

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

Data Requirement: PMRA Data Code:
EPA DP Barcode: D320283
OECD Data Point:
EPA Guideline: 162-4

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: Lisa Koterwas
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Date: 12/1/05


Secondary Reviewer: Kathleen Ferguson
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Company Code:

Active Code:

Use Site Category:

EPA PC Code: 108209

CITATION: Scacchi, A., L. Vanini, and D. Oriolo. 2005. Aerobic Aquatic Degradation of ¹⁴C-IR5878 in Paddy-field Soil under Sunlight. Unpublished study performed by Isagro Ricerca Srl, Environmental Chemistry, Metabolism & Environmental Fate, Novara, Italy; sponsored and submitted by Isagro SpA Department, Milano, Italy. Study No.: MEF.04.13. Experiment initiated on July 9, 2004 and completed on October 8, 2004. Final report issued on January 27, 2005. 198 pp.


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CITATION: Scacchi, A., L. Vanini, and D. Oriolo. 2005. Aerobic aquatic degradation of ¹⁴C-IR5878 in paddy-field soil under sunlight. Unpublished study performed by Isagro Ricerca Srl, Environmental Chemistry, Metabolism & Environmental Fate, Novara, Italy; and sponsored and submitted by Isagro SpA Department, Milano, Italy. Study No.: MEF.04.13. Experiment initiated on July 9, 2004 and completed on October 8, 2004 (p. 15). Final report issued on January 27, 2005.

2

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

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EXECUTIVE SUMMARY

The aerobic biotransformation of [^{14}C -5-pyrimidinyl]-labeled and [^{14}C -U-phenyl]-labeled 1-(4,6-dimethoxypyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)phenylsulfamoyl]urea {orthosulfamuron, IR5878}, at 0.75 mg a.i./L (equivalent to 75 g a.i./ha), was studied outdoors for 62 days in a water/loamy sand sediment (water pH 7.79, organic carbon not reported; sediment pH 6.3, organic carbon 1.30%) from Italy. During incubation, the samples were open to the environment; they were fully exposed to sunlight and air temperatures were not controlled. The water/sediment/water ratio was *ca.* 1:1. The study was conducted with significant deviations from the Council Directive 91/414/EEC, Part A of Annex II, Section 7 and OECD Guideline 307, and in compliance with OECD GLP standards. The test system consisted of glass trays (7.6 cm i.d., 45.34 cm² area) containing 1-cm of sediment covered with 1-cm of water. The open trays were placed outdoors with the objective of simulating field conditions. Volatiles were not collected or controlled. Duplicate samples were collected and analyzed after 0, 1, 2, 3, 4, 5, 7, 10, 15, 21, 30, 45 and 62 days of incubation. Prior to analysis, the water samples were basified using a saturated NaHCO₃ solution, and the sediment samples were extracted once with acetonitrile:33 mM NaHCO₃ (7:3, v:v) and once with acetonitrile:33 mM NaHCO₃ (1:1, v:v). Identification of the parent and major transformation products was done using TLC co-chromatography and LC-MS analysis. Minor transformation products were identified using TLC co-chromatography. Post-extraction soils that contained >20% of the applied were further extracted and separated into fulvic acids, humic acids, and humin.

During incubation, the samples were exposed to sunlight (maximum irradiance, 246 W/m² to 839 W/m²). Air temperatures ranged from 18.8-29.3°C (mean minimum and maximum). At the water-soil interface, redox potentials decreased *ca.* +210 to *ca.* +160 mV and the pH increased from *ca.* 7.2 to *ca.* 7.9. The viability of the sediment microflora was confirmed.

Overall recoveries of [^{14}C]residues averaged 83.45 ± 10.32% (decreasing from an average 101.92% to 68.27-68.45%) of the applied for the phenyl-labeled samples and 80.04 ± 9.02% (decreasing from 101.12% to 70.39-74.50%) for the pyrimidinyl-labeled samples. There was a rapid decline over time for both label test systems; final recoveries (day 62) of the phenyl- and pyrimidinyl-labeled materials were 68% and 74% of the applied, respectively. [^{14}C]Residues dissipated quickly from the water layer into the sediment, from 33-38:1 (water:sediment) at time 0 to 1-2:1 at day 1 posttreatment; the ratios were 1:2 at 30 days and 1:5 at 62 days for the phenyl label and 1:7 and 1:22-23 at 30 and 62 days, respectively, for the pyrimidinyl label.

In the total system (combined labels), [^{14}C]orthosulfamuron decreased from an average 95.33-96.91% of the applied at time 0 to 41.35-44.32% at 1 day posttreatment, 13.54-15.80% at 4 days, 2.77-5.41% at 7 days and ≤1.41% at and after 15 days. In the water, [^{14}C]orthosulfamuron decreased from an average 95.33-96.91% of the applied at time 0 to 21.07-24.80% at 1 day posttreatment, 4.19-4.88% at 4 days, and ≤0.64% at and after 7 days. In the sediment, [^{14}C]orthosulfamuron decreased from an average maximum of 16.57-21.96% of the applied at 1-3 days posttreatment to 4.63-7.78% at 5 days, and ≤2.40% at and after 10 days. Accurate half-

5

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

lives could not be calculated because >50% of the applied orthosulfamuron dissipated between time 0 and the next sampling interval (1 day posttreatment).

In the system treated with [¹⁴C-U-phenyl]orthosulfamuron, the only major transformation product was DBS acid (S1; IR7863, (2-dimethylcarbamoylphenyl) sulfamic acid} at a maximum of 54.47% of the applied in the total system at 7 days posttreatment (maximums 36.63% at 7 days in water, 19.45% at 4 days in sediment), decreasing to 13.13% (6.99% in water, 6.14% in sediment) at study termination (62 days). The three identified minor transformation products were DBS amide (S2; 2-[(aminosulfonyl)amino]-N,N-dimethylbenzamide}, DB amine (S4; 2-amino-N,N-dimethylbenzamide}, and O-desmethyl IR5878 (S9; IR8181, 1-(4-hydroxy-6-methoxy pyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)phenylsulfamoyl]-urea}; each averaged a maximum of <2% of the applied in the total system. DBS amide (S2) averaged a maximum of 1.98% of the applied (0.95% in water, 1.03% in sediment). DB amine (S4) was detected only in the sediment and averaged a maximum of 0.79% of the applied. O-Desmethyl IR5878 (S9) averaged a maximum of 1.81% of the applied (1.80% in water, 1.02% in sediment). S5 was observed at up to 16.14% of the applied in the total system; however, it was determined to be composed of 5 compounds. S8, which was not identified, averaged a maximum of 3.72% of the applied.

In the system treated with [¹⁴C-5-pyrimidinyl]orthosulfamuron, the only major transformation product was DOP urea (S12; IR7825, N-(4,6-dimethoxypyrimidin-2-yl)urea} at an average maximum of 56.95% of the applied at 5 days posttreatment (maximums 14.42% at 7 days in the water, 44.52% at 5 days in the sediment), decreasing to 32.78% (2.48% in water, 30.30% in sediment) at study termination. The three identified minor transformation products were O-desmethyl IR5878 (S9), DOP amine (S13; 4,6-dimethoxypyrimidin-2-yl amine} and O-desmethyl DOP urea (S15; N-(4-hydroxy-6-methoxypyrimidin-2-yl)urea} each averaged a maximum of <3% of the applied in the total system. O-Desmethyl IR5878 (S9) averaged a maximum of 2.78% of the applied (2.78% in water, 0.49% in sediment). DOP amine (S13) average a maximum of 2.80% of the applied (0.97% in water, 2.01% in sediment). O-Desmethyl DOP urea (S15) averaged a maximum of 2.18% of the applied (1.23% in water, 0.95% in sediment). S11, which was not identified, averaged a maximum of 5.03% of the applied.

In the sediment, extractable [¹⁴C]residues increased to average maximums of 39.43 and 54.09% in the phenyl and pyrimidinyl label systems, respectively, decreasing to 15.69 and 33.12%, respectively, at study termination. Nonextractable [¹⁴C]residues increased to an average maximum of 38.26-41.87% of the applied at 62 days. The soil residues from 21-62 days posttreatment were further extracted and fractionated into fulvic acids, humic acids and humin. The acidic extraction, fulvic acids, humic acids and humin were determined as 0.78-3.06%, 10.01-16.52%, 3.54-6.70% and 4.27-17.22%, respectively (combined radiolabels).

A biotransformation pathway was provided by the study authors. The main degradation pathway of orthosulfamuron was the hydrolytic cleavage of the sulfamoylurea linkage to give DOP urea and DBS acid. A minor degradation pathway was the demethylation of the methoxy group on the pyrimidinyl ring of orthosulfamuron to O-desmethyl IR5878, which also degraded to DBS

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

acid and O-desmethyl DOP urea. O-desmethyl DOP urea was also formed from the demethylation of DOP urea. Other minor transformation pathways occurred wherein orthosulfamuron degraded to DOP amine, DBS amide, and DB amine. Additionally, very polar compounds, which were generated from the degradation of unspecified compounds, quickly mineralized to carbon dioxide.

Results Synopsis:

Test system used: Italian water/loamy sand sediment system (combined labels).

Accurate half-lives could not be calculated because >50% of the applied orthosulfamuron dissipated between time 0 and the next sampling interval (1 day posttreatment).

Phenyl label/ Major transformation products:

DBS acid (S1) {(2-dimethylcarbamoylphenyl) sulfamic acid; maximum of 36.63%, 19.45% and 54.47% of the applied amount in the water, sediment and total system, respectively}.

S5 {composed of 5 compounds; maximum of 9.30%, 7.58% and 16.14% in the water, sediment and total system, respectively}.

Minor transformation products:

DBS amide (S2) {2-[(aminosulfonyl)amino]-N,N-dimethylbenzamide; maximum of 0.95%, 1.03% and 1.98% in the water, sediment and total system, respectively}.

DB amine (S4) {2-amino-N,N-dimethylbenzamide; maximum of 0.79%, detected only in the sediment}.

O-desmethyl IR5878 (S9) {maximum of 1.80%, 1.02% and 1.81% in the water, sediment and total system, respectively}.

Pyrimidinyl label/ Major transformation products:

DOP urea (S12) {N-(4,6-dimethoxypyrimidin-2-yl)urea; maximum of 14.42%, 44.52% and 56.95% in the water, sediment and total system, respectively}.

Minor transformation products:

O-desmethyl IR5878 (S9) {1-(4-hydroxy-6-methoxy pyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)phenylsulfamoyl]-urea; maximum of 2.78%, 0.49% and 2.78% in the water, sediment and total system, respectively}.

DOP amine (S13) {4,6-dimethoxypyrimidin-2-yl amine; maximum of 0.97%, 2.01% and 2.80% in the water, sediment and total system, respectively}.

O-desmethyl DOP urea (S15) {N-(4-hydroxy-6-methoxypyrimidin-2-yl)urea; maximum of 1.23%, 0.95% and 2.18% in the water, sediment and total system, respectively}.

Study Acceptability: This study is classified as **unacceptable**. The study was conducted outdoors, and samples were exposed to sunlight and fluctuating temperatures. The samples were open to the environment; volatiles were not collected and radioactivity was lost over time, resulting in poor material balance. Due to these deficiencies, this study does not fulfill OECD guidelines 307 or 308 or Subdivision N guidelines §162-1, §162-4, §164-1, or §164-2.

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

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I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: This study was conducted with significant deviations from Council Directive 91/414/EEC, Part A of Annex II, Section 7 and OECD Guideline 307 "Aerobic and Anaerobic Transformation in Soil" (April 2002; pp. 1, 15). Several significant deviations from the objectives of Subdivision N guidelines were noted:

The study was conducted outdoors, so that the samples were exposed to sunlight and temperatures were not controlled.

The samples were open to the environment. There was no attempt to control or measure volatiles, and radioactivity was lost from the system over time.

COMPLIANCE: This study was conducted in compliance with OECD Good Laboratory Practices, Council Directives 88/320/EEC and 90/18/EEC, and EC directive 2004/9/EC (1992; p. 3). Signed and dated Data Confidentiality, GLP, Certificate of Authenticity and Quality Assurance statements were provided (pp. 2-3, 5-6).

A. MATERIALS:

1. Test Materials

[¹⁴C-5-Pyrimidinyl] and [¹⁴C-U-phenyl]orthosulfamuron (p. 17).

Chemical Structure:

See DER Attachment 1.

Description:

Technical grade, solid.

**Purities:
Pyrimidinyl**

Radiochemical purity: >97% (by TLC; p. 17).
Lot/Batch No.: 208.
Analytical purity: Not reported.
Specific activity: 4.452 MBq/mg (120.323 μCi/mg, 267117 dpm/μg).
Locations of the label: The C5 carbon of the pyrimidinyl ring.

Phenyl

Radiochemical purity: >97% (by TLC; p. 17).
Lot/Batch No.: 209.

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

Analytical purity: Not reported.
 Specific activity: 7.357 MBq/mg (198.85 μ Ci/mg, 441447 dpm/ μ g).
 Locations of the label: Uniformly in the phenyl ring.

Storage conditions of test chemicals:

The test materials were stored frozen at -20°C (lighting conditions were not reported; p. 18).

Physico-chemical properties of orthosulfamuron:

Parameter	Value	Comment
Molecular weight	424.44 g/mol	
Molecular formula	$\text{C}_{16}\text{H}_{20}\text{N}_6\text{O}_6\text{S}$	
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 obtained from p. 14 of the study report.

2. Water-sediment collection, storage and properties

Table 1: Description of water collection and storage.

Description		Details
Geographic location		Cascina Bertolina Farm, Breme (PV), Lombardy, Italy.
Pesticide use history at the collection site		None.
Collection procedures for:	Water:	Not reported.
	Sediment	Not reported.
Sampling depth for:	Water:	Not reported; from the irrigation canal of the farm.
	Sediment:	Upper 20 cm layer.
Storage conditions		Water and sediment were stored at $1-7^{\circ}\text{C}$.
Storage length ¹		ca. 4 months.
Preparation of water and sediment samples		Water- filtered, paper filter (extra rapid). Sediment- sieved, 2 mm.

Data obtained from p. 18 and Appendix 4, p. 129 of the study report.

1. Storage length was estimated using the experimental start date (July 9, 2004; p. 15) and the collection date for the system (March 2004; Appendix 4, p. 129).

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

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Table 2: Properties of the water.

Description	Details
Temperature (°C)	Not reported
pH	7.79
Redox potential (mV) ¹	ca. +210
Oxygen concentration (mg/L)	Not reported
Dissolved organic carbon (%)	Not reported
Total organic carbon (µg/L)	613
Hardness (µg/L CaCO ₃)	352000
Electrical conductivity (mmhos/cm)	Not reported
Biomass (mg microbial C/100 g or CFU or other)	Not reported

Data obtained from Table 1, p. 51 and Appendix 5, p. 131 of the study report.

1. Redox potential was not reported, but estimated from a graphical representation of measurements taken at the "interface of the soil-water" (p. 20).

Table 3: Properties of the sediment.

Property	Details	
Soil texture (USDA)	Loamy sand	
% Sand (50-2000 µm)	77	
% Silt (2-50 µm)	22	
% Clay (<2 µm)	1	
pH	In water	6.3
	In 0.01 M CaCl ₂	4.7
Organic carbon (%)	1.30	
CEC(meq/100g)	7.74	
Redox potential (mV) ¹	ca. +210	
Moisture at 1/3 bar (%)	9.7	
Bulk density (g/cm ³)	1.26	
Biomass (mg microbial C/100 g dry weight)	20.96	
Biomass (% referred to total organic carbon)	1.61	

Data obtained from Table 1, p. 51 and Appendix 5, p. 131 of the study report.

1. Redox potential was not reported, but estimated from a graphical representation of measurements taken at the "interface of the soil-water" (p. 20).

B. EXPERIMENTAL DESIGN:

1. **Preliminary experiments:** No preliminary experiments were conducted.

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

2. Experimental conditions:

Table 4: Study design.

Parameter		Details	
Duration of the test		62 days	
Water: Filtered/unfiltered water: Type and size of filter used, if any:		Filtered. Paper filter, size not reported.	
Amount of sediment and water/ treatment		ca. 50 g soil (dry weight)	
Water/sediment ratio		1.1:1 [ca. 50 g soil (dry weight) and ca. 55 mL water]	
Application rates (mg a.i./L) Nominal: Actual:		0.75 mg a.i./L (equivalent to 75 g a.i./ha) Not reported.	
Control conditions, if used		Sterile controls were not used in this study.	
No. of replications Control, if used: Treatments:		Sterile controls were not used in this study. Two samples were collected at each sampling interval.	
Test apparatus (Type/material/volume):		Glass trays (7.6 cm i.d., 45.34 cm ² area) were filled with soil to a depth of 1 cm and with a 1-cm water layer. The incubation units were maintained outdoors (experimental conditions) for 8 days prior to test material application.	
Details of traps for CO ₂ and organic volatile, if any:		Volatile traps were not used.	
If no traps were used, is the system closed?		Open	
Identity and concentration of co-solvent		Acetonitrile, <0.01%.	
Pesticide application method	Volume of the test solution used/treatment:	1.1 mL of the pyrimidinyl dosing solution (34.05 µg) and the phenyl dosing solution (34.06 µg).	
	Application method:	Added dropwise, then the soil and water were mixed immediately.	
Any indication of the test material adsorbing to the walls of the test apparatus?		Not reported.	
Microbial biomass/microbial population of the test samples	Water:	Initial Not reported	Final Not reported
	Sediment:	20.96 mg C/100 g dry weight	64.85 mg C/100 g dry weight
Microbial biomass/microbial population of the control	Water:	Sterile controls were not used.	
	Sediment:	Sterile controls were not used.	
Experimental conditions:	Temperature (°C):	Air (mean): 18.8°C (min) and 29.3°C (max). Water (mean): 20.5°C (min) and 31.5°C (max).	
	Continuous darkness (Yes/No):	No. Sunlight maximum radiance ranged from 246 W/m ² to 839 W/m ² .	



Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

Parameter	Details
Other details, if any	Three additional samples of each radiolabel were prepared at <i>ca.</i> 40x the dose rate for confirmation of identification of the parent and transformation products.

Data obtained from pp. 11, 18, 20-22; Table 1, p. 51 of the study report.

3. Aerobic conditions: Aerobic conditions were maintained by incubating the soil-water systems outdoors, in direct contact with the atmosphere and solar radiation (p. 20). In the 8-day pre-incubation period, redox potentials and pH levels at the water-soil interface were *ca.* +210 to +220 mV and pH levels were *ca.* 7.1 to *ca.* 7.2 (Appendix 5, p. 131; redox potentials were estimated from a graphical representation of the data. Dissolved oxygen levels were not measured. Microbial biomass increased from 20.96 mg C/100 g dry weight at the start of the study to 64.85 mg C/100 g dry weight at the end of the study (Table 1, p. 51).

4. Supplementary experiments: No supplementary experiments were conducted.

5. Sampling:

Table 5: Sampling details.

Criteria	Details
Sampling intervals	0, 1, 2, 3, 4, 5, 7, 15, 21, 30, 45 and 62 days.
Sampling method	Two incubation units were collected at each sampling interval.
Method of collection of CO ₂ and organic volatile compounds	Volatiles were not collected.
Sampling intervals/times for: Sterility check: pH measurement:	None reported. At each sampling interval.
Sample storage before analysis	Water layers and soil extracts were analyzed by LSC immediately, but stored at 1-7°C prior to TLC (storage time < 1 week) and LC-MS analysis (storage time unreported).
Other observation, if any	None

Data obtained from pp. 11, 20, 22-23 and 25 of the study report.

C. ANALYTICAL METHODS:

Separation of the sediment and water: Water layer was removed from the sediment via pipette, except for time 0 samples which were separated by centrifugation (20 minutes at 15200 RCF; p. 22).

Extraction/clean up/concentration methods for water and sediment samples: The water layer was mixed with saturated NaHCO₃ solution until a basic mixture was achieved, then brought to volume (50 mL) with acetonitrile (p. 22).

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

The sediment layers were extracted sequentially with 250 mL of the following solvent mixtures: acetonitrile:33 mM NaHCO₃ (7:3, v:v; extraction A); and acetonitrile:33 mM NaHCO₃ (1:1, v:v; extraction B; p. 23). After the addition of the extraction solution, the mixture was shaken for 1 hour at 300 strokes/min and separated by centrifugation (20 minutes at 15,200 RCF). The supernatant was decanted and made to volume with acetonitrile. After the shaking of extraction solution B, the mixture was sonicated for 50 minutes at 40°C prior to centrifugation. Extracts A and B were not combined.

The extraction and analysis scheme was illustrated in Scheme 1, p. 45 of the study report.

Total ¹⁴C measurement: Duplicate aliquots of the water layers (2 x 1 mL), extracts A, B and C (acidic extraction; 2 x 1 mL) of the sediment layers, fulvic acid fractions (2 x 1 mL) and humic acid fractions (2 x 0.2 mL) were analyzed by LSC (pp. 22-24).

The total radioactivity measurement was determined as the sum of the radioactivity in the water layers, in the extracts A, B and C of the sediment layers, and in the bound residues (p. 24).

Determination of nonextractable residues: Aliquots (3 x 1.0-1.4 g) of dried extracted soil residues were combusted prior to radioanalysis by LSC (p. 23).

Post-extraction soils that contained greater than 20% of the applied radioactivity were further separated into fulvic acids, humic acids and humin (pp. 23-24). Prior to partitioning, 20-g aliquots of the post-extraction soil were extracted once with 0.1N HCl (100 mL) via continuous shaking (300 strokes/min) for 48 hours. The extraction mixture was centrifuged (20 minutes at 15,200 RCF), and the supernatant decanted (acidic extraction; extract C). Then the post-acidic extraction soil was partitioned into fulvic acids, humic acids and humin. The soil pellet was extracted with 0.5N NaOH (100 mL) via continuous shaking (300 strokes/min) for 48 hours. The extraction mixture was centrifuged (20 minutes at 15,200 RCF), and the supernatant decanted. The residue, the humin, was dried and combusted prior to radioanalysis by LSC (1.0-1.2 g aliquots). The pH of the supernatant was adjusted to 1 with 6N HCl. The precipitate was isolated via centrifugation (20 minutes at 15,200 RCF) and decanting, then re-dissolved in 100 mL of 0.5 N NaOH and acidified to pH 1 with 6N HCl. The second precipitate, the humic acid, was separated from supernatant via centrifugation (20 minutes at 15,200 RCF) and decanting, and then re-dissolved in 25 mL of 0.5N NaOH for analysis. The two acidic supernatants were combined to produce the fulvic acid fraction. The fractionation of the soil was illustrated in Scheme 2, p. 46 of the study report.

Derivatization method, if used: No derivatization method was employed.

Identification and quantification of parent compound: The parent was identified in [¹⁴C]residues in the water and sediment layers using normal-phase and reversed-phase TLC (pp. 25-27). The reversed-phase TLC was performed using RP-18 F_{254S} plates (0.2 mm thickness) that were developed using acetonitrile:water (92:8, v:v; solvent system 2). The normal-phase

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

TLC was performed using silica gel 60 F₂₅₄ plates (0.2 mm thickness) that were developed using chloroform:methanol:ammonium hydroxide 30% (75:22:3, v:v:v; solvent system 1). The amount of parent was quantified using a Bio-Imaging Analyzer. Identification was confirmed via co-chromatography of selected water and sediment samples with the unlabeled orthosulfamuron reference standard (IR5878; Lot/Batch No.: 25; Analytical purity: >97%; pp. 14, 17, 26, 34-35; Figure 26, p. 88; Figure 30, p. 92).

Confirmation of the identification of the parent was performed via LC-MS analysis of the additional 40x dose (pp. 27-28; for processing of the additional samples, see Reviewer's Comment #4). The LC-MS analysis conditions were the following: Supelcosil™ LC-18 column (250 x 4.6 mm, 5 μm); mobile phase of 1 mM CH₃COONH₄ (pH 4.5; solvent A) and acetonitrile (solvent B) with gradient elution conditions (percent A:B; time 0 80:20 and 20 min 10:90); flow rate 0.8 mL/min; and ESI positive ion source. Identification was confirmed via the ion fragmentation spectra of orthosulfamuron: [2M]⁺ 848, [M+H]⁺ 425 and fragmentation ions (244, 227, 199, 182, 163, 156, 120 and 92; p. 35; Figures 37-38, pp. 99-100).

Identification and quantification of transformation products: The transformation products were identified and quantified using the same TLC methods as described for the parent, except that 2-D TLC with solvent system 3 (acetonitrile:water:ammonium hydroxide 30%, 67:26:7, v:v:v; 1 run) and solvent system 4 (acetonitrile:water:ammonium hydroxide 30%, 65:28:7, v:v:v; 1 run) was subsequently used for unresolved fractions (p. 26).

The following radiolabeled reference standards were included for transformation product identification (pp. 19, 35-37, 41; Appendix 10, pp. 189 -194):

Code No.	Conventional Name	Lot No.	Radiochemical Purity	IUPAC Name
S1 ¹	DBS acid; IR7863	216	>97%	(2-Dimethylcarbamoylphenyl) sulfamic acid
S2 ¹	DBS amide	210	>98%	2-[(Aminosulfony)amino]-N,N-dimethylbenzamide
S4 ¹	DB amine	181	>96%	2-Amino-N,N-dimethylbenzamide
S9 ²	O-desmethyl IR5878; IR8181	225	>99%	1-(4-Hydroxy-6-methoxy pyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)phenylsulfamoyl]urea
S12 ²	DOP urea; IR7825	214	>99%	N-(4,6-Dimethoxypyrimidin-2-yl)urea
S13 ²	DOP amine	215	>99%	4,6-Dimethoxypyrimidin-2-yl amine
S15 ³	O-desmethyl DOP urea	isolated in Study MEF.01.13		N-(4-Hydroxy-6-methoxypyrimidin-2-yl)urea

1. Radiolabeled uniformly in the phenyl ring.
2. Radiolabeled on the C5 carbon of the pyrimidine ring.
3. Unconfirmed position of radiolabel.

Confirmation of the identification of the transformation products was performed via LC-MS analysis of the additional 40x dose samples (pp. 28-29). The LC-MS analysis conditions for S12 were the same as those for the parent. The LC-MS analysis conditions for S1 were the following: Synergi 4μ Polar-RP 80A column (250 x 4.6 mm, 4 μm); mobile phase of 5 mM

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

CH₃COONH₄ (pH 4.5; solvent A) and acetonitrile (solvent B) with isocratic elution conditions (percent A:B; 93:7); flow rate 0.6 mL/min; and ESI positive and negative ion source. Identification was confirmed via the ion fragmentation spectra.

Detection limits (LOD, LOQ) for the parent compound: The LOD for the LSC analysis was twice the background counting rate (pp. 24-25). The LOD for the TLC analysis was the minimum radioactivity amount detectable with a signal to noise ratio greater than 5 (p. 27). The LOQs were not reported.

Detection limits (LOD, LOQ) for the transformation products: The LOD and LOQ for the transformation products were the same as those for the parent.

II. RESULTS AND DISCUSSION

A. TEST CONDITIONS: The samples were kept outdoors open to the environment (simulated field conditions; p. 20). Temperatures were allowed to vary [air (mean): 18.8-29.3°C, water (mean): 20.5-31.5°C] and the samples were not shielded from sunlight (maximum irradiance, 246 W/m² to 839 W/m²). Microbial biomass increased from 20.96 mg C/100 g dry weight at the start of the study to 64.85 mg C/100 g dry weight at the end of the study (Table 1, p. 51). During the 62-day study, redox potentials at the water-soil interface decreased from *ca.* +210 mV to *ca.* +160 mV (Appendix 5, p. 131; redox potentials were estimated from a graphical representation of the data). The pH at the water-soil interface increased from *ca.* 7.2 to *ca.* 7.9. Dissolved oxygen levels were not measured.

B. MATERIAL BALANCE: Overall recoveries of the radiolabeled material were 83.45 ± 10.32% (range 67.90-102.32%) of the applied for the [¹⁴C-U-phenyl]orthosulfamuron samples and 80.04 ± 9.02% (67.98-101.91%) for the [¹⁴C-5-pyrimidinyl]orthosulfamuron samples (Appendix 7, Tables II-V, pp. 140-149, Tables VII-VIII, pp. 151-158; DER Attachment 2). There was a rapid decline over time for both label test systems; final recoveries (day 62) of the phenyl- and pyrimidinyl-labeled materials were 68% and 74% of the applied, respectively.

Through the course of both radiolabel experiments, [¹⁴C]residues dissipated quickly from the water layer into the sediment, but more quickly in the pyrimidinyl label experiment (DER Attachment 2). Distribution ratios (water:sediment) were 38:1 at time 0, 2:1 at day 1, 1:1 at days 2-21, 1:2 at day 30, 1:3 at day 45 and 1:5 at day 62 for [¹⁴C-U-phenyl]orthosulfamuron and 33:1 at time 0, 1:1 at day 1, 1:2 at days 2-3, 1:3-4 at days 4-21, 1:7 at day 30 and 1:22-23 at day 62 for [¹⁴C-5-pyrimidinyl]orthosulfamuron.

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

Table 6a: Biotransformation of [¹⁴C-U-phenyl]orthosulfamuron, expressed as percentage of applied radioactivity (mean ± s.d.), in a water/loamy sand sediment system under aerobic conditions.

Compound	Sampling times (days)													
	0	1	2	3	4	5	7	10	15	21	30	45	62	
Orthosulfamuron (S3)	water	96.91 ±2.85	24.80 ±2.20	16.42 ±1.50	8.32 ±1.00	4.19 ±0.52	1.99 ±0.28	0.64 ±0.17	<dl	<dl	<dl	<dl	<dl	<dl
	sediment	NA	19.52 ±0.95	21.96 ±1.00	18.97 ±4.75	11.60 ±0.07	7.78 ±0.27	4.77 ±0.27	2.40 ±0.17	1.41 ±0.15	0.66 ±0.13	0.74 ±0.06	<dl	<dl
	system	96.91 ±2.85	44.32 ±3.15	38.38 ±2.50	27.29 ±5.76	15.80 ±0.45	9.77 ±0.56	5.41 ±0.44	2.40 ±0.17	1.41 ±0.15	0.66 ±0.13	0.74 ±0.06	<dl	<dl
S1 (DBS acid: IR7863)	water	1.05 ¹	22.33 ±1.76	22.26 ±2.73	28.73 ±4.33	32.04 ±3.57	34.85 ±0.18	36.63 ±0.28	31.50 1.92	26.72 ±3.10	25.97 ±0.11	17.17 ±0.65	10.94 ±0.02	6.99 ±0.67
	sediment	NA	6.59 ±0.11	9.64 ±0.09	16.31 ±0.94	19.45 ±0.44	18.93 ±0.47	17.83 ±0.95	19.14 ±2.09	14.87 ±1.17	8.63 ±0.04	9.13 ±0.42	9.17 ±0.62	6.14 ±0.26
	system	1.05	28.93 ±1.65	31.90 ±2.63	45.04 ±3.40	51.50 ±3.12	53.78 ±0.64	54.47 ±0.68	50.64 ±0.16	41.60 ±1.93	34.61 ±0.06	26.30 ±0.23	20.12 ±0.59	13.13 ±0.40
S2 (DBS amide)	water	<dl	<dl	<dl	0.54 ¹	<dl	<dl	0.54 ±0.11	0.55 ±0.13	0.34 ¹	0.39 ¹	<dl	0.95 ±0.21	0.38 ¹
	sediment	NA	<dl	<dl	<dl	<dl	0.43 ¹	<dl	<dl	<dl	<dl	1.03 ±0.09	0.58 ±0.22	
	system	<dl	<dl	<dl	0.54 ¹	0.31 ¹	<dl	0.76 ±0.19	0.55 ±0.13	0.34 ¹	0.39 ¹	<dl	1.98 ±0.13	0.77 ±0.49
S4 (DB amine)	sediment	NA	<dl	<dl	<dl	0.64 ¹	0.64 ±0.14	0.55 ±0.12	0.52 ¹	0.49 ±0.04	0.37 ¹	<dl	0.79 ±0.10	0.71 ±0.03
	water	<dl	5.01 ±0.30	4.20 ±0.20	4.79 ±1.12	6.37 ±0.35	6.52 ±0.08	7.61 ±0.46	8.78 ±1.30	8.68 ±0.39	9.30 ±0.09	5.45 ±0.11	5.24 ±1.27	3.06 ±0.33
	sediment	NA	2.33 ±0.10	3.10 ±0.24	2.93 ±0.07	5.64 ±0.03	5.43 ±0.41	5.39 ±0.05	6.70 ±0.02	7.47 ±1.08	6.00 ±0.05	6.84 ±0.56	7.58 ±0.60	7.12 ±0.38
SS ²	system	<dl	7.34 ±0.40	7.31 ±0.04	7.72 ±1.05	12.02 ±0.32	11.96 ±0.49	13.00 ±0.42	15.48 ±0.32	16.14 ±0.69	15.30 ±0.13	12.30 ±0.45	12.82 ±0.67	10.19 ±0.71

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

Compound	Sampling times (days)																									
	0	1	2	3	4	5	7	10	15	21	30	45	62													
S8	water	<dl	2.21 ±0.18	1.86 ±0.19	2.16 ±0.23	2.33 ±0.22	2.32 ±0.03	2.31 ±0.03	1.94 ±0.38	1.83 ±0.08	1.77 ±0.12	1.84 ±0.04	1.11 ±0.05	0.65 ±0.19												
	sediment	N/A	0.68 ±0.06	0.99 ±0.07	<dl	1.38 ±0.13	1.24 ±0.02	1.37 ¹	1.37 ±0.03	1.25 ±0.23	0.72 ±0.07	1.41 ±0.00	1.45 ±0.04	0.94 ±0.05												
	system	<dl	2.90 ±0.12	2.85 ±0.12	2.16 ±0.22	3.72 ±0.08	3.57 ±0.02	3.00 ±0.94	3.31 ±0.42	3.08 ±0.15	2.49 ±0.19	3.25 ±0.04	2.57 ±0.09	1.59 ±0.23												
S9 (O-desmethyl 1RS5878; 1R8181)	water	1.80 ±1.08	1.06 ±0.02	0.90 ¹	1.00 ¹	<dl	<dl	0.77	<dl	<dl	<dl	<dl	<dl	<dl												
	sediment	N/A	0.75 ±0.05	1.02 ±0.16	0.98 ±0.02	0.88 ±0.02	0.61 ±0.10	0.71 ±0.02	0.64 ±0.01	0.50 ±0.08	0.40 ±0.06	0.40 ¹	<dl	0.40 ¹												
	system	1.80 ±1.08	1.81 ±0.06	1.47 ±0.47	1.48 ±0.72	0.88 ±0.02	0.61 ±0.10	1.10 ±0.56	0.65 ±0.01	0.50 ±0.09	0.40 ±0.06	0.40 ¹	<dl	0.40 ¹												
CO ₂	Not measured																									
Volatile organics																										
Not measured																										
Extractable sediment residues	2.68 ±0.46		29.88 ±0.93		36.70 ±1.56		39.18 ±5.78		39.43 ±0.01		34.64 ±0.82		30.16 ±0.17		30.52 ±2.59		25.99 ±2.45		16.60 ±0.44		18.32 ±0.77		20.02 ±1.37		15.69 ±0.26	
	<dl		3.31 ±0.24		4.69 ±0.17		6.60 ±0.64		8.83 ±1.73		9.55 ±0.55		7.49 ±0.50		10.71 ±0.00		19.89 ±0.12		21.93 ±0.15		25.80 ±0.83		29.99 ±0.32		41.87 ±1.28	
Nonextractable sediment residues	99.24 ±1.03		55.42 ±4.47		45.19 ±2.25		44.75 ±4.35		44.92 ±4.66		45.67 ±0.01		48.11 ±1.55		42.77 ±3.48		37.40 ±3.32		37.23 ±0.14		24.46 ±0.81		18.25 ±1.55		10.89 ±0.92	
	2.68 ±0.46		33.19 ±1.17		41.39 ±1.73		45.78 ±6.42		48.26 ±1.73		44.19 ±1.36		37.65 ±0.68		41.23 ±2.60		45.88 ±2.56		38.53 ±0.59		44.12 ±1.59		50.01 ±1.04		57.56 ±1.03	
Total recovery	101.92 ±0.57		88.61 ±5.63		86.58 ±0.52		90.53 ±2.07		93.18 ±2.93		89.86 ±1.36		85.76 ±0.87		84.00 ±0.88		83.26 ±0.76		75.76 ±0.45		68.58 ±0.78		68.26 ±0.52		68.45 ±0.11	

Data obtained from Table 2/A, p. 52; Tables 4-6, pp. 54-56; Appendix 7, Tables II-III, pp. 140-144; Appendix 7, Table VII, pp. 151-154; Appendix 8, Table XX, pp. 174-172; Appendix 8, Tables XXII-XXIII, pp. 174-177; and DER Attachment 2.

1. Single value reported instead of mean and standard deviation because one replicate had a value of " $<dl$ ".
 2. Composed of 5 compounds.
- <dl = below the detection limit
NA = not analyzed

15

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

Table 6b: Biotransformation of [¹⁴C-5-pyrimidinyl]orthosulfamuron, expressed as percentage of applied radioactivity (mean ± s.d.), in a water/loamy sand sediment system under aerobic conditions.

Compound	Sampling times (days)												
	0	1	2	3	4	5	7	10	15	21	30	45	62
Orthosulfamuron (S3)	water	95.33 ±3.45	21.07 ±1.87	14.41 ±2.42	9.68 ±0.88	4.88 ±0.94	1.59 ±0.06	0.57 ¹	<dl	<dl	<dl	<dl	<dl
	sediment	NA	20.27 ±0.78	18.84 ±0.59	16.57 ±2.78	8.66 ±1.52	4.63 ±1.43	2.48 ±0.39	1.08 ±0.07	0.81 ±0.11	0.39 ±0.02	<dl	<dl
	system	95.33 ±3.45	41.35 ±1.08	33.26 ±1.83	26.24 ±1.91	13.54 ±2.46	6.22 ±1.50	2.77 ±0.01	1.08 ±0.07	0.81 ±0.11	0.39 ±0.02	<dl	<dl
S9 (O-desmethyl IR5878)	water	2.78 ±2.41	0.62 ±0.04	0.50 ±0.06	<dl	<dl	<dl	<dl	<dl	<dl	<dl	<dl	<dl
	sediment	NA	0.47 ±0.00	0.49 ±0.00	0.46 ±0.05	<dl	<dl	<dl	<dl	<dl	<dl	<dl	<dl
	system	2.78 ±2.41	1.09 ±0.04	1.00 ±0.06	0.47 ±0.05	<dl	<dl	<dl	<dl	<dl	<dl	<dl	<dl
S11	water	<dl	1.72 ±0.08	1.08 ±0.25	2.44 ±0.28	2.31 ±0.20	2.00 ±0.18	2.52 ±0.25	2.56 ±0.58	2.40 ±0.43	2.71 ±0.11	1.14 ±0.29	0.70 ±0.13
	sediment	NA	0.65 ±0.09	0.89 ±0.11	1.03 ±0.20	1.03 ±0.12	1.06 ±0.06	2.13 ±0.04	2.14 ±0.38	2.63 ±0.81	1.63 ±0.37	1.13 ±0.04	2.64 ±0.09
	system	<dl	2.37 ±0.17	1.97 ±0.36	3.47 ±0.48	3.34 ±0.07	3.06 ±0.12	4.66 ±0.21	4.70 ±0.20	5.03 ±0.38	4.34 ±0.48	2.27 ±0.25	3.34 ±0.23
S12 (DOP urea: IR7825)	water	<dl	11.82 ±1.27	12.00 ±0.79	12.82 ±0.37	12.12 ±1.93	12.43 ±2.66	14.42 ±1.66	11.20 ±1.02	10.98 ±1.27	11.87 ±0.66	7.75 ±0.30	2.44 ±0.44
	sediment	NA	23.84 ±0.08	31.43 ±1.37	33.36 ±0.01	42.28 ±0.79	44.52 ±5.70	38.03 ±6.49	42.06 ±3.45	39.50 ±2.22	30.63 ±1.57	38.98 ±2.03	31.34 ±0.93
	system	<dl	35.67 ±1.20	43.44 ±2.16	46.18 ±0.38	54.40 ±1.13	56.95 ±3.04	52.45 ±4.84	53.26 ±2.44	50.48 ±0.95	42.50 ±2.23	46.72 ±2.33	33.78 ±1.37
S13 (DOP amine)	water	<dl	0.86 ±0.23	0.97 ±0.23	0.76 ±0.15	0.61 ¹	0.51 ±0.08	0.79 ±0.20	0.37 ¹	0.50 ±0.15	0.52 ¹	<dl	<dl
	sediment	NA	1.11 ±0.24	1.68 ±0.65	1.15 ±0.49	0.66 ±0.11	0.61 ±0.07	2.01 ±0.29	1.66 ±0.60	1.33 ±0.44	0.64 ±0.08	1.36 ¹	1.11 ±0.08
	system	<dl	1.97 ±0.47	2.65 ±0.42	1.91 ±0.34	0.97 ±0.32	1.13 ±0.02	2.80 ±0.50	1.84 ±0.86	1.84 ±0.30	0.90 ±0.45	1.36 ¹	1.11 ±0.08



Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

Compound	Sampling times (days)													
	0	1	2	3	4	5	7	10	15	21	30	45	62	
S15 (O-desmethyl DOP urea)	water	<dl	1.02 ±0.02	0.64 ±0.07	1.23 ±0.13	0.81 ±0.22	0.65 ±0.06	1.03 ±0.12	0.82 ±0.40	0.55 ±0.05	<dl	<dl	<dl	
	sediment	NA	0.57 ±0.03	0.76 ±0.24	0.95 ±0.09	0.59 ±0.09	0.53 ±0.17	0.70 ±0.20	0.76 ±0.09	0.84 ±0.09	0.55 ¹	<dl	<dl	
urea)	system	<dl	1.60 ±0.01	1.40 ±0.18	2.18 ±0.04	1.40 ±0.32	1.17 ±0.23	1.73 ±0.33	1.58 ±0.30	1.40 ±0.04	0.55 ¹	<dl	<dl	
CO ₂		Not measured												
Volatiles organics		Not measured												
Extractable sediment residues		3.01 ±0.08	46.92 ±0.56	54.09 ±0.21	53.51 ±2.23	53.20 ±2.40	51.35 ±7.28	45.35 ±7.42	47.68 ±4.45	45.11 ±3.68	33.57 ±2.43	40.79 ±1.03	35.08 ±0.94	33.12 ±1.07
	Nonextractable sediment residues	<dl	3.36 ±0.08	4.97 ±0.08	8.27 ±0.43	5.66 ±0.30	9.24 ±1.00	9.11 ±2.04	13.61 ±1.33	18.82 ±0.41	22.83 ±1.04	23.81 ±0.05	32.16 ±0.03	38.26 ±2.71
Total recovery	water	98.11 ±1.04	37.10 ±3.50	29.60 ±3.32	26.93 ±0.76	20.43 ±1.00	17.19 ±2.63	19.04 ±1.99	14.78 ±1.74	14.44 ±1.90	14.84 ±1.14	8.89 ±0.59	3.14 ±0.56	3.11 ±0.33
	sediment	3.01 ±0.08	50.28 ±0.48	59.06 ±0.29	61.78 ±2.65	58.86 ±2.09	60.59 ±8.28	54.46 ±5.38	61.29 ±5.78	63.93 ±3.26	56.40 ±3.47	64.60 ±1.07	67.24 ±0.91	71.38 ±1.65
	system	101.12 ±1.12	87.38 ±3.02	88.66 ±3.03	88.71 ±1.90	79.29 ±1.10	77.78 ±5.66	73.50 ±3.39	76.07 ±4.04	78.37 ±1.36	71.24 ±4.61	73.49 ±1.66	70.38 ±1.48	74.49 ±1.32

Data obtained from Table 3/A, p. 53; Tables 7-9, pp. 57-59; Appendix 7, Tables IV-V, pp. 145-149; Appendix 7, Table VIII, pp. 155-158; Appendix 8, Table XXV, pp. 179-180; Appendix 8, Tables XXVII-XXVIII, pp. 182-185; and DER Attachment 2.

1. Single value reported instead of mean and standard deviation because one replicate had a value of "<dl".
 <dl = below the detection limit.
 NA = not analyzed.

17

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

C. TRANSFORMATION OF PARENT COMPOUND: In the total system (combined labels), the concentration of orthosulfamuron decreased from 95.33-96.91% of the applied amount at time 0 to 41.35-44.32% at day 1 to 26.24-27.29% at day 3 to 13.54-15.80% at day 4 to 2.77-5.41% at day 7 to <dl-1.41% at days 15-30 and was below the detection limit at days 45-62 (study termination; combined radiolabels; Table 6, p. 56; Table 9, p. 59). In the water layers, [¹⁴C]orthosulfamuron decreased from 95.33-96.91% of the applied amount at time 0 to 21.07-24.80% at day 1 to 14.41-16.42% at day 2 to 4.19-4.88% at day 4 to 0.28-0.64% at day 7 and was below the detection limit at days 10-62 (Table 4, p. 54; Table 7, p. 57). The concentration of [¹⁴C]orthosulfamuron in the sediment decreased from 16.57-21.96% at days 1-3 to 8.66-11.60% at day 4 to 2.48-7.78% at days 5-7 to <dl-2.40% at days 10-30 and was below the detection limit at days 45-62 (not analyzed at time 0; Table 5, p. 55; Table 8, p. 58).

Half-Life/DT₅₀/DT₉₀: The half-lives of [¹⁴C]orthosulfamuron in aerobic water-sediment systems could not be accurately determined because >50% of the applied orthosulfamuron dissipated between time 0 and the next sampling interval (1 day posttreatment).

TRANSFORMATION PRODUCTS: In the system treated with [¹⁴C-U-phenyl]orthosulfamuron, the only major transformation product was S1 {DBS acid, IR7863, (2-dimethylcarbamoyl)phenyl sulfamic acid; pp. 19, 33, 35-37; Appendix 10, pp. 189 -194}. S5 was observed at >10% of the applied; however, it was determined to be composed of 5 compounds. The detected minor transformation products were S2 {DBS amide, 2-[(aminosulfonyl)amino]-N,N-dimethylbenzamide}, S4 {DB amine, 2-amino-N,N-dimethylbenzamide}; S8 {not identified}, and S9 {O-desmethyl IR5878, IR8181, 1-(4-hydroxy-6-methoxy pyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)phenylsulfamoyl]-urea}. DBS acid (S1) was identified via TLC co-chromatography and LC-MS analysis. DBS amide (S2), DB amine (S4), and O-desmethyl IR5878 (S9) were identified via TLC co-chromatography.

DBS acid (S1) was detected at a maximum of 36.63% (7 DAT), 19.45% (4 DAT) and 54.47% (7 DAT) of the applied amount in the water, sediment and total system, respectively, and at a final amount of 6.99%, 6.14% and 13.13% of the applied in the water, sediment and total system, respectively, at study termination (day 62; Tables 4-6, pp. 54-56). S5 was detected at a maximum of 9.30% (21 DAT), 7.58% (45 DAT) and 16.14% (15 DAT) of the applied amount in the water, sediment and total system, respectively, and at a final amount of 3.06%, 7.12% and 10.19% of the applied in the water, sediment and total system, respectively, at study termination. DBS amide (S2) was detected at a maximum of 0.95%, 1.03% and 1.98% of the applied in the water, sediment and total system, respectively. DB amine (S4) was detected only in the sediment at a maximum of 0.79% of the applied. O-desmethyl IR5878 (S9) was detected at a maximum of 1.80%, 1.02% and 1.81% of the applied in the water, sediment and total system, respectively. Unidentified transformation product S8 was detected at a maximum of 2.33%, 1.45% and 3.72% of the applied amount in the water, sediment and total system, respectively.

In the system treated with [¹⁴C-5-pyrimidinyl]orthosulfamuron, the only major transformation product was S12 {DOP urea, IR7825, N-(4,6-dimethoxypyrimidin-2-yl)urea; pp. 19, 35-37; Appendix 10, pp. 189 -194}. The detected minor transformation products were S9 {O-

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

desmethyl IR5878}, S11 {not identified}, S13 {DOP amine, 4,6-dimethoxypyrimidin-2-yl amine} and S15 {O-desmethyl DOP urea, N-(4-hydroxy-6-methoxypyrimidin-2-yl)urea}. DOP urea (S12) was identified via TLC co-chromatography and LC-MS analysis. O-desmethyl IR5878 (S9), DOP amine (S13) and O-desmethyl DOP urea (S15) were identified via TLC co-chromatography.

DOP urea (S12) was detected at a maximum of 14.42% (7 DAT), 44.52% (5 DAT) and 56.95% (5 DAT) of the applied in the water, sediment and total system, respectively, and at a final amount of 2.48%, 30.30% and 32.78% of the applied in the water, sediment and total system, respectively, at study termination (day 62; Tables 7-9, pp. 57-59). O-desmethyl IR5878 (S9) was detected at a maximum of 2.78%, 0.49% and 2.78% of the applied in the water, sediment and total system, respectively. DOP amine (S13) was detected at a maximum of 0.97%, 2.01% and 2.80% of the applied in the water, sediment and total system, respectively. O-desmethyl DOP urea (S15) was detected at a maximum of 1.23%, 0.95% and 2.18% of the applied in the water, sediment and total system, respectively. Unidentified transformation product S11 was detected at a maximum of 2.71%, 2.64% and 5.03% of the applied in the water, sediment and total system, respectively.

NONEXTRACTABLE AND EXTRACTABLE RESIDUES: Extractable [¹⁴C]residues in sediment increased quickly from 2.68-3.01% at day 0 to maximums of 39.43% (4 DAT, phenyl label) and 54.09% (2 DAT, pyrimidinyl label), then decreased gradually to 15.69% (phenyl) and 33.12% (pyrimidinyl) of the applied amount at the end of incubation period (day 62; combined radiolabels; Table 2/A-3/B, pp. 52-53). Nonextractable [¹⁴C]residues in sediment increased from <dl at day 0 to 3.31-3.36% at day 1 to 10.71-13.61% at day 10 to a maximum of 38.26-41.87% of the applied at the end of incubation period. The soil residues from days 21-62 were further extracted and fractionated into fulvic acids, humic acids and humin. The acidic extraction, fulvic acids, humic acids and humin were determined as 0.78-3.06%, 10.01-16.52%, 3.54-6.70% and 4.27-17.22%, respectively (combined radiolabels).

VOLATILIZATION: Volatilized ¹⁴CO₂ and volatile organic compounds were not collected.

TRANSFORMATION PATHWAY: The biotransformation pathway of orthosulfamuron in an aerobic water-sediment system under sunlight was illustrated by the study authors (p. 40). The main degradation pathway of IR5878 was the hydrolytic cleavage of the sulfamoylurea linkage to give S12 {DOP urea, N-(4,6-dimethoxypyrimidin-2-yl)urea} and S1 {DBS acid, (2-dimethylcarbamoylphenyl) sulfamic acid; p. 40; Appendix 10, pp. 189-194}. A minor degradation pathway was the demethylation of the methoxy group on the pyrimidinyl ring of IR5878 to S9 {O-desmethyl IR5878, 1-(4-hydroxy-6-methoxy pyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)phenylsulfamoyl]-urea}, which also degraded to DBS acid and S15 {O-demthyl DOP urea; N-(4-hydroxy-6-methoxypyrimidin-2-yl)urea}. O-desmethyl DOP urea was also formed from the demethylation of DOP urea. Other minor transformation pathways occurred wherein IR5878 degraded to S13 {DOP amine, 4,6-dimethoxypyrimidin-2-yl amine}, S2 {DBS amide, 2-[(aminosulfonyl)amino]-N,N-dimethylbenzamide} and S4 {DB amine, 2-

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

amino-N,N-dimethylbenzamide}. Additionally, very polar compounds, which were generated from the degradation of unspecified compounds, quickly mineralized to carbon dioxide.

Table 7: Chemical names and CAS numbers for the transformation products of orthosulfamuron.

Applicants Code Name	CAS Number	Chemical Name	Chemical Formula	Molecular Weight (g/mol)	Smiles String
DBS acid; IR7863	---	(2-Dimethylcarbamoylphenyl) sulfamic acid	C ₉ H ₁₂ N ₂ SO ₄	244.28	---
DBS amide	---	2-[(Aminosulfony)amino]-N,N-dimethylbenzamide	C ₉ H ₁₃ N ₃ SO ₃	243.28	---
DB amine	---	2-Amino-N,N-dimethylbenzamide	C ₉ H ₁₂ N ₂ O	164.21	---
O-desmethyl IR5878; IR8181	---	1-(4-Hydroxy-6-methoxy pyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)phenylsulfamoyl]-urea	C ₁₅ H ₁₈ N ₆ SO ₆	410.40	---
DOP urea; IR7825	151331-81-6	N-(4,6-Dimethoxypyrimidin-2-yl)urea	C ₇ H ₁₀ N ₄ O ₃	198.21	---
O-desmethyl DOP urea	---	N-(4-Hydroxy-6-methoxypyrimidin-2-yl)urea	---	---	---
DOP amine	36315-01-2	4,6-Dimethoxypyrimidin-2-yl amine	C ₆ H ₆ N ₃ O ₂	155.16	---

Data obtained from pp. 40-41 and Appendix 10, pp. 189-194 of the study report.

D. SUPPLEMENTARY STUDY- RESULTS: No supplementary studies were described.

III. STUDY DEFICIENCIES

1. The objective of the study was to determine the dissipation of orthosulfamuron under simulated field conditions. The study was conducted outdoors and environmental conditions were not controlled. The samples were exposed to sunlight, and air temperatures ranged from 18.8-29.3°C (mean minimum and maximum). There was no attempt to control or measure volatiles; the samples, which were held in trays, were open to the air and had to be rewetted twice daily. Due to these deficiencies, this study does not fulfill OECD guidelines 307 or 308 or Subdivision N guidelines §162-1, §162-4, §164-1, or §164-2.
2. There was a steady loss of [¹⁴C]residues from the system over time resulting in poor mass balance. Since the samples were open to the air, the loss may have been due to volatilization/evaporation. The nature of the lost material was not determined.
3. Accurate half-lives could not be calculated because >50% of the applied orthosulfamuron dissipated between time 0 and the next sampling interval (1 day posttreatment).

20

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

4. Nonextractable [¹⁴C]residues increased to *ca.* 40% of the applied at study termination. The study author did not demonstrate that the extraction procedure was adequate to remove all extractable identifiable residues from the sediment. Subdivision N §162-4 guidelines specify that that the extraction procedures be sufficiently harsh to remove all identifiable residues from the sediment without the formation of artifacts.
5. The Limit of Quantification (LOQ) for the TLC and LSC analyses were not reported. Subdivision N §162-4 guidelines require that the LOQs are reported.
6. The specific source of the water (pond or river) was not reported by the study authors.
7. The water and sediments were incompletely characterized. For the water, the collection procedures, sampling depth, temperature, oxygen concentration, dissolved oxygen content, electrical conductivity and microbial biomass were not reported. For the sediment, the collection procedures were not reported.
8. The analytical purity of the test materials and the actual application rates to the samples were not reported.

IV. REVIEWER'S COMMENTS

1. The sample processing for the additional *ca.* 40x dose rate samples was the same as the definitive samples, except that the surface waters were pooled, concentrated and extracted with ethyl acetate prior to LC-MS and TLC analyses (p. 28). The extraction and analysis scheme was illustrated by the study authors in Scheme 3, p. 47 of the study report.
2. The redox potentials and pH were estimated from graphical representations of the data (Appendix 5, p. 131). Due to the scales of the graphical representations, there is a certain amount of error in the interpretation of the reported values of redox potentials and pH. The values were measured at the soil-water interface.
3. The test application rate, to 75 g a.i./ha, was the maximum recommended field application rate (p. 11).
4. According to N. Wolfe, *et al.* (see reference below), redox potentials in the range of +400 to +800 mV are considered strongly oxidizing, +200 to +400 mV moderately oxidizing, -50 to +200 mV moderately reducing, -200 to -50 mV reducing, and -400 to -200 mV strongly reducing.
5. Representative TLC chromatographs were provided in Figures 8-36, pp. 70-98 of the study report. Representative LC-MS chromatographs were provided in Figures 37-43, pp. 99-105 of the study report. The experimental protocol and amendments were provided in Appendix

21

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

1, pp. 109-122 of the study report. Sample calculations were provided in Appendix 6, pp. 133-137 of the study report.

V. REFERENCES

1. U.S. Environmental Protection Agency. 1982. Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate, Section 162-3, Anaerobic Aquatic Metabolism 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-R-93-010.
4. Wolfe, N., *et al.* 1990. Abiotic transformations in water, sediments and soil. In Pesticides in the Soil Environment, Soil Science Society of America, pp. 103-110.

**Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a
Water/Sediment System**

PMRA Submission Number {.....}

EPA MRID Number 46588508

Attachment 1: Structures of Parent Compound and Transformation Products

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

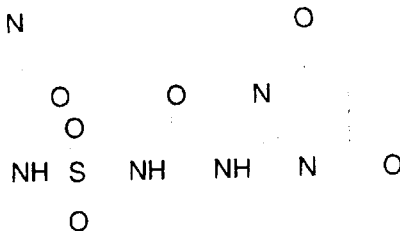
PMRA Submission Number {.....}

EPA MRID Number 46588508

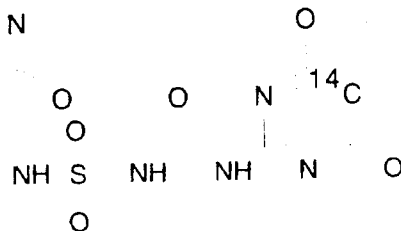
Orthosulfamuron [IR5878; S3]

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-5-¹⁴C]IR5878



¹⁴C = Location of the radiolabel.

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

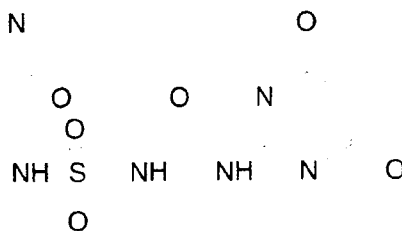
PMRA Submission Number {.....}

EPA MRID Number 46588508

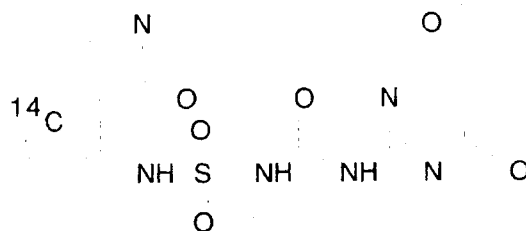
Orthosulfamuron [IR5878; S3]

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)c1cccc1NS(=O)(=O)NC(=O)Nc1nc(cc(n1)OC)OC)C
(ISIS v2.3/Universal SMILES).
No EPI Suite, v3.12 SMILES String found 11/21/05.

Unlabeled



[Phenyl-U-¹⁴C]IR5878



¹⁴C = Location of the radiolabel.

25

**Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a
Water/Sediment System**

PMRA Submission Number {.....}

EPA MRID Number 46588508

Identified Compounds



Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

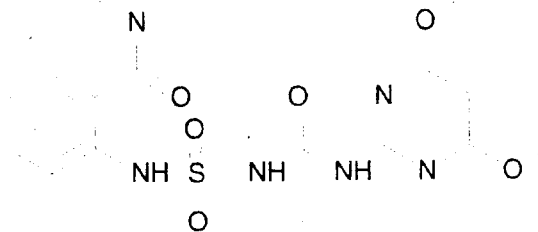
Orthosulfamuron [IR5878; S3]

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
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Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

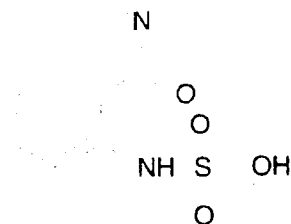
PMRA Submission Number {.....}

EPA MRID Number 46588508

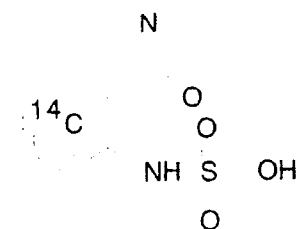
S1 [IR7863; DBS acid]

IUPAC Name: (2-Dimethylcarbamoylphenyl)sulfamic acid.
CAS Name: Sodium (2-dimethylcarbamoylphenyl)sulfamate.
CAS Number: Not reported.

Unlabeled



[Phenyl-U-¹⁴C]DBS acid



¹⁴C = Location of the radiolabel.



Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

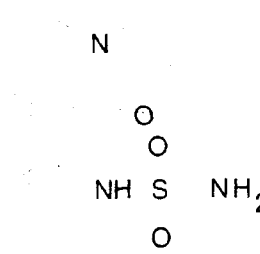
S2 [DBS amide]

IUPAC Name: 2-[(Aminosulfonyl)amino]-N,N-dimethylbenzamide.

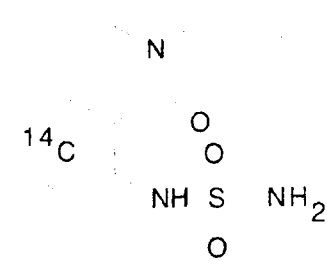
CAS Name: Not reported.

CAS Number: Not reported.

Unlabeled



[Phenyl-U-¹⁴C]DBS amide



¹⁴C = Location of the radiolabel.



Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

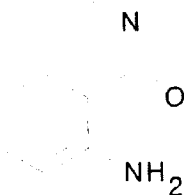
S4 [DB amine]

IUPAC Name: 2-Amino-N,N-dimethylbenzamide.

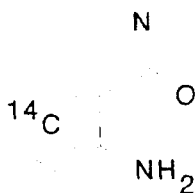
CAS Name: Not reported.

CAS Number: Not reported.

Unlabeled



[Phenyl-U-¹⁴C]DB amine



¹⁴C = Location of the radiolabel.

Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

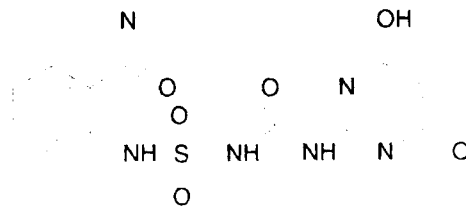
S9 [IR8181; O-desmethyl IR5878]

IUPAC Name: 1-(4-Hydroxy-6-methoxypyrimidin-2-yl)-3-[2-(2-dimethylcarbamoyl)phenylsulfamoyl]urea.

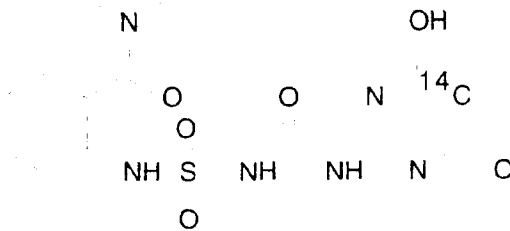
CAS Name: 1-[2(Dimethylcarbamoyl)phenylsulfamyl]-3-(4-hydroxy-6-methoxypyrimidin-2-yl)urea.

CAS Number: Not reported.

Unlabeled



[¹⁴C]O-desmethyl IR5878



¹⁴C = Location of the radiolabel.



Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

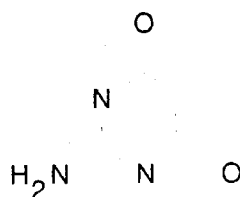
S13 [DOP amine]

IUPAC Name: 4,6-Dimethoxypyrimidin-2-yl amine.
2-Amino-4,6-dimethoxypyrimidine.

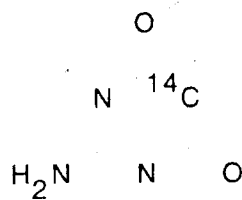
CAS Name: Not reported.

CAS Number: Not reported.

Unlabeled



[Pyrimidinyl-5-¹⁴C]DOP amine



¹⁴C = Location of the radiolabel.



Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

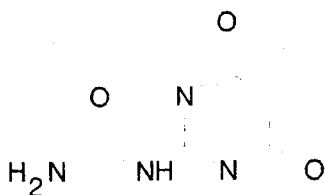
S12 [IR7825; DOP urea]

IUPAC Name: N-(4,6-Dimethoxypyrimidin-2-yl)-urea.

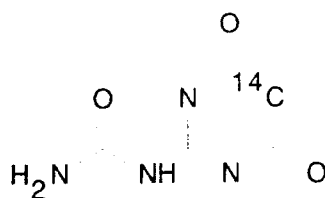
CAS Name: 4,6-Dimethoxy-2-pyrimidinyl urea.

CAS Number: Not reported.

Unlabeled



[Pyrimidinyl-5-¹⁴C]DOP urea



¹⁴C = Location of the radiolabel.



Data Evaluation Report on the Aerobic Biotransformation of Orthosulfamuron in a Water/Sediment System

PMRA Submission Number {.....}

EPA MRID Number 46588508

S15 [O-desmethyl DOP urea]

IUPAC Name: N-(4-Hydroxy-6-methoxypyrimidin-2-yl)-urea.

CAS Name: Not reported.

CAS Number: Not reported.

No structure was provided.

S5

IUPAC Name: Not reported.

CAS Name: Not reported.

CAS Number: Not reported.

No structure was provided.



Attachment 2: Excel Spreadsheets

Chemical Name: Orthosulfamuron
 PC Code: 108209
 MFRID: 46588508
 Guideline No.: 162-4

Soil/Water Ratios
 Pyrimidinyl label

Combined Radiolabels	
Overall Radioactivity	
Mean	81.74
SD	9.75

Days	Surface water		Soil extracts (A+B)		Bound residues		Total soil radioactivity		Total Radioactivity		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
0	98.85	98.12	1.04	3.06	3.01	0.08	3.06	3.01	0.08	101.91	1.12
1	39.58	37.11	3.50	46.53	46.93	0.56	2.95	3.01	0.08	100.33	1.12
2	27.26	29.61	3.32	47.32	54.24	0.21	49.94	50.28	0.48	89.52	3.02
3	31.95	26.93	0.76	53.94	54.09	0.21	50.62	59.06	0.29	85.25	3.03
4	27.46	20.44	1.00	51.93	4.91	0.08	59.26	59.06	0.29	86.52	
5	21.14	17.19	2.62	55.08	4.91	0.08	58.85	59.06	0.29	90.80	88.66
6	19.73	19.05	1.99	51.51	8.57	0.42	59.90	61.78	2.65	87.36	
7	19.04	19.05	1.99	54.90	7.97	0.42	63.65	61.78	2.65	90.04	88.70
8	15.33	17.19	2.62	46.20	5.45	0.30	57.39	58.87	2.09	78.53	1.90
9	17.64	19.05	1.99	56.50	5.88	0.42	60.35	58.87	2.09	80.08	79.31
10	20.45	19.05	1.99	51.51	8.53	1.00	54.73	60.59	8.28	81.77	77.77
11	13.55	19.05	1.99	40.10	9.94	1.00	66.44	60.59	8.28	75.91	77.77
12	13.55	19.05	1.99	50.60	7.67	2.04	58.27	54.47	5.38	81.77	77.77
13	16.00	14.78	1.73	50.83	10.56	2.04	50.66	54.47	5.38	71.11	73.51
14	13.09	14.44	1.90	44.54	14.55	2.04	65.38	54.47	5.38	78.93	3.99
15	15.78	14.44	1.90	47.71	12.67	1.33	57.21	61.30	5.78	73.21	76.07
16	14.03	14.84	1.14	35.29	18.53	0.42	66.24	61.30	5.78	79.33	77.41
17	8.47	14.84	1.14	42.51	19.12	0.42	61.63	63.94	3.26	77.41	78.37
18	9.30	8.89	0.59	31.85	23.57	1.04	58.86	56.41	3.47	74.50	71.24
19	2.74	8.89	0.59	40.06	22.10	0.05	53.95	56.41	3.47	67.98	71.24
20	3.54	3.14	0.57	41.51	23.84	0.05	65.35	64.59	1.07	72.30	73.48
21	3.54	3.14	0.57	34.42	32.18	0.03	66.60	67.25	0.91	69.34	71.43
22	3.35	3.14	0.57	35.75	32.14	0.03	67.89	67.25	0.91	71.43	70.39
23	2.88	3.12	0.33	33.88	36.34	0.03	70.22	71.39	1.65	73.57	1.48
24				32.37	40.18	2.72	72.55	71.39	1.65	75.43	74.50
Overall Radioactivity										Mean	80.04
										SD	9.02

Data obtained from Appendix 7, Tables IV-V, pp. 145-149, Table VIII, pp. 155-158 of the study report.

36

Chemical Name: Orthosulfamuron
 PC Code: 108209
 MRID: 46588508
 Guideline No.: 162-4

Soil/Water Ratios
 Phenyl label

Combined Radiolabels	
Overall Radioactivity	81.74
Mean	81.74
SD	9.75

Days	Surface water		Soil extracts (A+B)		Bound residues		Total soil radioactivity		Total Radioactivity	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
0	98.51		3.00				3.00		101.51	
0	99.97	99.24	2.35	2.68	3.14	0.46	2.35	2.68	102.32	0.57
1	52.26		29.22		3.48	0.24	32.36		84.62	
1	58.57	55.42	30.53	29.88	4.58	0.93	34.01	33.19	92.58	5.63
2	46.78		35.60		4.81		40.18		86.96	
2	43.60	45.19	37.81	36.71	4.70	0.16	42.62	41.40	86.22	0.52
3	41.68		43.27		7.05		50.32		92.00	
3	47.83	44.76	35.10	39.19	6.14	0.64	41.24	45.78	89.07	2.07
4	41.63		39.43		10.06		49.49		91.12	
4	48.22	44.93	39.44	39.44	7.61	0.01	47.05	48.27	95.27	2.93
5	45.67		34.06		9.16		43.22		88.89	
5	45.68	45.68	35.21	34.64	9.93	0.54	45.14	44.18	90.82	1.36
7	49.21		30.03		7.14		37.17		86.38	
7	47.02	48.12	30.28	30.16	7.85	0.50	38.13	37.65	85.15	0.87
10	40.31		32.35		10.71		43.06		83.37	
10	45.23	42.77	28.68	30.52	10.71	0.00	39.39	41.23	84.62	0.88
15	39.75		24.26		19.81		44.07		83.82	
15	35.05	37.40	27.72	25.99	19.97	0.11	47.69	45.88	82.74	0.76
21	37.14		16.91		22.04		38.95		76.09	
21	37.33	37.24	16.29	16.60	21.83	0.15	38.12	38.54	75.45	0.45
30	23.89		18.86		26.38		45.24		69.13	
30	25.03	24.46	17.78	18.32	25.21	0.83	42.99	44.12	68.02	0.78
45	17.15		20.99		29.76		50.75		67.90	
45	19.35	18.25	19.06	20.03	30.22	0.33	49.28	50.02	68.63	0.52
62	10.24		15.51		42.77		58.28		68.52	
62	11.54	10.89	15.87	15.69	40.96	1.28	56.83	57.56	68.37	0.11
Overall Radioactivity										83.45
Mean										10.32
SD										

Data obtained from Appendix 7, Tables II-III, pp. 140-144, Table VII, pp. 151-154 of the study report.

Chemical Name: Ortho sulfamuron
 PC Code: 108209
 MRID: 46588508
 Guideline No.: 162-4

Soil/Water Ratios
 Pyrimidinyl Label

Days	Aqueous %AR	Sed %AR	Ratio W:S			Ratio S:W		
			Mean	SD		Mean	SD	
0	98.85	3.06	32		0			
0	97.38	2.95	33	33	0	0	0	0
1	39.58	49.94	1	1	1	1	1	0
1	34.63	50.62	1	1	1	1	1	0
2	27.26	59.26	0	0	2	2	2	0
2	31.95	58.85	1	1	2	2	2	0
3	27.46	59.90	0	0	2	2	2	0
3	26.39	63.65	0	0	2	2	2	0
4	21.14	57.39	0	0	3	3	3	0
4	19.73	60.35	0	0	3	3	3	0
5	19.04	54.73	0	0	3	3	3	0
5	15.33	66.44	0	0	4	4	4	1
7	17.64	58.27	0	0	3	3	3	1
7	20.45	50.66	0	0	2	2	3	1
10	13.55	65.38	0	0	5	5	3	1
10	16.00	57.21	0	0	4	4	4	1
15	13.09	66.24	0	0	5	5	4	1
15	15.78	61.63	0	0	4	4	4	1
21	15.64	58.86	0	0	4	4	4	1
21	14.03	53.95	0	0	4	4	4	0
30	8.47	63.83	0	0	8	8	4	0
30	9.30	65.35	0	0	7	7	7	0
45	2.74	66.60	0	0	24	24	7	0
45	3.54	67.89	0	0	19	19	22	4
62	3.35	70.22	0	0	21	21	23	4
62	2.88	72.55	0	0	25	25	23	3

Data obtained from Appendix 7, Table IV, pp. 145-148 of the study report.

Chemical Name: Orthosulfamuron
 PC Code: 108209
 MRID: 46588508
 Guideline No.: 162-4

Soil/Water Ratios
 Phenyl Label

Days	Aqueous %AR	Sed %AR	Ratio W:S		Ratio S:W	
			Mean	SD	Mean	SD
0	98.51	3.00	33	38	0	0
0	99.97	2.35	43	38	0	0
1	52.26	32.36	2	2	1	1
1	58.57	34.01	2	2	1	1
2	46.78	40.18	1	1	1	1
2	43.60	42.62	1	1	1	1
3	41.68	50.32	1	1	1	1
3	47.83	41.24	1	1	1	1
4	41.63	49.49	1	1	1	1
4	48.22	47.05	1	1	1	1
5	45.67	43.22	1	1	1	1
5	45.68	45.14	1	1	1	1
7	49.21	37.17	1	1	1	1
7	47.02	38.13	1	1	1	1
10	40.31	43.06	1	1	1	1
10	45.23	39.39	1	1	1	1
15	39.75	44.07	1	1	1	1
15	35.05	47.69	1	1	1	1
21	37.14	38.95	1	1	1	1
21	37.33	38.12	1	1	1	1
30	23.89	45.24	1	1	2	2
30	25.03	42.99	1	1	2	2
45	17.15	50.75	0	0	3	3
45	19.35	49.28	0	0	3	3
62	10.24	58.28	0	0	6	6
62	11.54	56.83	0	0	5	5

Data obtained from Appendix 7, Table II, pp. 140-143 of the study report.

Attachment 3: Transformation Pathway Presented by Registrant

45

05-01-06 DER ON The Aerobic Biotransformation of Orthosulfamuron - 46588508

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- Identity of the source of product ingredients.
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