

(12-9-02)

DATA EVALUATION RECORD

Document Number

STUDY 1



2001009

CHEM 122101

Propiconazole

§163-1

CAS No. 60207-90-1

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 44701801

Atkins, R. H. 1998. Aged leaching of [^{14}C]propiconazole in four soil types. Laboratory Project ID: 1093. Unpublished study performed by PTRL East, Inc., Richmond, KY; and submitted by Novartis Crop Protection, Inc., Greensboro, NC.

DIRECT REVIEW TIME = 99 Hours

REVIEWED BY: M. T. Holdsworth, M.S. Signature:
TITLE: Scientist Date:
M. K. Mahoney, M.S.
Scientist

EDITED BY: C. A. Sutton, Ph.D. Signature:
TITLE: Sr. Scientist/Asst. Project Manager Date:

APPROVED BY: P. H. Howard, Ph.D. Signature:
TITLE: Project Manager Date:

ORG: Syracuse Research Corp.
Arlington, VA 22202

TEL: 703/413-9369

APPROVED BY: Santhini Ramasamy
TITLE: Environmental Scientist
ORG: ERB I/EFED/OPP
TEL: 703/305-8133

SIGNATURE:

Santhini Ramasamy 12.9.02

DATA EVALUATION RECORD

STUDY 1

CHEM 122101 Propiconazole §163-1
 CAS No. 60207-90-1
 FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 44701801

Atkins, R. H. 1998. Aged leaching of [¹⁴C]propiconazole in four soil types. Laboratory Project ID: 1093. Unpublished study performed by PTRL East, Inc., Richmond, KY; and submitted by Novartis Crop Protection, Inc., Greensboro, NC.

DIRECT REVIEW TIME = 99 Hours

REVIEWED BY: M. T. Holdsworth, M.S. Signature: *M.K. Mahoney*
 TITLE: Scientist Date: *8/15/00*
 M. K. Mahoney, M.S.
 Scientist

EDITED BY: C. A. Sutton, Ph.D. Signature: *C.A. Sutton*
 TITLE: Sr. Scientist/Asst. Project Manager Date: *8/15/00*

APPROVED BY: P. H. Howard, Ph.D. Signature: *C.A. Sutton for P. Howard*
 TITLE: Project Manager Date: *8/15/00*

ORG: Syracuse Research Corp.
 Arlington, VA 22202

TEL: 703/413-9369

APPROVED BY: Kevin Costello
 TITLE: Geologist
 ORG: ERB I/EFED/OPP
 TEL: 703/305-5026

SIGNATURE:

CONCLUSIONS

Mobility - Leaching & Adsorption/Desorption

1. This study is scientifically valid and provides useful information on the soil mobility (column leaching) of propiconazole in four soils. However, due to the relatively long aerobic soil metabolism half-life (288 days to 3.2 years as reported in this study for four soils and 60-84 days for silt loam as reported in MRID 67908 and MRID 133376), the incubation period of 30 days prior to column leaching did not provide sufficient information on the mobility of propiconazole degradates.
2. The soil mobility of triazole ring-labeled [3,5-¹⁴C]propiconazole, applied at nominal rate of 1.8 ppm (equivalent to the recommended maximum application rate of 1.8 lb a.i./acre applied with 0" to 3" soil incorporations) and aged (30 days), was studied in sand, sandy loam, silt loam, and clay loam soil columns which were leached with 0.01 M CaCl₂ solution over ≤25 hours.

Of the aged (30 days) pesticide applied to the sand soil column, 95.0% was parent, 1.5% was unidentified degradates, 3.2% was uncharacterized, and 2.3% was nonextractable [¹⁴C]residues; total [¹⁴C]volatiles were negligible. Based on LSC analysis, most of the [¹⁴C]residues retained in the soil column following leaching remained in the 0- to 6-cm depth (75.1%). Residues were also detected in the 6- to 12-cm (8.1%), 12- to 18-cm (6.6%), 18- to 24-cm (3.8%), and 24- to 30-cm (2.0%) depths. The parent was 67.7% of the applied radioactivity in the 0- to 6-cm depth, was 7.6% in the 6- to 12-cm depth, was 5.6% in the 12- to 18-cm depth, was 3.9% in the 18- to 24-cm depth, and was 1.9% in the 24- to 30-cm depth. Total [¹⁴C]residues in the leachate were 2.5% of the applied radioactivity.

Of the aged (30 days) pesticide applied to the sandy loam soil column, 91.3% was parent, 2.3% was unidentified degradates, 3.5% was uncharacterized, and 4.2% was nonextractable [¹⁴C]residues; [¹⁴C]volatiles were not detected. Based on LSC analysis, most of the [¹⁴C]residues retained in the soil column following leaching remained in the 0- to 6-cm (49.6%) and 6- to 12-cm (34.9%) depths. Residues were also detected in the 12- to 18-cm (8.3%), 18- to 24-cm (1.6%), and 24- to 30-cm (0.2%) depths. The parent was 42.1% of the applied radioactivity in the 0- to 6-cm depth, was 30.8% in the 6- to 12-cm depth, was 6.8% in the 12- to 18-cm depth, and was 1.4% in the 18- to 24-cm depth. Total [¹⁴C]residues in the leachate were 2.9% of the applied radioactivity.

Of the aged (30 days) pesticide applied to the silt loam soil column, 74.0% was parent, 4.5% was unidentified degradates, 12.8% was uncharacterized, and 7.3% was nonextractable [¹⁴C]residues; total [¹⁴C]volatiles were negligible. Based on further HPLC analysis of a single day-30 sample, the minor degradates CGA-71019, CGA-217495, and CGA-91305 were present at 3.6%, 6.2%, and 3.9% of the applied radioactivity,

respectively. Based on LSC analysis, most of the [^{14}C]residues retained in the soil column following leaching remained in the 0- to 6-cm depth (84.8%). Residues were also detected in the 6- to 12-cm (6.3%), 12- to 18-cm (1.8%), 18- to 24-cm (1.0%), and 24- to 30-cm (1.0%) depths. The parent was 72.5% of the applied radioactivity in the 0- to 6-cm depth, was 4.5% in the 6- to 12-cm depth, was 0.7% in the 12- to 18-cm depth, and was last detected at 0.1% (one of two replicates) in the 18- to 24-cm depth. Total [^{14}C]residues in the leachate were 5.8% of the applied radioactivity.

Of the aged (30 days) pesticide applied to the clay loam soil column, 84.4% was parent, 2.6% was unidentified degradates, 8.8% was uncharacterized, and 5.7% was nonextractable [^{14}C]residues; [^{14}C]volatiles were not detected. Based on LSC analysis, most of the total [^{14}C]residues retained in the soil column following leaching remained in the 0- to 6-cm depth (88.0%). Residues were also detected in the 6- to 12-cm (5.0%), 12- to 18-cm (2.2%), 18- to 24-cm (1.2%), and 24- to 30-cm (0.6%) depths. The parent was 72.6% of the applied radioactivity in the 0- to 6-cm depth, was 3.6% in the 6- to 12-cm depth, was 1.4% in the 12- to 18-cm depth, and was 0.45% in the 18- to 24-cm depth. Total [^{14}C]residues in the leachate were 2.9% of the applied radioactivity.

METHODOLOGY

Samples of sieved (2 mm) Kickapoo sand (Madison Co., KY), Hanford sandy loam (Fresno Co., CA), Huntington silt loam (Madison Co., KY), and Niagara clay loam (Columbia Co., NY) soils (Table I, p. 77) were adjusted to 75% of the soil moisture content at 0.33 bar and pre-incubated at 25°C for up to 13 days (p. 36). Preliminary studies were conducted to determine the aerobic half-life of the parent compound in the four soils (p. 37). Samples of each soil were treated with the parent (unspecified rate) and incubated at $26.3 \pm 0.27^\circ\text{C}$ (sand and sandy loam) or $25.4 \pm 0.18^\circ\text{C}$ (silt loam and clay loam) for up to 30 days; results indicated that the half-life of propiconazole in the four soils was >30 days (p. 59; Tables XIV-XVII, pp. 92-95). Two subsamples of air-dried, sieved (2 mm) sand, sandy loam, silt loam, and clay loam soils were placed into Erlenmeyer flasks, adjusted to 75% of the moisture content at 0.33 bar, and pre-incubated in darkness for 12-13 days (pp. 34, 36). Samples of the pre-incubated soils were treated with triazole ring-labeled [3,5- ^{14}C]propiconazole {CGA-64250; 1-[(2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl)methyl]-1H-1,2,4-triazole; radiochemical purity 98.2%, specific activity 56.8 $\mu\text{Ci}/\text{mg}$; p. 32; Figure 1, p. 159}, dissolved in acetonitrile, at a nominal rate of 1.8 ppm. Flasks containing the treated samples were capped and aerobically aged for 30 days in darkness at $25.1 \pm 0.18^\circ\text{C}$ (sand and sandy loam soils) or $25.2 \pm 0.19^\circ\text{C}$ (silt loam and clay loam soils; pp. 37-38). To capture volatiles, effluent air was passed through the samples and into organic volatile (polyurethane foam plug and ethylene glycol) and two CO_2 (10% KOH) traps in succession (Figure 1, p. 270). The soil moisture content of each samples was maintained

at approximately 75% of the moisture content at 0.33 bar by the periodic additions of water as needed.

Following the aging period, soil samples were extracted three times by shaking with acetonitrile:water (8:2, v:v) and centrifuged (p. 39). The supernatant was decanted and filtered (Whatman 934-AH glass microfibre), and aliquots of the combined extracts were analyzed for total radioactivity by LSC; the limit of detection was twice background (96 dpm; p. 43). Selected samples were further extracted by refluxing with acetonitrile:water (8:2, v:v) and centrifuged. The supernatants were decanted, filtered, and analyzed by LSC. Aliquots of soil extracts were analyzed by reverse-phase HPLC (Zorbax ODS column) using a mobile phase gradient of 0.1% formic acid in acetonitrile:phosphate buffer (pH 6.5; 25:75 to 35:65 to 60:40 to 100:0, v:v) with UV (205 nm) and radioactive flow detection (p. 44); the limit of detection was twice background. Eluent fractions were collected at half-minute intervals and analyzed by LSC. Samples were co-chromatographed with nonradiolabeled reference standards of the parent and the following potential degradates: CGA-71019, CGA-91305, CGA-93590, CGA-93591, CGA-136735, CGA-188244, CGA-188245, and CGA-217495. To identify compounds in the HPLC 8- to 30-minute retention time range, extracts were analyzed by reverse-phase HPLC as previously described with the exception of the mobile phase gradient (0:100 to 25:75 to 35:65 to 60:40 to 100:0, v:v); the limit of detection was twice background. To confirm the identity of the degradate CGA-71019, extracts were analyzed by normal-phase HPLC (Accubond Amino column) using an isocratic mobile phase of 0.1% formic acid in acetonitrile (p. 47). Selected silt loam and clay loam soil extracts (reflux) were analyzed by reverse-phase HPLC (Spherisorb ODS-1 column) using an isocratic mobile phase of 0.1-0.01% triethylamine in water. Eluent fractions were concentrated to dryness by rotary and nitrogen evaporation, dissolved in 0.1% formic acid in acetonitrile, and analyzed by normal-phase HPLC (Accubond Amino column) using an isocratic mobile phase of 0.1% formic acid in acetonitrile. To confirm compound identities, aliquots of selected soil extracts were analyzed by two-dimensional TLC on silica gel plates developed in chloroform:isopropanol (75:25, v:v) followed by ethyl acetate:ethyl ether (75:25, v:v). Areas of radioactivity were quantitated by radioimage scanning, scraped from the plates, dissolved in methanol, and analyzed by LSC. Samples were co-chromatographed with nonradiolabeled reference standards which were visualized using phosphomolybdic acid. Soil extracts were further analyzed by two-dimensional TLC on silica gel plates developed in chloroform:methanol:88% formic acid:water (80:15:4:2, v:v:v:v) followed by ethyl acetate:methylene chloride:17.4 N glacial acetic acid (80:5:15, v:v:v). Samples were co-chromatographed with nonradiolabeled reference standards which were visualized by UV (254 nm) light after the plates were exposed to chlorine gas. Triplicate subsamples of air-dried post-extracted soil were analyzed by LSC following combustion (p. 40).

To isolate an unidentified degradate ("Unknown 2"), silt loam soil extracts (day 30) from the preliminary and definitive aging periods were concentrated by rotary and nitrogen

evaporation, combined, and partitioned three times with ethyl acetate (p. 51). The aqueous fraction (containing CGA-217495 and the unidentified degradate) was concentrated by rotary evaporation and the unknown was isolated by reverse-phase HPLC (Spherisorb ODS-1 column) using a mobile phase gradient of 0.01% aqueous triethylamine:0.2% aqueous acetic acid (100:0 to 75:25 to 65:35 to 50:50, v:v) with UV (220 nm) and radioactive flow detection. Selected eluent fractions (19-25 minutes) were collected, concentrated by rotary evaporation, and further isolated by reverse-phase HPLC (Phenomenex Spherclone ODS 2 column) using a mobile phase gradient of water:acetonitrile (95:5 to 90:10, v:v). An aliquot of the selected eluent was analyzed by reverse-phase HPLC (Zorbax ODS column) with a mobile phase gradient of 0.1% formic acid in acetonitrile:phosphate buffer (pH 6.5; 25:75 to 35:65 to 60:40 to 100:0, v:v). Triplicate aliquots of the remaining eluent were analyzed for total radioactivity by LSC. The isolated degradate was tentatively identified by electrospray LC/MS, GC/MS, MS/MS in ESI and CI modes, and NMR analysis (p. 72).

At each sampling interval during the aging period, the foam plugs were extracted with acetonitrile (p. 39). Aliquots of the extracts, ethylene glycol, and KOH trapping solutions were analyzed by LSC. The presence of $^{14}\text{CO}_2$ was confirmed by precipitation with BaCl_2 .

To determine pesticide mobility, glass columns (2 in. i.d.) equipped with conical bottoms (containing 6 inches of cotton gauze) were packed (while agitating) to a depth of 30 cm with untreated, air-dried, sieved (2 mm) sand, sandy loam, silt loam, and clay loam soils (p. 40; Figure 2, p. 164); two columns were utilized for each soil. Columns were equilibrated with 0.01 M CaCl_2 solution. The aged, treated soil samples were added on top of the soil columns and covered with a filter paper disk (Whatman No. 1). The columns were leached with 1030 mL (20 in.) of 0.01 M CaCl_2 solution over a period of ≤ 24 hours for the sand, silt loam, and clay loam soil columns, and approximately 25 hours for the sandy loam soil columns (p. 64). Leachate was collected in approximately 150-mL fractions (p. 41). Following leaching, the columns were divided into five 6-cm sections.

Following leaching, aliquots of the leachate fractions were analyzed for total radioactivity by LSC (p. 41). Aliquots of selected leachate fractions (those containing $\geq 1.0\%$ of the applied radioactivity) were combined, concentrated, redissolved in acetonitrile, and analyzed by LSC. Samples were further analyzed by HPLC and/or TLC as previously described.

Subsamples of soil from each section were analyzed by LSC following combustion (p. 41). Subsamples of soil from each section containing $\geq 1.0\%$ of the applied radioactivity were weighed into Nalgene centrifuge bottles and extracted twice by shaking with acetonitrile:water (8:2, v:v; p. 42). The samples were centrifuged and the supernatants were decanted and filtered. Aliquots of the combined extracts were analyzed by LSC.

6

Selected samples were further extracted by refluxing with acetonitrile:water (8:2, v:v) and centrifuged. The supernatants were decanted, filtered, and aliquots were analyzed by LSC. Extracts were concentrated by rotary evaporation and analyzed by HPLC and/or TLC as previously described. Triplicate subsamples of post-extracted, air-dried soil were analyzed by LSC following combustion (p. 43).

To determine the viability of the soils prior to treatment, soil samples were serially diluted, plated on selective media, and enumerated for colony forming units (p. 34); results indicated that the soils were viable (Table IV, p. 80). Substrate-induced respiration was used to estimate the microbial populations in the soil (p. 35); results indicated that the soils were viable (Table V, p. 81).

The frozen storage stability of propiconazole in each soil type was evaluated using samples from the half-life preliminary studies. Soil samples were fortified with the parent and stored frozen for up to 414 days (sand and sandy loam) or 399 days (silt loam and clay loam). [^{14}C]Propiconazole accounted for $\geq 97.9\%$ of the applied radioactivity following frozen storage; tabular data for each soil were not reported. The soil column sections were stored frozen for up to 71 days prior to extraction, and the post-extracted soils were stored for up to 70 days (p. 70). The leachate fractions were stored frozen for up to 54 days prior to analysis. Selected aliquots of the sand and silt loam leachate were frozen for up to 304 additional days prior to re-analysis.

DATA SUMMARY

The soil mobility of triazole ring-labeled [3,5- ^{14}C]propiconazole (radiochemical purity 98.2%), applied at nominal rate of 1.8 ppm and aged (30 days), was studied in sand, sandy loam, silt loam, and clay loam soil columns which were leached with 0.01 M CaCl_2 solution over ≤ 25 hours.

Kickapoo sand soil

Of the aged (30 days) pesticide applied to the sand soil column, 95.0% was parent, 1.5% was unidentified degradates (designated as Unknown Regions 1 and 3), 3.2% was uncharacterized (Region 2), and 2.3% was nonextractable [^{14}C]residues (Tables XIX, XX, pp. 97, 98); total [^{14}C]volatiles were negligible.

Based on LSC analysis, most of the [^{14}C]residues retained in the soil column following leaching remained in the 0- to 6-cm depth (75.1%; Table XXXIII, p. 111). Residues were also detected in the 6- to 12-cm (8.1%), 12- to 18-cm (6.6%), 18- to 24-cm (3.8%), and 24- to 30-cm (2.0%) depths. The parent compound was present at 67.7% of the applied radioactivity in the 0- to 6-cm depth, was 7.6% of the applied in the 6- to 12-cm depth, was 5.6% of the applied in the 12- to 18-cm depth, was 3.9% of the applied in the 18- to

24-cm depth, and was 1.9% of the applied in the 24- to 30-cm depth (Table XLI, p. 119). Two unidentified minor degradates (designated as Unknown Regions 1 and 3) were each present at $\leq 1.5\%$ of the applied radioactivity throughout the soil column. Uncharacterized [^{14}C]residues (HPLC Region 2) were $\leq 3.1\%$ of the applied radioactivity throughout the soil column. Nonextractable [^{14}C]residues were 3.3% of the applied radioactivity in the 0- to 6-cm depth and were $\leq 0.69\%$ of the applied in each of the 6- to 12-cm, 12- to 18-cm, 18- to 24-cm, and 24- to 30-cm depths (reviewer-calculated values; Table XXXVII, p. 115; see Comment #3). Total [^{14}C]residues in the leachate were 2.5% of the applied radioactivity (Table XXXIII, p. 111). [^{14}C]Volatiles were not detected.

Following the aging period and column leaching, respective material balances were 101.2-103.6% and 95.4-100.7% of the applied radioactivity (Tables XIX, XXXIII, pp. 97, 111).

Hanford sandy loam soil

Of the aged (30 days) pesticide applied to the sandy loam soil column, 91.3% was parent, 2.3% was unidentified degradates (designated as Unknown Regions 1 and 3), 3.5% was uncharacterized (Region 2), and 4.2% was nonextractable [^{14}C]residues (Tables XXI, XXII; pp. 99, 100); [^{14}C]volatiles were not detected.

Based on LSC analysis, most of the [^{14}C]residues retained in the soil column following leaching remained in the 0- to 6-cm (49.6%) and 6- to 12-cm (34.9%) depths (Table XXXIV, p. 112). Residues were also detected in the 12- to 18-cm (8.3%), 18- to 24-cm (1.6%), and 24- to 30-cm (0.2%) depths. The parent compound was present at 42.1% of the applied radioactivity in the 0- to 6-cm depth, was 30.8% of the applied in the 6- to 12-cm depth, was 6.8% of the applied in the 12- to 18-cm depth, and was 1.4% of the applied in the 18- to 24-cm depth (Table XLII, p. 120). Two unidentified degradates (designated as Unknown Regions 1 and 3) were each present at $\leq 0.25\%$ of the applied radioactivity throughout the soil column. Uncharacterized [^{14}C]residues (HPLC Region 2) were $\leq 0.95\%$ of the applied radioactivity throughout the soil column. Nonextractable [^{14}C]residues were 4.1% of the applied radioactivity in the 0- to 6-cm depth and were $\leq 2.0\%$ of the applied in each of the 6- to 12-cm, 12- to 18-cm, and 18- to 24-cm depths (reviewer-calculated values; Table XXXVIII, p. 116; see Comment #3). Total [^{14}C]residues in the leachate were 2.9% of the applied radioactivity (Table XXXIV, p. 112). [^{14}C]Volatiles were not detected.

Following the aging period and column leaching, respective material balances were 100.6-102.9% and 95.2-99.7% of the applied radioactivity (Tables XXI, XXXIV; pp. 99, 112).

8

Huntington silt loam soil

Of the aged (30 days) pesticide applied to the silt loam soil column, 74.0% was parent, 4.5% was unidentified degradates (designated as Unknown Regions 1 and 3), 12.8% was uncharacterized (Region 2), and 7.3% was nonextractable [^{14}C]residues (Tables XXIII, XXIV; pp. 101, 102); total [^{14}C]volatiles were negligible. Based on further HPLC analysis of a single day-30 sample, the minor degradates CGA-71019, CGA-217495, and CGA-91305 (chemical names not provided; structures presented in Figure 1, pp. 159-163) were present at 3.6%, 6.2%, and 3.9% of the applied radioactivity, respectively (Table XXV, p. 103). An unidentified minor degradate (designated as Unknown 2) was present at 5.6% of the applied radioactivity; further analysis tentatively identified this degradate as the cis-isomer of CGA-217945 (p. 60).

Based on LSC analysis, most of the [^{14}C]residues retained in the soil column following leaching remained in the 0- to 6-cm depth (84.8%; Table XXXV, p. 113). Residues were also detected in the 6- to 12-cm (6.3%), 12- to 18-cm (1.8%), 18- to 24-cm (1.0%), and 24- to 30-cm (1.0%) depths. The parent compound was present at 72.5% of the applied radioactivity in the 0- to 6-cm depth, was 4.5% of the applied in the 6- to 12-cm depth, was 0.7% of the applied in the 12- to 18-cm depth, and was last detected at 0.1% (one of two replicates) of the applied in the 18- to 24-cm depth (Table XLIII, p. 121). Two unidentified minor degradates (designated as Unknown Regions 1 and 3) were each present at $\leq 1.9\%$ of the applied radioactivity throughout the soil column. Uncharacterized [^{14}C]residues (Region 2) were 5.7% of the applied radioactivity in the 0- to 6-cm depth and were 0.45-0.55% of the applied in each of the 6- to 12-cm, 12- to 18-cm, 18- to 24-cm, and 24- to 30-cm depths. Nonextractable [^{14}C]residues were 8.3% of the applied radioactivity in the 0- to 6-cm depth and were $\leq 0.77\%$ of the applied in each of the 6- to 12-cm, 12- to 18-cm, 18- to 24-cm, and 24- to 30-cm depths (reviewer-calculated values; Table XXXIX, p. 117; see Comment #3). Total [^{14}C]residues in the leachate were 5.8% of the applied radioactivity (Table XXXV, p. 113). [^{14}C]Volatiles were negligible.

Following the aging period and column leaching, respective material balances were 100.8-103.7% and 96.7-105.0% of the applied radioactivity (Tables XXIII, XXXV, pp. 101, 113).

Niagra clay loam soil

Of the aged (30 days) pesticide applied to the clay loam soil column, 84.4% was parent, 2.6% was unidentified degradates (designated as Unknown Regions 1 and 3), 8.8% was uncharacterized (Region 2), and 5.7% was nonextractable [^{14}C]residues (Tables XXVI, XXVII, pp. 104, 105); [^{14}C]volatiles were not detected.

Based on LSC analysis, most of the total [^{14}C]residues retained in the soil column following leaching remained in the 0- to 6-cm depth (88.0%; Table XXXVI, p. 114). Residues were also detected in the 6- to 12-cm (5.0%), 12- to 18-cm (2.2%), 18- to 24-cm (1.2%), and 24- to 30-cm (0.6%) depths. The parent compound was present at 72.6% of the applied radioactivity in the 0- to 6-cm depth, was 3.6% of the applied in the 6- to 12-cm depth, was 1.4% of the applied in the 12- to 18-cm depth, and was 0.45% of the applied in the 18- to 24-cm depth (Table XLIV, p. 122). Two unidentified minor degradates (designated as Unknown Regions 1 and 3) were each $\leq 0.7\%$ of the applied radioactivity throughout the soil column. Uncharacterized [^{14}C]residues (HPLC Region 2) were 4.7% of the applied radioactivity in the 0- to 6-cm depth and were 0.35-0.4% of the applied throughout the remaining soil column. Nonextractable [^{14}C]residues were 11.6% of the applied radioactivity in the 0- to 6-cm depth and $\leq 0.24\%$ of the applied in each of the 6- to 12-cm, 12- to 18-cm, 18- to 24-cm, and 24- to 30-cm depths (reviewer-calculated values; Table XL, p. 118; see Comment #3). Total [^{14}C]residues in the leachate were 2.9% of the applied radioactivity (Table XXXVI, p. 114). [^{14}C]Volatiles were not detected

Following the aging period and column leaching, respective material balances were 100.7-104.9% and 91.1-108.8% of the applied radioactivity (Tables XXVI, XXXVI; pp. 104, 114).

COMMENTS

1. Due to the relatively long (288 days-3.2 years) half-life of the compound in each of the four soils, the 30-days incubation was not long enough for determining the soil mobility of potential propiconazole degradates.
2. The new study differs from the older aerobic soil metabolism data (MRID 67908 and MRID 133376 both in the rate of degradate formation and in the identification of degradates. MRID 133376 includes the aerobic soil metabolism data of triazole labeled propiconazole reported in MRID 67908. The reviewer (S. Ramasamy) calculated first order linear degradation half-lives for silt loam ranged between 60 and 84 days depending on the position of the labeling (84, 70, and 60 days for the ^{14}C -triazole or -phenyl or -dioxolane rings of propiconazole, respectively; refer p. 11 of this DER). The new study identified the degradates as CGA-71019, CGA-217495, CGA-91305. Two metabolites were identified in the older studies as U_1 and U_3 . U_1 was not characterized further but U_3 was characterized as CGA-101507 which corresponds to CGA-118245 reported in Figure 1 on page 161 of the new study.
3. The parent exists as cis and trans isomers (CGA 93590, CGA 93591) and therefore, may have distinct physical properties and chemical characteristics. The formation of degradates introduces another chiral carbon that increasing the number of isomer

degradates (CGA118244 cis isomer A, CGA118244 cis isomer B, CGA118244 trans isomer A, CGA118244 trans isomer B).

4. The study was conducted using triazole ring-labeled [3,5-¹⁴C]propiconazole (Figure 1, p. 159). The compound contained two additional ring structures that were not radiolabeled.
5. Nonextractable [¹⁴C]residues in the soil columns following leaching were reported as percentages of the total radioactivity in each soil depth (Tables XXVII-XL, pp. 115-118). The reviewer calculated and reported nonextractable [¹⁴C]residues as percentages of the applied radioactivity by dividing the dpm values in each soil depth by the total dpm applied to the column.
6. The study author stated that HPLC Unknown Region 1 consisted primarily of the degradate CGA-70179 (p. 60; Table XX, p. 98). HPLC Unknown Region 2 consisted primarily of CGA-217495, CGA-91305, and the tentatively identified cis-isomer of CGA-217495. HPLC Unknown Region 3 consisted of CGA-64250 and other unidentified degradates. Major degradates were not detected in any of the extracts or leachates, and all unidentified degradates were <1% of the applied radioactivity.
7. The reviewer noted that TLC data for the silt loam soil column (first extract of the 0- to 6-cm depth) indicated that 0.1-2.9% of the applied radioactivity was present as the degradate CGA-70179 following the aging period, whereas the degradate was not detected in the extracts by HPLC or FC/HPLC analyses (Table L, p. 129).
8. The limit of detection was reported for LSC and HPLC analyses, but not for TLC analysis. Both limits of detection and quantitation should be reported for each method utilized to allow the reviewer to evaluate the adequacy of the method for the determination of the parent and its degradates.
9. The study author stated that the unidentified [¹⁴C]residues (region 1) in the day-30 extracts from the aged sand soil compared to the radioactive zone which was found to contain primarily CGA-70179 (p. 60). The structure of CGA-70179 was not reported in Figure 1 (pp. 159-163).
10. The K_ds reported in this study correspond to desorption constants. The K_d adsorption values could be obtained from the older batch equilibrium studies (MRID 67903, MRID 41727001).

MINI 13376
Months
0
0.92
1.85
2.77
5.54
12

Silt beam
Days
0
27.6
55.5
83.1
166.2
360

Triaxial label
Percent radioactivity (via La radioactivity)
90.7
75.3
59.7
40.9
19.7
4.8

Half-life
84 days

Months
0
0.92
1.84
2.76
5.52

Silt beam
Days
0
27.6
55.2
82.8
165.6

Phenyl label
Percent radioactivity
96.3
54.8
38.7
28.6
17.2

La radioactivity
4.5675
4.0007
3.6558
3.3534
2.8449

Half-life
70 days

Months
0
0.92
1.94
2.36
5.52

Silt beam
Days
0
27.6
55.2
70.8
165.6

Dioxane label
Percent radioactivity
98.2
54
34.6
23.5
12.2

La radioactivity
4.4796
3.9890
3.5439
3.1570
2.5014

Half-life
60 days

SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.997
R Square	0.994
Adjusted R Square	0.992
Standard Error	0.096
Observations	6

ANOVA

	df	SS	MS	F	Significance F
Regression	1	6.04	6.04	457.00	0.00001
Residual	4	0.04	0.01		
Total	5	6.08			

	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%
Intercept	4.48546	0.05	82.97	0.00	4.34	4.64
X Variable 1	-0.00428	0.00	-25.63	0.00	-0.01	-0.01

SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.9630
R Square	0.9273
Adjusted R Square	0.9031
Standard Error	0.2028
Observations	5

ANOVA

	df	SS	MS	F	Significance F
Regression	1	1.5735	1.573526	38.72377	0.0085687
Residual	3	0.1233	0.0411139		
Total	4	1.6969			

	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%
Intercept	4.3382	0.13926	31.15628	0.0001	3.8957	4.7821
X Variable 1	-0.00967	0.00160	-6.186467	0.0085	-0.0149	-0.0048

SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.96451
R Square	0.93028
Adjusted R Square	0.90704
Standard Error	0.23168
Observations	5

ANOVA

	df	SS	MS	F	Significance F
Regression	1	2.1486	2.1485715	40.02913	0.00798298
Residual	3	0.1610	0.0536752		
Total	4	2.3096			

	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%
Intercept	4.27706	0.1566	27.312956	0.0001	3.78	4.78
X Variable 1	-0.01164	0.0018	-6.326837	0.0080	-0.02	-0.01

Page ____ is not included in this copy.

Pages 13 through 75 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☒ FIFRA registration data.
- ☐ The document is a duplicate of page(s) _____.
- ☐ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
