DATA EVALUATION RECORD

STUDY 12

CHEM 129112 Trifloxystrobin §163-1
CAS No. 141517-21-7
FORMULATION--00-ACTIVE INGREDIENT

STUDY ID 44496804
Heim, L. G. and R. Velagaleti. 1997. Adsorption-desorption of [phenyl (B)-U-^{14}C]-CGA-357276 in soil. ABC Study No.: 43840. Novartis Study No.: 210-97. Unpublished study performed by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO; and submitted by Novartis Crop Protection, Inc., Greensboro, NC.

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CONCLUSIONS

Mobility - Leaching & Adsorption/Desorption

1. This study is scientifically valid and provides useful information on the soil mobility (batch equilibrium) of the trifloxystrobin degradate CGA-357276 in five soils.

2. This study meets Subdivision N Guidelines for the partial fulfillment of EPA data requirements on soil mobility (batch equilibrium).

3. Uniformly phenyl ring-labeled [^{14}C]CGA-357276, at nominal concentrations of 10, 25, 100 and 250 µg/mL, was determined to be mobile in the sand, Hanford sandy loam, and Saw-Wake sandy loam soil:solution slurries and to have low mobility in the loam and clay loam soil:solution slurries that were equilibrated in darkness for 48 hours at 25 ±1 °C. Freundlich K_{ads} values were 48.5 for Hanford sandy loam soil (1.0% o.m.), 207 for the loam soil (5.4% o.m.), 75.1 for Saw-Wake sandy loam soil, 79.4 for the sand soil, and 169 for the clay loam soil; corresponding K_{oc} values were 8345, 6587, 9228, 9756 and 6934 mL/g. Respective 1/N values (reviewer-calculated) were 0.95, 0.81, 0.96, 0.85 and 0.81 for the adsorption phase. Freundlich K_{des} values determined after a 48-hour equilibration period were 88.2 for Hanford sandy loam soil, 263 for the loam soil, 91.2 for Saw-Wake sandy loam soil, 110 for the sand soil and 206 for the clay loam soil; corresponding K_{oc} values were 15169, 8386, 11206, 13575 and 8434 mL/g. Respective 1/N values (reviewer-calculated) were 1.04, 0.79, 0.94, 0.86 and 0.80 for the desorption phase. The reviewer-calculated coefficient of determination (r^2) values for the relationships K_{ads} vs. organic matter and K_{ads} vs. pH were 0.99 and 0.11, respectively.

METHODOLOGY

Based on the results of a preliminary study for the adsorption of uniformly phenyl ring-labeled [^{14}C]CGA-357276 {(E)-2-[[[[1-[3-(trifluoromethyl)phenyl]ethylidene]amino]oxy] methyl]benzonitrile; radiochemical purity 99.3%, specific activity 39.8 µCi/mg; p. 18} to loam, sand, clay loam, and two sandy loam soils, an equilibration period of 48 hours was chosen for both the adsorption and desorption phases (Table V, p. 55). In a separate preliminary study, adsorption of the test compound to borosilicate glass test tubes, silanized borosilicate glass test tubes and Teflon centrifuge tubes was studied (p. 29); borosilicate glass test tubes had the least adsorption (3.3%) and were selected for the definitive study (p. 44; Appendix V, p. 266). Based on the results of a preliminary study, a soil:solution ratio of 1:50 (w:v) was chosen for the definitive study (p. 45).

For the adsorption phase of the definitive study, aliquots (40 mL) of 0.01 M $CaCl_2$ solution containing uniformly phenyl ring-labeled [^{14}C]CGA-357276, dissolved in acetonitrile, at nominal concentrations of 10, 25, 100 and 250 µg/L were added to

borosilicate glass test tubes containing samples (0.8 g) of preincubated (3 days at 75% of the soil moisture content at 0.33 bar), sieved (2 mm) Hanford sandy loam, Gardena loam, Saw-Wake sandy loam, Lynchburg sand, and Bearden-Perella clay loam soils (p. 32; Table I, p. 51). Duplicate tubes were prepared for each soil type/treatment rate combination. The soil:solution slurries (1:50, w:v) were mechanically shaken in darkness for 48 hours at 25 ±1°C. Following the equilibration period, samples were centrifuged and the supernatant was decanted. Triplicate aliquots of the supernatant from each sample were analyzed for total radioactivity by LSC. Aliquots of selected supernatants (250 µg/L treatment) were diluted with acetonitrile, filtered (0.45 µm), and analyzed by HPLC (Hibar LiChrosorb RP-18 column) using a mobile phase gradient of acetonitrile:0.1% formic acid in water (0:100 to 65:35, v:v) with UV (254 nm) and radioactive flow detection (p. 24). Eluent fractions were collected at half-minute intervals and analyzed by LSC. Samples were co-chromatographed with nonradiolabeled reference standards (p. 34). An aliquot of a selected supernantant (Hanford sandy loam soil treated at 250 µg/L) was further analyzed using two-dimensional TLC on silica gel plates developed with toluene:chloroform:ethylether:formic acid (60:34:5:1, v:v:v:v) followed by toluene:ethyl acetate:acetic acid (70:30:1.5; v:v:v; pp. 26, 33). Samples were co-chromatographed with nonradiolabeled reference standards which were visualized with UV light. Areas of radioactivity were determined by radioimage scanning. Areas of radioactivity were scraped from the plates and analyzed by LSC.

For the desorption phase of the study, an aliquot of pesticide-free 0.01 M $CaCl_2$ solution equivalent to the volume of supernatant decanted following adsorption was added to soil pellets from the adsorption phase of the study (p. 33). The samples were mechanically shaken in darkness for 48 hours at 25 ±1°C. Following the equilibration period, samples were centrifuged and the supernatants were decanted. Triplicate aliquots of the supernatant from each sample were analyzed for total radioactivity by LSC. Aliquots of selected supernatants (250 µg/L treatment) were diluted with acetonitrile, filtered (0.45 µm), and analyzed by HPLC as previously described. An aliquot of a selected supernatants (Saw-Wake sandy loam and the loam soils treated at 250 µg/L) was further analyzed by TLC as previously described (p. 34).

Following the adsorption and desorption phases, selected soil pellets (250 µg/L treatment) were extracted three times with acetonitrile:acidified water (pH adjusted to 4 with formic acid; 8:2, v:v) followed by centrifugation (pp. 27, 33). The supernatants were decanted and combined. Triplicate aliquots of the combined supernatants were analyzed by LSC. Selected soil pellets (desorption phase only) were evaporated to dryness under nitrogen, reconstituted with acetonitrile:water (50:50, v:v), filtered (0.45 µm), and analyzed by HPLC as previously described. Following extraction, soil pellets were dried under nitrogen and triplicate subsamples were analyzed for total radioactivity by LSC following combustion (p. 33).

DATA SUMMARY

Uniformly phenyl ring-labeled [^{14}C]CGA-357276 (radiochemical purity 99.3%), at nominal concentrations of 10, 25, 100 and 250 µg/L, was determined to be mobile in the sand, Hanford sandy loam, and Saw-Wake sandy loam soil:solution slurries and to have low mobility in the loam and clay loam soil:solution slurries that were equilibrated in darkness for 48 hours at 25 ±1 °C. Freundlich K_{ads} values were 48.5 for Hanford sandy loam soil (1.0% o.m.), 207 for the loam soil (5.4% o.m.), 75.1 for Saw-Wake sandy loam soil, 79.4 for the sand soil, and 169 for the clay loam soil (Table XXII, p. 72); corresponding K_{oc} values were 8345, 6587, 9228, 9756 and 6934 mL/g. Respective 1/N values (reviewer-calculated) were 0.95, 0.81, 0.96, 0.85 and 0.81 for the adsorption phase. The reviewer-calculated coefficient of determination (r^2) values for the relationships K_{ads} *vs.* organic matter and K_{ads} *vs.* pH were 0.99 and 0.11, respectively. Freundlich K_{des} values determined after a 48-hour equilibration period were 88.2 for Hanford sandy loam soil, 263 for the loam soil, 91.2 for Saw-Wake sandy loam soil, 110 for the sand soil and 206 for the clay loam soil; corresponding K_{oc} values were 15169, 8386, 11206, 13575 and 8434 mL/g. Respective 1/N values (reviewer-calculated) were 1.04, 0.79, 0.94, 0.86 and 0.80 for the desorption phase.

During the 48-hour equilibration period, 48.5-56.5% of the applied radioactivity was adsorbed to Hanford sandy loam soil (across all application levels; Table XI, p. 61), 88.0-94.0% of the applied was adsorbed to the loam soil (Table XII, p. 62), 60.0-65.7% of the applied was adsorbed to Saw-Wake sandy loam soil (Table XIII, p. 63), 69.7-81.0% of the applied was adsorbed to the sand soil (Table XIV, p. 64) and 86-3-92.7% of the applied was adsorbed to the clay loam soil (Table XV, p. 65). Following a single 48-hour desorption equilibration period, 37.8-43.2% of the previously adsorbed radioactivity was desorbed from Hanford sandy loam soil (across all application levels), 3.5-8.3% was desorbed from the loam soil, 24.4-31.4% was desorbed from Saw-Wake sandy loam soil, 15.1-23.6% was desorbed from the sand soil, and 4.8-10.3% was desorbed from the clay loam soil.

Based on HPLC analysis to confirm compound stability, the test compound comprised 100.0% of the recovered radioactivity in the supernatants of all five soils following both adsorption and desorption (Tables XXIV-XXV, pp. 74, 75; Appendix IV, p. 159). In soil extracts, 97.4-98.7% of the recovered radioactivity was present as the parent compound (Table XXVI, p. 76).

Material balances (across all applications) were 95.5-100.7% for Hanford sandy loam soil, 98.7-105.5% for the loam soil, 96.7-102.3% for the Saw-Wake sandy loam soil, 97.0-99.9% for the sand soil, and 97.7-103.8% for the clay loam soil (Tables XI-XV, pp. 61-65).

COMMENTS

1. The qualitative classifications of soil mobility reported in the conclusions and data summary were determined by the reviewer using "Table III: The general relationship between the soil/solution partition coefficient K, R_f, and soil mobility" (*Federal Register*, Vol. 44, No. 53) and are based on the K_{ads} values (Freundlich) reported by the study author. The qualitative determinations reported by the study author in the form of a McCall mobility class were based on K_{oc} values associated with the adsorption phase of the experiment (p. 49); these class determinations were not reported by the reviewer. It is preferred that the reported mobility class be based on K_{ads} values.

2. Limits of detection were not reported as required by Subdivision N Guidelines. It is necessary that both limits of detection and quantitation be reported to allow the reviewer to evaluate the adequacy of the method.

3. The study authors stated that the loam and Saw-Wake sandy loam soils were used in aerobic metabolism studies of the parent compound, trifloxystrobin (CGA-279202; p. 18). The reviewer notes that loam and sandy loam soils were used in two aerobic soil metabolism studies (MRIDs 44496730, 44496731), but that the soil series names were not reported in those studies.

4. A method validation study was conducted (p. 29); data indicated that the method was valid for all five soils (Tables III-IV; pp. 53-54).

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