 6, p. 21); residues detected in depths below 0- to 1-inch were not characterized. Nonextractable [^{14}C]residues accounted for 17.6% of the applied radioactivity in the 0- to 1-inch depth. Total [^{14}C]residues in the leachate were 0.48% of the applied radioactivity (Table 3, p. 18).

Material balances (based on LSC analysis of individual replicates) following the aging period and column leaching were 100.3-101.8% and 79.3-98.0% of the applied radioactivity, respectively (Tables 1, 4; pp. 16, 19; see Comment #4).

COMMENTS

1. The experimental method was inadequate because the soil columns were leached with deionized, distilled water rather than 0.01-0.02 *N* $CaCl_2$, as required by Subdivision N Guidelines (p. 11). The use of distilled water could cause particles to disperse, thereby

decreasing the rate of infiltration and leaching. Also, the use of distilled water may lead to the removal of sorbed ions from the soil particles, thereby affecting the degree of adsorption of the test material. Additionally, the leaching was not conducted in a timely manner; 26 days were required for the completion of leaching.

2. The reviewer notes that this study was not conducted in accordance with Good Laboratory Practices (GLP) as specified in 40 CFR 160. The study was conducted in accordance with the EPA GLP Standards in place at the time of the study.

3. A constant head of water was not maintained above the soil surface of the columns. Instead, the columns were leached with approximately 2317 mL (50.8 cm) of deionized, distilled water over a period of 26 days (p. 11; Table 3, p. 18); 116 mL (2.5 cm; 1 inch) of water was added to the column on each of 20 days, and the leachate was collected following each one-inch addition of water. Subdivision N Guidelines require that the leaching solution be percolated through the column at a rate which maintains a constant head above the soil surface.

4. The mean material balance for the soil columns was 91.6% of the applied radioactivity (Tables 1, 3, pp. 16, 18); however, the material balance was 79.3% of the applied for one of the three columns utilized. Subdivision N Guidelines require that material balances be between 90-110% of the applied radioactivity. The study author did not provide an explanation for this loss.

5. The method detection limit was reported for LSC, but not for TLC analysis. Both limits of detection and quantitation should be reported to allow the reviewer to evaluate the adequacy of the method for the determination of the test compound.

6. The study author stated that the loam soil was the same type of soil used in an aerobic soil metabolism study (p. 9). The reviewer was able to confirm (based on soil characterization data) that the soil used in the current study was also used in the aerobic soil metabolism study presented in MRID 42245132.

7. The soil series name was not provided for the loam soil, as required by Subdivision N Guidelines.

RIN 0509-04

EFED Review for MRID # 422451-38

Page_____ is not included in this copy.

Pages 6 through 13 are not included.

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