Data Evaluation Report on the Leaching of Orthosulfamuron (IR5878) in Soil Columns

PMRA Submission Number {.....} EPA MRID Number 46578968

Data Requirement: PMRA Data Code:
EPA DP Barcode: D320283
OECD Data Point:
EPA Guideline: 163-1

Test material:

Common name: Orthosulfamuron

Chemical name:

IUPAC name: 1-(4,6-Dimethoxypyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)phenyl-sulfamoyl]urea.

CAS name: 2-[[[[[(4,6-Dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]-amino]-N,N-dimethylbenzamide.

CAS No.: 213464-77-8.

Synonyms IR5878.

Smiles string: CN(C(=O)c1ccccc1NS(=O)(=O)NC(=O)Nc1nc(cc(n1)OC)OC)C (ISIS v2.3/Universal SMILES).
No EPI Suite, v3.12 SMILES String found as of 11/21/05.

Primary Reviewer: Kindra Bozicevich
Cambridge Environmental

Signature:
Date: 12/1/05

Secondary Reviewer: Joan Harlin
Cambridge Environmental

Signature:
Date: 12/1/05

QC/QA Manager: Joan Gaidos
Cambridge Environmental

Signature:
Date: 12/1/05

Final Reviewer: Greg Orrick
EPA Reviewer

Signature: Greg Orrick
Date: 7/26/06

Company Code:
Active Code:
Use Site Category:
EPA PC Code: 108209

CITATION: Scacchi, A., L. Vanini, and G. Pizzingrilli. 2004. Soil Column Leaching of ^{14}C-IR5878. Unpublished study performed by Isagro Ricerca Srl, Novara, Italy; sponsored and submitted by Isagro SpA, Milano, Italy. Study Number: MEF.03.17. Experiment initiation January 08, 2004 and completion April 02, 2004. Final report issued May 26, 2004. 162 pp.

Data Evaluation Report on the leaching of orthosulfamuron (IR5878) in unaged soil

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Cambridge Environmental

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Date: 12/1/05

Secondary Reviewer: Joan Harlin
Cambridge Environmental

Signature: Joan Harlin
Date: 12/1/05

QC/QA Manager: Joan Gaidos
Cambridge Environmental

Signature:
Date: 12/1/05

Final Reviewer: Roxolana Kashuba
EPA Reviewer

Signature:
Date:

Company Code:
Active Code:
Use Site Category:
EPA PC Code: 108209

CITATION: Scacchi, A., L. Vanini, and G. Pizzingrilli. 2004. Soil column leaching of ^{14}C-IR5878. Unpublished study performed by Isagro Ricerca Srl, Novara, Italy; sponsored and submitted by Isagro SpA, Milano, Italy. Study Number: MEF.03.17. Experiment initiation January 08, 2004 and completion April 02, 2004 (p. 14). Final report issued May 26, 2004.

EXECUTIVE SUMMARY:

The column leaching of unaged [^{14}C-5-pyrimidinyl]-labeled 1-(4,6-dimethyoxypyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)phenylsulfamoyl]urea (orthosulfamuron; IR5878; radiochemical purity >98%; specific activity 4.452 MBq/mg, 120.323 µCi/mg, 267117 dpm/µg; Lot # 280) was investigated in two sandy loam soils [pH 6.50, organic matter 1.79%; pH 5.66, organic matter 0.60%] from Arkansas, a sand soil [pH 4.70, organic matter 1.77%] from Minnesota, a clay loam [pH 5.37, organic matter 5.18%] from North Dakota, and a silt loam [pH 7.50, organic matter 1.58%] from Italy. The surface of each air-dried, untreated test soil sample [30 cm of soil per glass column (40-cm length; 5.0 cm i.d.)] was treated with unaged [^{14}C-5-pyrimidinyl]-orthosulfamuron at a nominal test concentration of *ca.* 5 µg/mL, corresponding to a treatment rate of 75 g/ha assuming a surface area of 19.63 cm^2. Duplicate soil columns were prepared for each test soil. The samples were wrapped in aluminum foil to exclude light and incubated for up to 119 hours (temperature not reported). The columns were continuously leached under saturated conditions with 997 mL (equivalent to 508 mm of rainfall) of 0.01M $CaCl_2$ solution. The flow rate ranged from 8.42 to 125.11 mL/h, and the infiltration rate ranged from 0.43 to 6.37 cm/h. A constant head (*ca.* 3 cm) was maintained (method not specified) on the top of each column. Mean data are reported for each test soil.

During leaching, leachate volumes were collected in volumetric flasks and duplicate aliquots were analyzed for total radioactivity using LSC. In addition, aliquots of the Ark-1 sandy loam and PC-1 silt loam soils were partitioned three times with CH_2Cl_2, then separated, evaporated to dryness, redissolved in CH_3CN:33 mM $NaHCO_3$ (7:3, v:v), and analyzed using LSC. The soils were extruded from each column by gentle nitrogen pressure, then separated into six equal segments (1s, 2s, 3s, 4s, 5s, and 6s), each 5 cm in length. Each soil segment was extracted by shaking with aliquots of CH_3CN:33 mM $NaHCO_3$ (7:3, v:v; Extract I) or CH_3CN:33 mM $NaHCO_3$ (1:1, v:v; Extract II). Following each extraction, the samples were centrifuged, the supernatants were brought to volume with acetonitrile, and aliquots were pooled, concentrated under vacuum, and analyzed using LSC. The remaining soils were air-dried, and duplicate aliquots were analyzed for total radioactivity using LSC following combustion. Aliquots of the column leachates and soil segment extracts were analyzed for [^{14}C-5-pyrimidinyl]-orthosulfamuron using reversed-phase and normal-phase TLC analysis. Orthosulfamuron and its transformation products were identified by comparison to [^{14}C]-labeled reference standards of orthosulfamuron and its transformation products, N-(4,6-dimethoxypyrimidin-2-yl)-urea (S12, DOP urea) and 4,6-dimethoxypyrimidin-2-ylamine (S13, DOP amine).

Mean mass balances were 99.30%, 97.05%, 94.83%, 95.79%, and 95.44% of the applied for the Ark-1 sandy loam, Ark-2 sandy loam, Benson sand, M-CL clay loam, and PC-1 silt loam test soils, respectively.

For the Ark-1 sandy loam soil, an average of 8.68% of the applied was recovered in the 1s segment (top 5-cm segment), 16.06% in the 2s segment, 26.71% in the 3s segment, 31.11% in the 4s segment, 14.84% in the 5s segment, and 1.27% of the applied in the 6s segment (bottom 5-cm segment). Based on TLC analysis, [^{14}C]orthosulfamuron (IR5878; S3) comprised 88.51% of

the applied, of which 6.18%, 13.08%, 24.35%, 29.47%, 14.33%, and 1.10% of the applied was recovered in soil segments 1s, 2s, 3s, 4s, 5s, and 6s, respectively. Transformation product S12 [DOP urea; N-(4,6-dimethoxypyrimidin-2-yl)-urea] was found in the top 25 cm of soil and totaled 8.22% of the applied. Transformation product S13 [DOP amine; 4,6-dimethoxypyrimidin-2-ylamine] was not detected. Total extractable [^{14}C]residues accounted for 96.86% of the applied, and unextractable residues accounted for 1.81% of the applied. Radioactivity in the leachate samples totaled 0.63% of the applied. Based on TLC analysis, [^{14}C]orthosulfamuron comprised all of the radioactivity recovered in the leachate samples.

For the Ark-2 sandy loam soil, an average of 31.32% of the applied was recovered in the 1s segment, 50.13% in the 2s segment, and 15.60% of the applied in the 3s segment. Radioactivity was not recovered in the 4s, 5s, and 6s soil segments. Based on TLC analysis, [^{14}C]orthosulfamuron (IR5878; S3) comprised a total of 72.51% of the applied, of which 18.64%, 40.32%, and 13.55% of the applied was recovered in soil segments 1s, 2s, and 3s, respectively. Transformation product S12 (DOP urea) was found in the top 15 cm of soil and totaled 22.22% of the applied. Transformation product S13 (DOP amine) was found in the top 5 cm of soil and totaled 0.29% of the applied. Total extractable [^{14}C]residues accounted for 95.00% of the applied, and unextractable residues accounted for 2.05% of the applied. Radioactivity in the leachate samples was not detected.

For the Benson sand soil, an average of 32.60% of the applied was recovered in the 1s segment, 29.86% in the 2s segment, 22.65% in the 3s segment, 9.26% in the 4s segment, and 0.46% of the applied in the 5s segment. Radioactivity was not recovered in the 6s (bottom) soil segment. Based on TLC analysis, [^{14}C]orthosulfamuron (IR5878; S3) comprised a total of 52.80% of the applied, of which 11.95%, 17.31%, 15.99%, and 7.55% of the applied was recovered in soil segments 1s, 2s, 3s, and 4s, respectively. Transformation product S12 was found in the top 20 cm of soil and totaled 38.16% of the applied. Transformation product S13 was found in the top 15 cm of soil and totaled 1.35% of the applied. Total extractable [^{14}C]residues accounted for 92.44% of the applied, and unextractable residues accounted for 2.39% of the applied. Radioactivity in the leachate samples was not detected.

For the M-CL clay loam soil, an average of 84.60% of the applied was recovered in the 1s segment, 10.94% in the 2s segment, and 0.25% of the applied in the 3s segment. Radioactivity was not recovered in the remaining 4s, 5s, and 6s soil segments. Based on TLC analysis, [^{14}C]orthosulfamuron (IR5878; S3) comprised a total of 72.22% of the applied, of which 64.01% and 8.21% of the applied was recovered in soil segments 1s and 2s, respectively. Transformation product S12 was found in the top 10 cm of soil and totaled 18.04% of the applied. Transformation product S13 was found in the top 5 cm of soil and totaled 0.67% of the applied. Total extractable [^{14}C]residues accounted for 91.17% of the applied, and unextractable residues accounted for 4.62% of the applied. Radioactivity in the leachate samples was not detected.

For the PC-1 silt loam soil, an average of 13.50% of the applied was recovered in the 1s segment, 11.16% in the 2s segment, 15.37% in the 3s segment, 20.61% in the 4s segment, 22.63% in the 5s segment, and 10.08% of the applied in the 6s segment. Based on TLC analysis,

[^{14}C]orthosulfamuron (IR5878; S3) comprised a total of 80.99% of the applied, of which 10.78%, 8.39%, 13.18%, 18.31%, 20.77%, and 9.56% of the applied was recovered in soil segments 1s, 2s, 3s, 4s, 5s, and 6s respectively. Transformation product S12 was found in all soil segments and totaled 9.68% of the applied. Transformation product S13 was not detected. Total extractable [^{14}C]residues accounted for 90.65% of the applied, and unextractable residues accounted for 2.70% of the applied. Radioactivity in the leachate samples totaled 2.09% of the applied. TLC analysis showed that [^{14}C]orthosulfamuron accounted for all of the radioactivity recovered in the leachate samples.

Study Acceptability: This soil column leaching study is classified as **supplemental**. The study is valid for orthosulfamuron parent. However, as only one compound ring was radiolabelled and the compound was not aged in soil, this study does not evaluate the leaching potential of major degradates.

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: This study was conducted in accordance with USEPA Guidelines for Pesticides Registration, Subdivision N §163-1 (p. 14). Significant deviations from the objectives of Subdivision N guidelines include:

> The test substance was not aged in the soil. Subdivision N guidelines specify that the test substance should be aged in soil under aerobic conditions for 30 days or one half-life, whichever is shorter.
>
> The test material was radiolabeled only on the pyrimidinyl ring, not on the phenyl ring. Phase 3 Technical Guidance indicates that studies of compounds of multiple ring structure should be conducted with each respective ring labeled.

COMPLIANCE: This study was conducted in compliance with OECD principles of Good Laboratory Practice, Council Directives 88/320/EEC and 90/18/EEC, and EC Directive 2004/9/EC (pp. 3-4; Appendix 10, pp. 159-162). Signed and dated GLP, Quality Assurance, and No Data Confidentiality statements were provided (pp. 2-5; Appendix 10, pp. 159-162). A Certificate of Authenticity was not provided.

A. MATERIALS:

1. Test Material [^{14}C-5-Pyrimidinyl]orthosulfamuron (IR5878; p. 16).

Chemical Structure: See DER Attachment 1.

Description: Technical grade, solid (p. 13).

Purity:

Radiolabeled: Radiochemical purity: >98% (by TLC; p. 16).
Lot/Batch No. 208.
Specific activity: 4.452 MBq/mg; 120.323 µCi/mg; 267117 dpm/µg.
Locations of the label: 5 Carbon of the pyrimidinyl ring.

Storage conditions of test chemicals: Stored at <-10°C (p. 16).

Physico-chemical properties of orthosulfamuron (IR5878):

Parameter	Value	Comment
Molecular formula	$C_{16}H_{20}N_6O_6S$	
Molecular weight	424.44 g/mole	
Water Solubility	Not reported.	
Vapor Pressure/Volatility	Not reported.	
UV Absorption	Not reported.	
Pka	Not reported.	
K_{ow}/log K_{ow}	Not reported.	
Stability of compound at room temperature, if provided	Not reported.	

Data were obtained from p. 13 of the study report.

2. Soil Characteristics

Table 1: Description of soil collection and storage.

Description	Ark 1	Ark 2	Benson	M-CL	PC-1
Geographic location	Shoffner Farm Research, Arkansas	Shoffner Farm Research, Arkansas	Minnesota	Mutchler Farm, North Dakota	Italy
Pesticide use history at the collection site	Not reported.	Not reported.	Not reported.	Not reported.	Not reported.
Collection procedures	Not reported.	Not reported.	Not reported.	Not reported.	Not reported.
Sampling depth (cm)	0-20	0-20	0-20	0-20	0-20
Storage conditions	Not reported.	Not reported.	Not reported.	Not reported.	Not reported.
Storage length[1]	*Ca.* 16 months.	*Ca.* 16 months.	*Ca.* 21 months.	*Ca.* 30 months.	*Ca.* 22 months.
Soil preparation (eg: 2 mm sieved; air dried etc.)	Air-dried, sieved (2 mm).	Air-dried, sieved (2 mm).	Air-dried, sieved (2 mm).	Air-dried, sieved (2 mm).	Air-dried, sieved (2 mm).

Data were obtained from pp. 16-17 and Appendix 3, p. 103 of the study report and p. 17 and Appendix 4, p. 125 of MRID 46578971.

[1] Storage length was determined as the interval from the date of sampling (September 2001 for M-CL; May 2002 for PC-1; June 2002 for Pratt and Benson; November 2002 for Ark-1 and Ark-2) to experiment initiation (March 2004).

Table 2: Properties of the soils.

Property	Ark-1	Ark-2	Benson	M-CL	PC-1
Soil texture	Sandy loam	Sandy loam	Sand	Clay loam	Silt loam
%Sand	58.25	60.00	87.25	24.75	13.50
%Silt	36.25	32.00	11.00	44.50	72.50
%Clay	5.50	8.00	1.75	30.75	14.00
pH (0.01M $CaCl_2$)	6.50	5.66	4.70	5.37	7.50
Organic carbon (%) [1]	1.05	0.35	1.04	3.05	0.92
Organic matter (%)	1.79	0.60	1.77	5.18	1.58
CEC(meq/100g)	7.19	5.89	1.46	27.18	17.01
Moisture at 1/3 atm (%)	17.19	15.04	7.46	36.07	27.13
Bulk density (g/cm^3)	1.37	1.52	1.54	1.15	1.48
Biomass (mg microbial C/100 g or CFU or other)	Not reported.				
Soil taxonomic classification	Not reported.				
Soil mapping unit (for EPA)	Not reported.				

Data were obtained from pp. 16-17 and Tables 1-5, pp. 39-43 of the study report.

[1] Calculated as % organic matter ÷ 1.7.

C. STUDY DESIGN:

1. Preliminary study: No preliminary studies were reported.

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2. Definitive study experimental conditions: The mobility of [^{14}C-5-pyrimidinyl]-labeled 1-(4,6-dimethyoxypyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)phenylsulfamoyl]urea (orthosulfamuron; IR5878; S-3; radiochemical purity >98%; specific activity 4.452 MBq/mg, 120.323 µCi/mg, 267117 dpm/µg; Lot # 208) was investigated in one sand, one clay loam, one silt loam, and two sandy loam soils (pp. 13, 16-17, 32).

Prior to study initiation, the test soils were sieved (2 mm; p. 17). Soil biomass determinations for the test soils were not conducted.

The soil column leaching study was conducted by packing three glass columns (40-cm length; 5.0-cm i.d.; two treated columns, one blank column) with air-dried, untreated soil using vibration (30 cm; p. 19; Appendix 4, p. 105). Duplicate columns were prepared for each test soil. Prior to packing, the column outlets were plugged with quartz wool and the conical parts were filled with sea sand. The soil columns were saturated with 0.01M $CaCl_2$ solution from the bottom (incubation time and temperature were not reported; Appendix 9, Figure 1, p. 157). Following saturation, the surface of each soil column containing the Ark-1 sandy loam, Benson sand, and PC-1 silt loam soils were treated with 2.4-mL aliquots of an acetonitrile solution containing [^{14}C-5-pyrimidinyl]orthosulfamuron, dissolved in 0.01M $CaCl_2$ solution, at a nominal test concentration of *ca.* 5 µg/mL (Test Solution 1; actual concentration 6.13 µg/mL; p. 25). The surface of each soil column containing the Ark-2 sandy loam and M-CL clay loam soils was treated with 2.47-mL aliquots of an acetonitrile solution containing [^{14}C-5-pyrimidinyl]-orthosulfamuron, dissolved in 0.01M $CaCl_2$ solution, at a nominal test concentration of *ca.* 5 µg/mL (Test Solution 2; actual concentration 6.02 µg/mL; p. 25). Both applications corresponded to a nominal treatment rate of 75 g/ha, assuming a surface area of 19.63 cm^2 (p. 19). The top of each soil column was covered with glass fiber filters and the columns were wrapped in aluminum foil (Appendix 9, Figure 2, p. 157). The columns were then leached with 997 mL of 0.01M $CaCl_2$ solution (equivalent to 508 mm of rain), maintaining a constant head of *ca.* 3 cm (method not specified) for up to 119 hours (flow rate range 8.42 to 125.11 mL/h; infiltration rate range 0.43 to 6.37 cm/h; pp. 20, 27; Appendix 4, p. 105).

Following leaching, column leachates were collected in volumetric flasks (p. 20). The soils were extruded from each column by gentle nitrogen pressure, then separated into six equal segments (1s, 2s, 3s, 4s, 5s, and 6s), each 5 cm in length.

3. Description of analytical procedures:

Extraction/clean up/concentration methods: Following leaching, 1000-mL aliquots of the Ark-1 sandy loam soil and 500-mL aliquots of the PC-1 silt loam soil were partitioned three times with CH_2Cl_2 (100-200 mL; p. 21; Scheme 1, p. 35). The CH_2Cl_2 phase was separated, evaporated to dryness, and redissolved in CH_3CN:33 mM $NaHCO_3$ (7:3, v:v, 0.5 mL). Each soil segment was extracted by shaking for 1 hour at 300 strokes/minute with 250 mL each of a CH_3CN:33 mM $NaHCO_3$ mixture (7:3, v:v; Extract I) and a CH_3CN:33 mM $NaHCO_3$ mixture (1:1, v:v; Extract II). Following each extraction, the samples were centrifuged for 20 minutes

and the supernatants were removed and brought to 250 mL with acetonitrile. Aliquots (50 mL) of each extract were pooled and concentrated under vacuum to 0.5-1.0 mL.

Total ^{14}C measurement: Following leaching, leachate volumes were brought to 1 L with 0.01M $CaCl_2$ solution. Duplicate 5-mL aliquots were analyzed for total radioactivity using LSC (pp. 20-22; Scheme 1, p. 35; Appendix 9, Figure 3, p. 157). In addition, duplicate aliquots of the soil extracts I and II (1 mL), organic phases (10 µL), and aqueous phases (5 mL) were analyzed for total radioactivity using LSC. Mass balances were determined by summing the radioactivity recovered in the leachate samples, the segment extracts, and the bound residues (p. 22).

Non-extractable residues, if any: The remaining soil was air-dried, and duplicate aliquots were analyzed for total radioactivity using LSC following combustion; combustion efficiency was >93% (pp. 21-22).

Derivatization method, if used: A derivatization method was not employed in this study.

Identification and quantification of parent compound: Aliquots of the column leachates and soil segment extracts were analyzed for [^{14}C-5-pyrimidinyl]orthosulfamuron using TLC analysis (p. 23). Normal-phase TLC was performed using silica gel coated 60 F_{254} plates (0.20-mm thickness) developed in chloroform:methanol:30% ammonium hydroxide (75:22:3, v:v:v; Solvent System 1). Reversed-phase TLC was performed using RP-18 F_{254S} plates (0.20-mm thickness) developed in acetonitrile:water (92:8, v:v; Solvent System 2). [^{14}C]Orthosulfmuron was identified by co-chromatography with a reference standard of [^{14}C]-labeled orthosulfamuron. Following development, areas of radioactivity were detected and quantified using Fuji BAS 1500 and 2500 Bio-Imaging Analyzers, with two-dimensional images generated using a Fuji BAS 1500 Autoradiographic Imaging System (p. 23). The imaging plates were coated with photostimulable phosphor $BaFBr:Eu^{2+}$, from which the luminescence was detected using a photomultiplier tube and analyzed using Tina 2.10 software.

Identification and quantification of transformation products, if appropriate: Transformation products were identified as described for the parent compound. A representative segment extract sample for the Benson sand soil and a representative leachate sample for the PC-1 silt loam soil were co-chromatographed with the following [^{14}C]-labeled reference standards (pp. 17, 23, 32; Appendix 8, pp. 155-156):

Chemical Name	Molecular formula	Molecular weight	Lot #	Specific activity	Radiochemical purity	CAS No.
DOP urea [N-(4,6-dimethoxypyrimidin-2-yl)-urea; S12]	$C_7H_{10}N_4O_3$	198.21 g/mole	214	8.891 MBq/mg (240.2976 µCi/mg)	>99%	151331-81-6
DOP amine [4,6-dimethoxypyrimidin-2-ylamine; S13]	$C_6H_9N_3O_2$	155.16 g/mole	178	13.235 MBq/mg (357.695 µCi/mg)	>99%	Not reported.

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Detection limits (LOD, LOQ) for the parent compound: Limits of detection (LOD) for LSC analysis were twice the background radioactivity (p. 22). Limits of quantification (LOQ) were not reported. The LOD for TLC analysis was 16 dpm (p. 24).

Detection limits (LOD, LOQ) for the transformation products, if appropriate: The LODs for LSC and TLC analyses were the same as reported for the parent compound. The LOQ for LSC analysis was not reported.

II. RESULTS AND DISCUSSION

A. TEST CONDITIONS: The incubation temperature employed during the study was not reported.

B. MASS BALANCE: Mean mass balances were 99.30%, 97.05%, 94.83%, 95.79%, and 95.44% of the applied for the Ark-1 sandy loam, Ark-2 sandy loam, Benson sand, M-CL clay loam, and PC-1 silt loam test soils, respectively (p. 26; Tables 6-10, pp. 44-48).

C. LEACHING: For the Ark-1 sandy loam soil, an average of 8.68% of the applied was recovered in the 1s segment (top 5-cm segment), 16.06% in the 2s segment, 26.71% in the 3s segment, 31.11% in the 4s segment, 14.84% in the 5s segment, and 1.27% in the 6s segment (bottom 5-cm segment; p.25; Table 6, p. 44; Figure 1, p. 57). Based on TLC analysis, [^{14}C]orthosulfamuron (IR5878; S3) comprised 88.51% of the applied radioactivity, of which 6.18%, 13.08%, 24.35%, 29.47%, 14.33%, and 1.10% of the applied was recovered in soil segments 1s, 2s, 3s, 4s, 5s, and 6s, respectively (p. 28; Table 12, p. 50). Transformation product S12 (DOP urea) was found in the top 25 cm of soil and totaled 8.22% of the applied. Transformation product S13 (DOP amine) was not detected. Total extractable [^{14}C]residues accounted for 96.86% of the applied, and unextractable residues accounted for 1.81% of the applied. Radioactivity in the leachate samples accounted for a total of 0.63% of the applied. Based on TLC analysis, [^{14}C]orthosulfamuron comprised all of the radioactivity recovered in the leachate samples (p. 27; Table 11, p. 49).

For the Ark-2 sandy loam soil, an average of 31.32% of the applied was recovered in the 1s segment, 50.13% in the 2s segment, and 15.60% in the 3s segment (p. 25; Table 7, p. 45; Figure 2, p. 58). Radioactivity was not recovered in the 4s, 5s, and 6s soil segments. Based on TLC analysis, [^{14}C]orthosulfamuron (IR5878; S3) comprised 72.51% of the applied radioactivity, of which 18.64%, 40.32%, and 13.55% of the applied was recovered in soil segments 1s, 2s, and 3s, respectively (p. 28; Table 13, p. 51). Transformation product S12 was found in the top 15 cm of soil and totaled 22.22% of the applied. Transformation product S13 was found in the top 5 cm of soil and totaled 0.29% of the applied. Total extractable [^{14}C]residues accounted for 95.00% of the applied, and unextractable residues accounted for 2.05% of the applied. Radioactivity in the leachate samples was not detected.

For the Benson sand soil, an average of 32.60% of the applied was recovered in the 1s segment, 29.86% in the 2s segment, 22.65% in the 3s segment, 9.26% in the 4s segment, and 0.46% in the 5s segment (p. 26; Table 8, p. 46; Figure 3, p. 59). Radioactivity was not recovered in the 6s soil segment. Based on TLC analysis, [^{14}C]orthosulfamuron (IR5878; S3) comprised 52.80% of the applied radioactivity, of which 11.95%, 17.31%, 15.99%, and 7.55% of the applied was recovered in soil segments 1s, 2s, 3s, and 4s, respectively (p. 28; Table 14, p. 52). Transformation product S12 was found in the top 20 cm of soil and totaled 38.16% of the applied. Transformation product S13 was found in the top 15 cm of soil and totaled 1.35% of the applied. Total extractable [^{14}C]residues accounted for 92.44% of the applied, and unextractable residues accounted for 2.39% of the applied. Radioactivity in the leachate samples was not detected.

For the M-CL clay loam soil, an average of 84.60% of the applied was recovered in the 1s segment, 10.94% in the 2s segment, and 0.25% in the 3s segment (p. 26; Table 9, p. 47; Figure 4, p. 60). Radioactivity was not recovered in the 4s, 5s, and 6s soil segments. Based on TLC analysis, [^{14}C]orthosulfamuron (IR5878; S3) comprised 72.22% of the applied, of which 64.01% and 8.21% of the applied was recovered in soil segments 1s and 2s, respectively (pp. 28-29; Table 15, p. 53). Transformation product S12 was found in the top 10 cm of soil and averaged 18.04% of the applied. Transformation product S13 was found in the top 5 cm of soil and averaged 0.67% of the applied. Total extractable [^{14}C]residues accounted for an average 91.17% of the applied, and unextractable residues accounted for 4.62% of the applied. Radioactivity in the leachate samples was not detected.

For the PC-1 silt loam soil, an average of 13.50% of the applied was recovered in the 1s segment, 11.16% in the 2s segment, 15.37% in the 3s segment, 20.61% in the 4s segment, 22.63% in the 5s segment, and 10.08% in the 6s segment (p. 26; Table 10, p. 48; Figure 5, p. 61). Based on TLC analysis, [^{14}C]orthosulfamuron (IR5878; S3) averaged 80.99% of the applied, of which 10.78%, 8.39%, 13.18%, 18.31%, 20.77%, and 9.56% of the applied was recovered in soil segments 1s, 2s, 3s, 4s, 5s, and 6s, respectively (p. 29; Table 16, p. 54). Transformation product S12 was found in all soil segments and averaged 9.68% of the applied. Transformation product S13 was not detected. Total extractable [^{14}C]residues accounted for an average 90.65% of the applied, and unextractable residues accounted for 2.70% of the applied. Radioactivity in the leachate samples totaled 2.09% of the applied. Based on TLC analysis, [^{14}C]orthosulfamuron accounted for all of the radioactivity recovered in the leachate samples (p. 27; Table 11, p. 49).

III. STUDY DEFICIENCIES

1. The test substance was not aged in the soil. Subdivision N guidelines specify that the test substance should be aged in soil under aerobic conditions for 30 days or one half-life, whichever is shorter, in order to investigate the leaching potential of degradates.

2. The test material was radiolabeled only on the pyrimidinyl ring, not on the phenyl ring. Phase 3 Technical Guidance indicates that studies of compounds of multiple ring structure

should be conducted with each respective ring labeled in order to investigate the leaching potential of all major degradates.

3. The incubation temperature during the study was not reported. The temperature of the soil columns should be maintained at a temperature within the range of normal environmental parameters (18-30°C).

4. The method used to maintain a constant head during leaching of the soil columns was not reported.

5. Following the leaching phase, the leachates and extracts were stored at 1-7°C when not in use (p. 21). TLC analysis was performed within 15 days from the collection and extraction of samples (p. 23). Storage stability data were not provided.

6. Limits of quantification (LOQ) were not reported.

IV. REVIEWER'S COMMENTS

1. The column leachates and soil segment extracts were analyzed for [^{14}C-5-pyrimidinyl]orthosulfamuron using reversed-phase and normal-phase TLC analysis. Representative chromatograms were presented in Figures 6-19, pp. 62-75 of the study report. Orthosulfamuron and its transformation products were identified by comparison to [^{14}C]-labeled reference standards of orthosulfamuron, DOP urea, and DOP amine. Representative chromatograms for the Benson sand soil segment extracts and PC-1 silt loam leachate samples were presented in Figures 20-27, pp. 76-83 of the study report.

2. Figures depicting the soil columns were included in Appendix 9 of the study report (pp. 157-158). An experimental protocol was included in Appendix 1 of the study report (pp. 87-98).

V. REFERENCES

1. U.S. Environmental Protection Agency. 1982. Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate, Section 163-1. Mobility studies. Office of Pesticide and Toxic Substances, Washington, DC. EPA 540/9-82-021.

2. U.S. Environmental Protection Agency. 1989. FIFRA Accelerated Reregistration, Phase 3 Technical Guidance. Office of the Prevention, Pesticides, and Toxic Substances, Washington, DC. EPA 540/09-90-078.

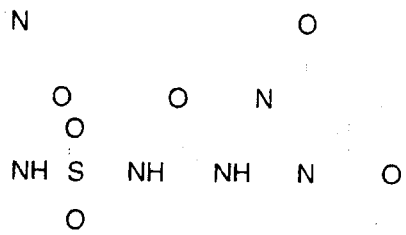
3. U.S. Environmental Protection Agency. 1993. Pesticide Registration Rejection Rate Analysis - Environmental Fate. Office of the Prevention, Pesticides, and Toxic Substances, Washington, DC. EPA 738.

Attachment 1: Structures of Parent Compound and Transformation Products

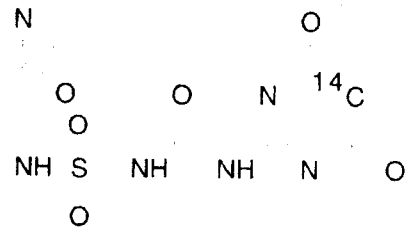
Orthosulfamuron [IR5878; S3]

IUPAC Name:	1-(4,6-Dimethoxypyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)phenylsulfamoyl]urea.
CAS Name:	2-[[[[[(4,6-Dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]amino]-N,N-dimethylbenzamide.
CAS Number:	213464-77-8.
SMILES String:	CN(C(=O)c1ccccc1NS(=O)(=O)NC(=O)Nc1nc(cc(n1)OC)OC)C (ISIS v2.3/Universal SMILES). No EPI Suite, v3.12 SMILES String found as of 11/21/05.

Unlabeled



[Pyrimidinyl-5-^{14}C]IR5878

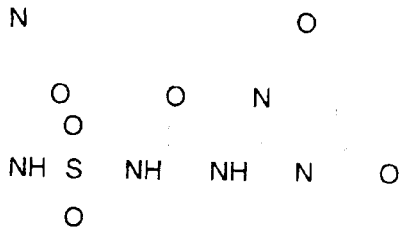


^{14}C = Location of the radiolabel.

Identified Compounds

Orthosulfamuron [IR5878; S3]

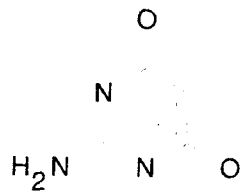
IUPAC Name:	1-(4,6-Dimethoxypyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)phenylsulfamoyl]urea.
CAS Name:	2-[[[[[(4,6-Dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]amino]-N,N-dimethylbenzamide.
CAS Number:	213464-77-8.
SMILES String:	CN(C(=O)c1ccccc1NS(=O)(=O)NC(=O)Nc1nc(cc(n1)OC)OC)C (ISIS v2.3/Universal SMILES). No EPI Suite, v3.12 SMILES String found as of 11/21/05.



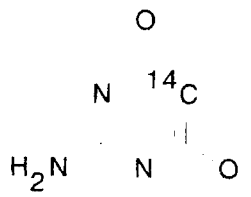
S13 [DOP amine]

IUPAC Name: 4,6-Dimethoxypyrimidin-2-yl amine.
2-Amino-4,6-dimethoxypyrimidine.
CAS Name: Not reported.
CAS Number: Not reported.

Unlabeled



[Pyrimidinyl-5-^{14}C]DOP amine

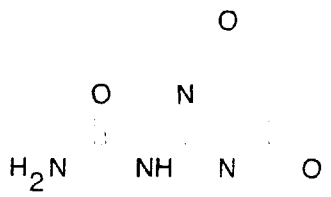


^{14}C = Location of the radiolabel.

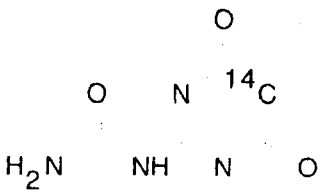
S12 [IR7825; DOP urea]

IUPAC Name: N-(4,6-Dimethoxypyrimidin-2-yl)-urea.
CAS Name: 4,6-Dimethoxy-2-pyrimidinyl urea.
CAS Number: Not reported.

Unlabeled



[Pyrimidinyl-5-^{14}C]DOP urea



^{14}C = Location of the radiolabel.

Attachment 2: Scheme of extraction and analyses of leachates and soil column segments
Illustration of test apparatus

7-26-06 DER on the Leaching of Orthosulfamuron in Soil Column 46578968

Page _____ is not included in this copy.

Pages 20 through 82 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.

_____ Internal deliberative information.

_____ Attorney-Client work product.

_____ Claimed Confidential by submitter upon submission to the Agency.

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.
