



Document Title

**Summary of the fate and behaviour in the environment for  
Foramsulfuron**

Data Requirements

**EU Regulation 1107/2009 & EU Regulation 283/2013**

**Document MCA**

**Section 7: Fate and behaviour in the environment**

According to the guidance document, SANCO 10481/2013, for  
preparing dossiers for the approval of a chemical active substance

Date

**20<sup>th</sup> November 2013**

Author(s)



**BayerCropScience**

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### Version history

Date	Data points containing amendments or additions <sup>1</sup>	Document identifier or version number

<sup>1</sup> Changes will be presented according to the approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment report.

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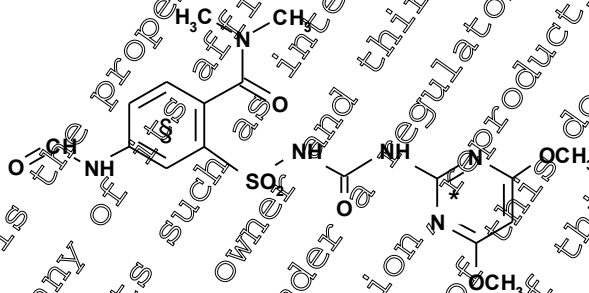
## CA 7 FATE AND BEHAVIOUR IN THE ENVIRONMENT

Information on the updated dossier for the Annex I Renewal

Data on the fate and behaviour of foramsulfuron (AE F130360) in soil, water and air were submitted within the EU Basic Dossier for Annex I inclusion in the year 2000. This document therefore focuses on those environmental fate studies which were not submitted within the EU Basic Dossier.

For a better overview, existing data and their evaluation resulting from the process of Annex I inclusion are summarised and shortly amended by new data generated in order to fulfil current requirements. The numbering and the headlines correspond to latest EU requirements. Previously evaluated studies (EU level) are presented in grey boxes and full study summaries are not presented. Copies of the study reports are included in the electronic dossier.

The studies investigating into the environmental fate of foramsulfuron were performed with the following positions of  $^{14}\text{C}$ -radiolabel in the active substance:



(§) Label 1: [phenyl- $^{14}\text{C}$ ]  
(\*) Label 2: [pyrimidyl-2- $^{14}\text{C}$ ]

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CA 7.1 Fate and behaviour in soil

CA 7.1.1 Route of degradation in soil

CA 7.1.1.1 Aerobic degradation

<b>Report:</b>	[redacted]; 2000;M-185910-01
<b>Title:</b>	Degradation of (U- <sup>14</sup> C-phenyl) and (2- <sup>14</sup> C-pyrimidyl)-AF130360 in three European soils under laboratory aerobic conditions at 20 degrees C Code: AE F130360
<b>Report No:</b>	C003294
<b>Document No(s):</b>	Report includes Trial Nos.: 522CF M-185910-01-1
<b>Guidelines:</b>	PMRA: T-1-255; SETAC: 1; USEPA (=EPA): Section 7, 16; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[redacted]; 1999;M-186637-01
<b>Title:</b>	Degradation of (U- <sup>14</sup> C-phenyl) and (2- <sup>14</sup> C-pyrimidyl)-AF130360 in two U.S. soils under laboratory aerobic conditions at 25 degrees C Code: AF 130360
<b>Report No:</b>	C003704
<b>Document No(s):</b>	Report includes Trial Nos.: 513CF M-186637-01-1
<b>Guidelines:</b>	EU (=EEC): 95/36; 1.1.1; PMRA: T-1-255; SETAC: 1995; USEPA (=EPA): N 161; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[redacted]; 2002;M-240732-01
<b>Title:</b>	Assessment of the risk from non-extractable soil residues of foramsulfuron
<b>Report No:</b>	B00372
<b>Document No(s):</b>	Report includes Trial Nos.: 602CF M-240732-01-1
<b>Guidelines:</b>	EU (=EC): Annex II, Section 5, Point 7.1.1.1; Deviation not specified
<b>GLP/GEP:</b>	no

The route of degradation in aerobic soil had been investigated under laboratory conditions in two studies following application of phenyl-<sup>14</sup>C- and pyrimidyl-<sup>14</sup>C- labeled active substance to:

- 3 soils under standard conditions of 20°C and moisture at 40 % maximum water holding capacity, MWHC (KCA 7.1.1.1 /01).
- 1 soil under sterile conditions (KCA 7.1.1.1 /02);
- 2 soils at 25°C and moisture at 75% of field capacity at 0.33 bar) (KCA 7.1.1.1 /02).

The risk from non-extractable residues formed in soil was additionally assessed in a separate document (KCA 7.1.1.1 /03).

The data requirement was addressed under Point 7.1.1.1.1 of the Dossier submitted and evaluated within the process of evaluation for Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2004) and its amendments. Consequently there is no detailed description of this existing data in this update.

The evaluation revealed that the degradation of foramsulfuron predominantly proceeded *via* loss of the formyl group as a biotically induced hydrolysis step to result in the formation of the major (>10% AR)

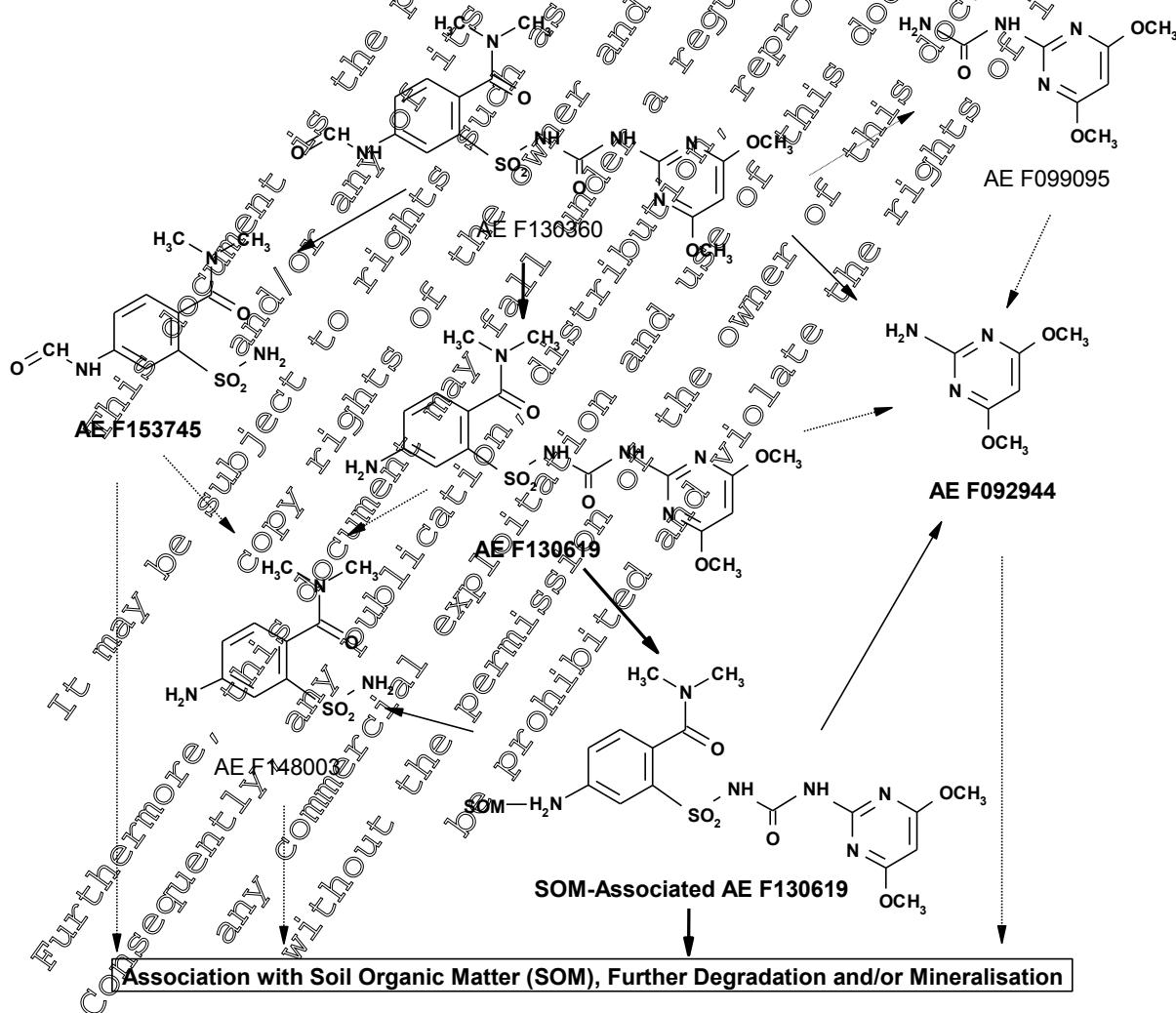
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and predominant metabolite AE F130619. Additional abiotic or biotic hydrolysis at the sulfonyl urea bridge resulted in the formation of AE F092944 as a major metabolite besides AE F153745 and trace amounts of metabolite AE F099095 and AE F148003. The degradation in aerobic soil was accompanied by extensive formation of non-extractable residues (NER) while the rate of mineralization was negligible under the conditions of laboratory testing.

At the time of review for Annex I inclusion, metabolites AE F130619 and AE F092944 were considered within the environmental risk assessments for soil, ground water and surface water in the existing basic dossier due to their occurrence as major compounds at >10% AR in tests on route of degradation in aerobic soil. For current risk assessments metabolite AE F153745 was additionally considered following the introduction of new data requirements including new trigger values starting at 5% AR as laid out in Commission Regulation 283/2013 amending Regulation 1107/2009.

The metabolic pathway from results of degradation tests in aerobic soil under conditions of the laboratory is summarised in Figure 7.1.1.1-1.

Figure 7.1.1.1-1 Proposed pathway of metabolism of foramsulfuron (AE F130360) in aerobic soil







**CA 7.1.1.2 Anaerobic degradation**

Report:	[REDACTED]; [REDACTED]; [REDACTED]; 2000;M-238343-02; Amended: 2000-02-29
Title:	Degradation of [U-14C-phenyl] and [2-14C-pyrimidyl] AE F130360 in a European soil under laboratory anaerobic conditions at 20°C: AE F130360
Report No:	B002603
Document No(s):	Report includes Trial Nos.: CF97E524 CF97E524A M-238343-02-1
Guidelines:	EU (=EEC): Annex II Point 7.1.1.2; PMR: T-1-255; US EPA (=EPA): 62-2; Deviation not specified
GLP/GEP:	yes

The route of degradation in anaerobic soil had been investigated under laboratory conditions in

- 1 flooded soil at 20°C following application of phenyl-U-<sup>14</sup>C- and pyrimidyl-<sup>14</sup>C-labeled active substance (KCA 7.1.1.2 /01).

The data requirement was addressed under Point 7.1.1.2.0 of the Dossier submitted and evaluated within the process of evaluation for Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments. Consequently there is no detailed description of this existing data in this update.

The evaluation revealed that foramsulfuron degraded slowly under the anaerobic conditions of the test via chemical hydrolysis of the formamide moiety to form AE F130619. In addition, hydrolysis at the sulfonylurea bridge resulted in the formation of AE F153745 and ACF092944 besides traces of AE F148003 and AE F099095. Again, the degradation products readily formed a significant portion of non-extractable residues of 23% of AR in maximum.

Based on the results, it has been concluded that the anaerobic soil degradation pathway is identical to that observed for degradation in aerobic soil.

**CA 7.1.1.3 Soil photolysis**

Report:	[REDACTED]; [REDACTED]; 2000;M-194958-01
Title:	Photolysis of 14C-AE F130360 on soil surface under laboratory conditions
Report No:	C000964
Document No:	M-194958-01-1
Guidelines:	SETAC: Part 1, 2.; EPA (=EPA): Subdiv. N, § 161-3; Deviation not specified
GLP/GEP:	yes

The route of degradation on irradiated soil surfaces had been investigated under laboratory conditions in:

- 1 soil under standard conditions (20°C, 75 % of field capacity at 0.33 bar) following application of pyrimidyl-2-<sup>14</sup>C-labeled active substance (KCA 7.1.1.3 /01).



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The data requirement was addressed under Point 7.1.1.1.2.2 of the Dossier submitted and evaluated within the process of evaluation for Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments.

Consequently there is no detailed description of this existing data in this update.

The evaluation revealed that foramsulfuron was stable towards photo-chemical transformation under the conditions of the test. Metabolite AE F099095 was observed as the only degradation product clearly below 10% AR in irradiated samples. This compound was also formed in dark control samples being therefore not specific to photolytic processes.

For Annex I Renewal the existing soil photolysis data was amended by a new study performed with phenyl-UL-<sup>14</sup>C-labeled active substance as the second position of radiolabel.

<b>Report:</b>	[REDACTED] § [REDACTED] 2012-M-422619-01
<b>Title:</b>	[Phenyl-UL- <sup>14</sup> C]Foramsulfuron Phototransformation on soil
<b>Report No:</b>	MEFSL009
<b>Document No:</b>	M-422619-01
<b>Guidelines:</b>	<b>US EPA Fate, Transport and Transformation Guidelines. OPPTS 838.2410 OECD Guidelines for the Testing of Chemicals. 2002 Draft Document. Phototransformation of Chemicals on Soil Surfaces; none</b>
<b>GLP/GEP:</b>	yes

**Executive Summary**

The photo-transformation of [phenyl-UL-<sup>14</sup>C]Foramsulfuron was studied on a silt loam at 20 ± 2 °C and 75% soil moisture of water holding capacity at 0.33 bar. Samples treated at a rate equivalent to 60 g/ha were continuously irradiated by artificial sunlight (xenon lamp with < 290 nm filter for cut-off) for 10 days equivalent to 30.9 days of light intensity at summer solstice at Phoenix, Arizona, USA. The samples were removed for analysis after 0, 1, 3, 6 and 9 days of irradiation. A series of control samples were incubated under the same conditions of temperature and moisture but in the dark.

Following extraction soil samples were analysed by HPLC using <sup>14</sup>C-flow through detection. Identification of parent compound and transformation products was performed by HPLC/MS coupling techniques, co-elution with authentic reference material and comparison of retention times.

The mean recovered radioactivity was more than 96% on average for all samples investigated. Extractable <sup>14</sup>C-residues in irradiated samples decreased from 97.1% of AR by day zero to 68.9% at the end of the test. Non-extractable radioactivity increased from 2.9% at start to 21.8% at the last sampling interval. Formation of <sup>14</sup>C carbon dioxide and other volatile degradation products was confirmed to be minimal (≤ 1.1% AR at study end) by determination for samples incubated for more than 4 days.

In irradiated samples, the parent compound decreased from 94.7% of AR by day zero to 58.6% at the last sampling interval. Metabolite AE F153745 (foramsulfuron sulfonamide) was observed as the only major, but transient transformation product at 10.4% AR after 4 days showing a decrease to 4.5% at study end.

In dark controls, the parent compound decreased significantly from 94.9% of AR by day zero to 12.2% at the last sampling interval with AE F130619 (foramsulfuron amine) detected as a major biotransformation product.

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A comparison of metabolic profiles between irradiated samples and dark controls indicated rapid transformation by biological processes while conversion by photolytic processes was slow. As a consequence no meaningful ‘net’ transformation rate constant for photo-transformation could be derived. Following application of UL-<sup>14</sup>C-phenyl-labeled foramsulfuron the photolysis on soil surfaces resulted in an experimental DT<sub>50</sub> of 15.9 days. This experimental half-life is equivalent to 30.5 environmental days under Arizona (US) light conditions and translates into a half-life of 47 environmental days for the lower light intensity of Athens in the EU.

Compared to biologically induced processes, (experimental DT<sub>50</sub> of 1.6 days) the contribution of photolytic processes to the elimination of foramsulfuron residues from the soil environment is estimated to be minimal.

**I. Material and Methods**

**A. Materials**

1. **Test Material:** [phenyl-UL-<sup>14</sup>C]Foramsulfuron  
 Specific radioactivity: 4.44 MBq/mg (54.29 mCi/mmol, 266,686 dpm/μg)  
 Radiochemical purity: 98.3%  
 Sample ID: C-1038
2. **Soil:** The soil was collected from Springfield, Nebraska, US

**Table 7.1.1.3-1: Characteristics of soil used for the photolysis study**

Geographic Location (City / Farm / Country)	Springfield / Nebraska / US
GPS coordinates	N 41° 0.03725° W 96° 0.15085°
Pesticide use history	None used for over 5 years
Collection procedure	Shovel
Sampling depth	10 – 20 cm (0 – 8 inches)
Storage Conditions	2 to 5°C
Storage length	Max. 69 days before application
Soil preparation	Sieved (2 mm)
Soil Taxonomic Classification (USDA)	Fine-silty, mixed, superactive, mesic Typic Hapludolls
Soil Series	Marshall
Texture Class (USDA)	silt loam
Sand [50 μm - 2 mm] (%)	14.8
Silt [2 μm - 50 μm] (%)	59.6
Clay [ < 2 μm ] (%)	25.6
pH in 0.01 M CaCl <sub>2</sub>	6.6
pH in Water	7.0
pH in saturated paste	6.8
Organic Matter <sup>A</sup> (%)	3.3
Organic Carbon (%)	1.9
Microbial biomass (mg microbial C/kg dry weight of soil)	404
CEC (meq/100 g)	17.4
Max. Water Holding Capacity (g/100 g)	44.3
Water Holding Capacity at 0.1 bar (pF2, g/100 g)	36.4
Water Holding Capacity at 0.33 bar (pF2.5, g/100 g)	25.8

<sup>A</sup>) % organic matter = % organic carbon × 1.724; CEC: Cation exchange capacity



## B. Study design

**1. Experimental conditions:** The test soil had been freshly collected from the field and shipped air-dried and sieved to 2 mm. The soil was adjusted to moisture of 75% of the water holding capacity at 0.33 bar and acclimated prior to the start of the test. Moisture was controlled and corrected on a daily basis throughout the exposure period.

An aqueous solution of [phenyl-UL-<sup>14</sup>C]Foramsulfuron (100 µL) was applied to the soil surface surface area of 12.57 cm<sup>2</sup> for each sample. The actual application rate of 8.91 µg a.s. (71 g a.s./ha) to 3.0 g dry soil was close to the intended dose of 7.54 µg a.s. calculated from the single maximum field use rate of 60 g a.s./ha.

The treated samples were continuously exposed to artificial irradiation by a xenon lamp with cut-off filters for light for wavelengths below 290 nm. The light intensity of the artificial sunlight was determined to 1092 W/m<sup>2</sup>. Considering light conditions at summer solstice at Phoenix, AZ, US in June expressed by its global radiation, one solar outdoor day was equivalent to 7883 hours irradiation in the experiment. The maximum irradiation time of 10 days in the experiment was thus equivalent to 30.4 days of Phoenix outdoor conditions.

The quartz glass test vessels were attached to traps for the collection of volatile components (ethylene glycol) and <sup>14</sup>C-carbon dioxide (2 M aqueous KOH). The samples were irradiated at 20 ± 2°C and at moisture of 75% of the water holding capacity at 0.33 bar. Non-irradiated controls samples were incubated under the same conditions in the dark.

**2. Sampling:** Duplicates of entire samples were removed for analysis each for irradiated flasks and dark controls after 0, 1, 4, 7 and 10 days of incubation. Soil moisture was checked at each sampling interval to result in negligible losses during incubation. Traps for <sup>14</sup>C-carbon dioxide were analysed after 4, 7 and 10 days of incubation.

**3. Analytical procedures:** Soil samples were extracted three times with acetonitrile/water (80/20, v/v) at room temperature. Analysis of soil extracts was performed by reversed phase HPLC with radioactivity detection after concentration as the primary analytical method. Identification and confirmation of Foramsulfuron was performed by HPLC with comparison to certified reference standards. The identity of parent compound Foramsulfuron was additionally confirmed by HPLC/MS as the confirmatory analytical method with selected samples.

Liquid samples were directly measured by liquid scintillation counting (LSC), total radioactivity of extracted soil was determined after air-drying by combustion and LSC determination. Radioactive residues in each trap were determined with LSC of sub-samples of the trap solutions.

**4. Kinetic evaluation:** The kinetic analysis of data was performed by the use of KinGUI, a tool for calculation within the framework of the mathematical software MATLAB (Ver.7.0.4).

## II. Results and Discussion

**A. Mass balance:** For irradiated samples, average material balances ranged from 91.3 to 101.1% of AR to result in an overall mean of 96.8% ± 3.6% (mean values of duplicates). For dark test systems, the average material balances ranged from 92.3 to 100.5% of AR with an overall mean of 96.6 ± 2.5%.

**B. Extractability of radioactive residues:** For irradiated samples, radioactivity was quantitatively extracted (97.1% by DAT-0) to show a decrease to 68.9% by DAT-10. In turn, non-extractable residues



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(NER) increased from 2.9% of AR by DAT-0 to 21.8% by the end of the study (DAT-10). For dark controls, radioactivity was quantitatively extracted (97.1%) by DAT-0 to show a decrease to 32.4% by DAT-10 while non-extractable residues (NER) increased from 2.9% of AR by DAT-0 to 61.2% by the end of the study (DAT-10).

**C. Volatile radioactivity:** There was no analysis for organic volatiles other than <sup>14</sup>CO<sub>2</sub>. Determination of <sup>14</sup>CO<sub>2</sub> started with DAT-4 to result in minimal amounts formed from irradiated samples (maximum of 1.1% AR, DAT-7) or dark controls (maximum of 0.1% AR, DAT-4, 7 and 10).

**D. Transformation of parent compound:** For irradiated samples, the parent compound showed a slow decline from 94.7% of AR by DAT-0 to 58.6% by DAT-10. For dark controls, the decline of foramsulfuron was significantly faster from 94.9% of AR by DAT-0 to 2.2% by DAT-10.

For irradiated samples, the occurrence of metabolites resulting from photo-degradation was generally low resulting in the formation of the hydrolysis product AF F153745 (foramsulfuron sulfonamide) as the only major product at 10.4% by DAT-4. All other transformation products occurred at trace level at or below 2.5% of AR in the course of the study. For dark controls, the predominance of biotical induced degradation is documented by the observation of AF F130619 (foramsulfuron amine) which is well in line with the results of aerobic soil degradation. AF F130619 was observed at maximum values of 38.7% of AR by DAT-2 to show a decline to 17.3% by DAT-10. The formation of other metabolites was low with none of the components observed at more than 1.9% of AR each in the course of the test.

**E. Kinetic analysis of data:** For irradiated samples, degradation of foramsulfuron was slow to result in values of the experimental DT<sub>50</sub>, DT<sub>75</sub> and DT<sub>90</sub> of 15.9, 31.9, and 52.9 days, respectively, when following the simple first order kinetic model (Table 7.1.1.3-2). An experimental half-life of 15.9 days is equivalent to 30.5 environmental days under Arizona (US) light conditions. For the lower light intensity of Athens in the EU this is equivalent to a half-life of 47 environmental days.

For dark controls, degradation of foramsulfuron was fast to result in an experimental DT<sub>50</sub>, DT<sub>75</sub> and DT<sub>90</sub> of 1.6, 3.1, and 5.1 days, respectively, again following the simple first order kinetic model.

Table 7.1.3-2: Kinetic analysis of photolytic degradation of foramsulfuron on soil surfaces

Test Matrix	Kinetic Model	Rate Constant (day <sup>-1</sup> )	DT <sub>50</sub> (days)	DT <sub>75</sub> (days)	DT <sub>90</sub> (days)	χ <sup>2</sup> test error (%)	t-test* (Prob> t)	Corr. of Det. (r <sup>2</sup> )
Irradiated	SFO	0.0435	15.9	31.9	52.9	9.2	0.0024	0.578
Dark controls	SFO	0.4406	1.55	3.10	5.14	15.8	0.00001	0.956
Net Phototransformation rate	n.a.	-0.4041	n.c.	n.c.	n.c.	n.a.	n.a.	n.a.

Net phototransformation rate = k<sub>irradiated soil</sub> - k<sub>dark control soil</sub>

n.a. = not applicable

n.c. = not calculated since rate of photolysis was slower than rate of soil metabolism in dark controls



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Table 7.1.1.3-3: Photo-transformation of Foramsulfuron on soil surfaces, expressed as percentage of AR (mean ± SD)

Compound		Sampling time (days)					
		0	1	2	4	7	14
Foramsulfuron	irradiated	94.7 ± 0.4	76.8 ± 1.5	75.3 ± 2.1	55.4 ± 4.1	67.8 ± 4.0	58.6 ± 4.7
	dark	94.9 ± 1.9	50.8 ± 0.5	33.4 ± 0.0	19.3 ± 4.1	14.3 ± 4.6	12.2 ± 2.5
A	irradiated	0.2 ± 0.3	0.0 ± 0.0	0.0 ± 0.0	0.8 ± 0.9	1.2 ± 0.3	0.9 ± 0.0
	dark	0.3 ± 0.1	0.0 ± 0.0	0.4 ± 0.6	1.2 ± 0.1	1.3 ± 0.1	1.9 ± 0.0
B	irradiated	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.2	0.2 ± 0.2	0.0 ± 0.0	0.2 ± 0.2
	dark	0.0 ± 0.0	0.0 ± 0.3	0.2 ± 0.2	0.0 ± 0.3	0.2 ± 0.0	0.0 ± 0.3
AE F130619 (Foramsulfuron amine)	irradiated	0.8 ± 0.0	2.3 ± 0.1	2.6 ± 0.0	1.1 ± 1.6	0.4 ± 0.4	2.0 ± 0.3
	dark	0.0 ± 0.0	30.6 ± 0.4	38.7 ± 1.1	30.6 ± 0.4	22.4 ± 1.4	17.3 ± 6.3
D	irradiated	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.4	0.3 ± 0.4	0.6 ± 0.8	0.5 ± 0.1
	dark	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0
E	irradiated	0.0 ± 0.0	0.1 ± 0.0	0.4 ± 0.1	0.5 ± 0.1	0.7 ± 0.0	0.5 ± 0.2
	dark	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0
AE F153745 (Foramsulfuron sulfonamide)	irradiated	1.8 ± 0.0	5.0 ± 1.1	2.8 ± 0.6	10.4 ± 1.4	4.0 ± 1.0	4.5 ± 0.8
	dark	2.0 ± 0.1	9.4 ± 0.0	0.1 ± 0.2	0.2 ± 0.2	0.2 ± 0.3	0.5 ± 0.3
G	irradiated	0.1 ± 0.2	0.5 ± 0.1	0.2 ± 0.2	1.6 ± 0.3	0.4 ± 0.3	0.4 ± 0.1
	dark	0.0 ± 0.0	0.9 ± 0.2	0.7 ± 0.0	0.6 ± 0.1	0.6 ± 0.1	0.3 ± 0.4
H	irradiated	0.2 ± 0.2	0.0 ± 0.0	0.0 ± 0.0	0.3 ± 0.0	0.5 ± 0.0	0.6 ± 0.1
	dark	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0
I	irradiated	0.0 ± 0.0	0.5 ± 0.1	0.6 ± 0.0	0.6 ± 0.3	1.1 ± 0.1	0.8 ± 0.2
	dark	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0
Total extractable residues	irradiated	97.1 ± 0.0	85.3 ± 2.4	82.2 ± 2.1	71.2 ± 2.5	77.7 ± 4.7	68.9 ± 3.8
	dark	97.1 ± 1.9	82.5 ± 1.3	73.5 ± 0.6	56.1 ± 4.5	39.0 ± 2.6	32.4 ± 1.4
Non-extractable residues	irradiated	2.9 ± 0.9	14.6 ± 0.8	15.3 ± 0.6	22.4 ± 1.5	18.8 ± 1.4	21.8 ± 4.3
	dark	2.9 ± 1.2	12.8 ± 0.6	24.0 ± 1.7	41.5 ± 7.1	56.5 ± 0.8	61.2 ± 0.7



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Compound		Sampling time (days)					
		0	1	2	4	7	10
CO <sub>2</sub> and other volatiles	irradiated	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.8 ± 0.1	1.1 ± 0.2	0.9 ± 0.0
	dark	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.1 ± 0.0	0.1 ± 0.0	0.1 ± 0.0
Total recovery	irradiated	100.0 ± 0.9	99.9 ± 1.7	97.5 ± 2.7	94.4 ± 4.1	91.6 ± 3.4	91.6 ± 4.7
	dark	100.0 ± 0.7	99.2 ± 0.7	97.5 ± 2.3	97.7 ± 2.6	95.6 ± 1.8	92.7 ± 2.0

SD = standard deviation

### III. Conclusions

The contribution of photolytic processes on soil surfaces to the elimination of foramsulfuron residues from the soil environment can be regarded as minimal.

Tests performed with UL-<sup>14</sup>C-phenyl-labeled foramsulfuron resulted in an experimental DT<sub>50</sub> of 15.9 days. This is equivalent to 50.5 environmental days under Arizona (US) light conditions and equivalent to 47 environmental days for lower light conditions of Athens in the EU.

Photolytically induced degradation is significantly slower when being compared to biotic processes of degradation (experimental DT<sub>50</sub> of 1.6 days). Since both degradation processes can be expected to occur in parallel under conditions of the outdoor environment, microbial degradation of residues after application is significantly faster thus leaving low residues of active substance available for photolytic degradation.

Photolytic degradation of UL-<sup>14</sup>C-phenyl-labeled foramsulfuron was accompanied by the formation of AE F153745 (foramsulfuron sulfonamide) as a major (i.e. >10% AR), but transient degradation product.

#### Overall conclusion for photolytic degradation of foramsulfuron on soil surfaces:

The results of studies performed with the active substance at two positions of radiolabel indicated slow transformation by photolytic processes on soil surfaces. The contribution of photolytic transformation is thus insignificant to the elimination of foramsulfuron residues from the soil environment.

From tests performed with phenyl-UL-<sup>14</sup>C-labeled active substance the formation of AE F153745 (foramsulfuron sulfonamide) was observed as a major, but transient degradation product while tests with pyrimidine-2-<sup>14</sup>C-labeled foramsulfuron resulted in the formation of AE F099095 as a minor degradation product observed at <10% of AR.



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CA 7.1.2 Rate of degradation in soil

CA 7.1.2.1 Laboratory studies

The data requirement had been addressed under Point 7.1.1.2 of the Dossier submitted and evaluated within the process of evaluation for Annex I inclusion as published in the corresponding Monographs of RMS Germany (April 01, 2001) and its amendments.

Data on rate of degradation of foramsulfuron and metabolites AE F130619 and AE F092944 in soil had been derived from a set of laboratory studies performed with the active substance as well as from separate degradation tests performed with metabolites.

Following latest guidance on kinetic evaluation the data from existing studies have been re-evaluated.

Moreover a separate test on rate of degradation in the laboratory was performed with phenyl-<sup>14</sup>C-labeled AE F153745 in order to support the risk assessment by generation of robust data.

CA 7.1.2.1.1 Aerobic degradation of the active substance

Report:	[REDACTED]; 2006; M-185910-01
Title:	Degradation of (U- <sup>14</sup> C-phenyl) and (2- <sup>14</sup> C-pyrimidyl)-AE F130360 in three European soils under laboratory aerobic conditions at 20 degrees C Code: AE F130360
Report No:	C03294
Document No(s):	Report includes Trial Nos.: 52241 M-185910-01-1
Guidelines:	PMRA: T-1-255; SETAC: 1; USEPA (=EPA): Section N, 162-1; Deviation not specified
GLP/GEP:	yes

Report:	[REDACTED]; 1999; M-186637-01
Title:	Degradation of (U- <sup>14</sup> C-phenyl) and (2- <sup>14</sup> C-pyrimidyl)-AE F130360 in two U.S. soils under laboratory aerobic conditions at 25 degrees C Code: AE F130360
Report No:	G00370
Document No(s):	Report includes Trial Nos.: 518 M-186637-01-1
Guidelines:	EU (=EPA): 95-6 7.1.1; PMRA: T-1-255; SETAC: 1995; USEPA (=EPA): N 162-1; Deviation not specified
GLP/GEP:	yes

Report:	[REDACTED]; 2000; M-238314-01
Title:	Degradation of [U- <sup>14</sup> C-phenyl] and [2- <sup>14</sup> C-pyrimidyl] AE F130360 in a European soil under laboratory aerobic conditions at 10' C: AE F130360
Report No:	B0025
Document No(s):	Report includes Trial Nos.: CF97E523 M-238314-01-2
Guidelines:	USEPA (=EPA): 162-1; Deviation not specified
GLP/GEP:	yes





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<b>Report:</b>	[redacted]; 2000; M-238491-01
<b>Title:</b>	Kinetic Evaluation of the Aerobic Degradation of AE F130360 and its Metabolites in Five Different Soils using TopFit 2.0
<b>Report No:</b>	B002763
<b>Document No(s):</b>	Report includes Trial Nos.: CF00E578 M-238491-01-2
<b>Guidelines:</b>	not applicable
<b>GLP/GEP:</b>	no (calculation)

For the active substance foramsulfuron data on the rate of degradation in aerobic soil can be derived from laboratory studies performed under the following conditions:

- 3 soils under standard conditions of 20°C and moisture at 40 % maximum water holding capacity, MWHC, following application of phenyl-UL-<sup>14</sup>C- and pyrimidyl-2-<sup>14</sup>C- labeled active substance (KCA 7.1.2.1.1 /01);
- 2 soils at 25°C and 75% moisture of the field capacity at 0.33 bar and application of phenyl-UL-<sup>14</sup>C- and pyrimidyl-2-<sup>14</sup>C- labeled active substance (KCA 7.1.2.1.1 /02);
- 1 soil at 10°C and 40 % MWHC and application of phenyl-UL-<sup>14</sup>C and pyrimidyl-2-<sup>14</sup>C-labeled active substance (KCA 7.1.2.1.1 /03).

A kinetic evaluation of degradation data had been performed in document KCA 7.1.2.1.1 /04.

This data requirement had been addressed under Point 7.1.1.2 of the Dossier submitted and evaluated within the process of evaluation for Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments.

Following latest guidance on kinetic evaluation the data from existing studies have been re-evaluated therefore superseding the existing kinetic evaluations.

<b>Report:</b>	[redacted]; 2013; M-453563-02;
<b>Title:</b>	Amended: 2013-07-19 Kinetic evaluation of laboratory aerobic soil degradation of foramsulfuron and its metabolites according to Focus
<b>Report No:</b>	EnSa 12-0246
<b>Document No:</b>	M-453563-02-1
<b>Guidelines:</b>	not applicable; not applicable
<b>GLP/GEP:</b>	no

**Executive Summary**

For the active substance foramsulfuron degradation data as referenced under KCA 7.1.2.1.1 /01 to KCA 7.1.2.1.1 /03 were kinetically evaluated according to FOCUS Guidance to derive endpoints for use in trigger evaluation and optimised degradation parameters for use in modelling exposure in environmental assessments.

For metabolites AE F092944, AE F130619 and AE F153745 the kinetic analysis was performed in combination with parent compound data, amended by aerobic soil degradation data from separate tests with AE F130619, AE F153745 and AE F092944. For the latter compound, these data were publicly available and summarised under Point CA 7.1.2.1.2.



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The degradation of the active substance foramsulfuron in soil under aerobic conditions of the laboratory was investigated in three studies following application of two positions of radiolabel to five different soils.

For the calculation of normalised half-lives in soil for use in modeling, a stepwise approach was made. The initial step consisted of fitting the SFO kinetic model to the measured data. In case of unacceptable fits according to the criteria set bi-phasic models, i.e. FOMC or DFOP were applied. The procedure resulted in the bi-phasic best fits according to FOMC for four soils and to DFOP for one soil and the two label positions. In these cases non-normalised SFO-type half-lives were derived by 'back-calculation' from non-normalised values of the DT<sub>90</sub> in case of FOMC and using the kinetic rate of the slower degrading compartment in case of DFOP. Finally, values were normalised to reference conditions (20°C, pF2 moisture) with results summarised in Table 7.1.2.1.1 -1.

For use as modelling endpoint, an overall mean normalised half-life of 13.5 days was calculated for the active substance foramsulfuron.

For comparison with trigger values, non-normalised values of the DT<sub>50</sub> and the DT<sub>90</sub> were derived from FOMC best fits in four soils and DFOP best fit in one soil with results summarised in Table 7.1.2.1.1 -2. Non-normalised half-lives were found to vary from 1.1 days for soil Orainville to 9.2 days for soil Shuttleworth while values for the DT<sub>90</sub> ranged from 10.9 days for soil Orainville to 178.8 days for soil Iowa. For tests performed at 10°C the corresponding values for the DT<sub>50</sub> and DT<sub>90</sub> were 19.5 days and 232.6 days in soil Shuttleworth.

Formation fractions were derived for metabolites AE F092944, AE F130619 and AE F153745. For the formation of AE F092944 from the active substance a mean value of 0.22 was derived. For metabolite AE F130619, a mean formation fraction of 0.92 was estimated as a result of rapid and major formation from the parent compound foramsulfuron. AE F130619 is rapidly and irreversibly bound to soil under formation of non-extractable residues. For metabolite AE F153745, no formation fraction could be derived from the active substance. AE F153745 and AE F092944 are the two products of the cleavage of the sulfonylurea bond and should thus be formed with the same rate. Therefore the formation fraction of AE F153745 was assumed to be equal to that of AE F092944.

Table 7.1.2.1.1-1: Normalised laboratory DT<sub>50</sub>-values in aerobic soil for parent compound foramsulfuron for use as modelling input parameters in environmental exposure assessments

Soil (origin)	Label position	DT <sub>50</sub> (days)	Model
Orainville (Study 1)	1 + 2	1.9	FOMC
Chantepie (Study 1)	1	6.1	FOMC
Shuttleworth (Study 1 + 3)	Study 1: 1 + 2 Study 3: 1 + 2	20.6	Study 1: FOMC Study 3: DFOP
Iowa (Study 2)	1 + 2	65.9	FOMC
North Carolina (Study 2)	1 + 2	28.4	FOMC
<b>Mean (geometric)</b>		<b>13.5</b>	

Geometric mean values from two positions of radiolabel

Label position: 1 = phenyl, 2 = pyrimidyl

Study 1: KCA 7.1.2.1.1 /01; Study 2: KCA 7.1.2.1.1 /02; Study 3: KCA 7.1.2.1.1 /03

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Soil (Origin)	Label position	DT <sub>50</sub> (days)	DT <sub>90</sub> (days)	Model
Orainville, 20°C (Study 1)	1 + 2	1.1	16.9	FOMC
Chantepie, 20°C (Study 1)	1 + 2	3.5	35.0	FOMC
Shuttleworth, 20°C (Study 1)	1 + 2	9.2	58.1	FOMC
Iowa, 25°C (Study 2)	1 + 2	8.1	178.8	FOMC
North Carolina, 25°C (Study 2)	1 + 2	6.8	97.7	FOMC
Shuttleworth, 10°C (Study 3)	1 + 2	19.5	232	DFOP

Geometric mean values from two positions of radiolabel  
 Label position: 1 = phenyl, 2 = pyrimidyl  
 Study 1: KCA 7.1.2.1.1 /01; Study 2: KCA 7.1.2.1.1 /02; Study 3: KCA 7.1.2.1.1 /03

### I. Material and Methods

For the parent compound foramsulfuron details on study conduct and its results have been summarised under Point 7.1.1.1. The degradation data were kinetically evaluated following FOCUS guidance with the software KinGUI, version 2.

The measured values were taken into account as reported and thus treated as individual replicates. All sets with their data points were weighted equally. The concentration at time zero was included in the parameter optimization with the initial value being allowed to be estimated by the model. In cases where the radioactive residues in soil were below the limit of detection (LOD) the respective values were set to 0.5 LOD for the evaluation of time points before or after which a value above LOD was determined. For some studies no LOD was given in the original report. In these cases no values were added. In some cases degradation products of the applied substance were already detected at time zero. In such cases the respective percentages were added to the parent values and the values for the metabolite were set to zero.

All radioactive residues in soil were used for the kinetic evaluation. For some of the studies performed for very long periods of up to one year the evaluations for deriving modelling endpoints used only data measured up to day 120 days which is the maximum recommended duration for laboratory studies according to OECD Guideline 307 (2002).

For fits of compounds under evaluation, SF<sub>0</sub> kinetics was tested first due to its simplicity and its nearly exclusive use in environmental exposure models. In general, also the use of other kinetic model approaches is possible as proposed by FOCUS. The evaluation thus considered also the model approaches first order multiple compartment (FOMC), dual first order in parallel (DFOP) and Hockey Stick (HS), in principle, following the scheme for identification of the appropriate kinetic model as proposed by FOCUS.

To check the parameters for their significance a single-sided t-test was used. The probability of t should be low or equal to zero as this probability can be assumed to be higher the more uncertain a parameter is. In general, a value of 0.05 for the probability of t is considered as appropriate with degradation parameters being regarded as significant at this level.

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The DT<sub>50</sub>-values derived were normalised to standard reference temperature 20 °C and soil moisture 100 % field capacity in order to obtain standardised input parameters for predictions of environmental concentrations. This normalisation was conducted according to the standard approach by FOCUS.

The degradation of foramsulfuron in aerobic soil resulted in the predominant formation (> 80%) of non-extractable residues (NER). Similar results were obtained for tests with metabolites AE F130619 and AE F153745 following their separate application to soil.

The results suggest that the amino group at the phenyl ring of AE F130619 is responsible for such irreversible binding to the soil matrix. The lower portion of bound residues found after application of pyrimidyl labelled AE F130619 can be explained by cleavage of the sulfonylurea bridge as structural element thus losing the respective amino-phenyl containing residues.

Metabolite AE F148003 may result from the formation of AE F153745. By containing the same structural element responsible for irreversible binding AE F148003 has a transient character. AE F148003 was not included into the kinetic evaluations since the compound was observed at trace level only.

The overall importance of bound residues was considered by introduction as a separate compartment into the kinetic evaluations for studies performed with the parent compound foramsulfuron. This resulted in compartmental models as shown in Figure 7.1.2.1.1-1 for the phenyl label and Figure 7.1.2.1.1-2 for the pyrimidine label. The inclusion of bound residues into the model optimisation resulted in an improvement of certainty for the parameter determination since more experimental information had been considered.

Figure 7.1.2.1.1-1. Compartment model for the degradation of phenyl-<sup>14</sup>C-labelled foramsulfuron in aerobic soil

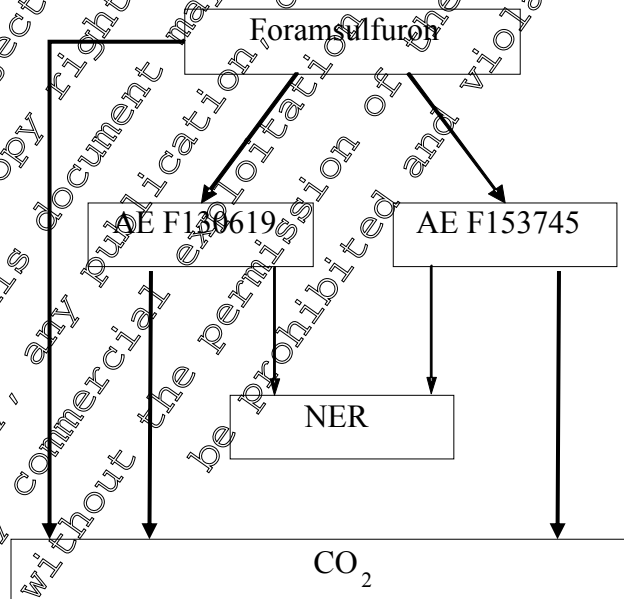
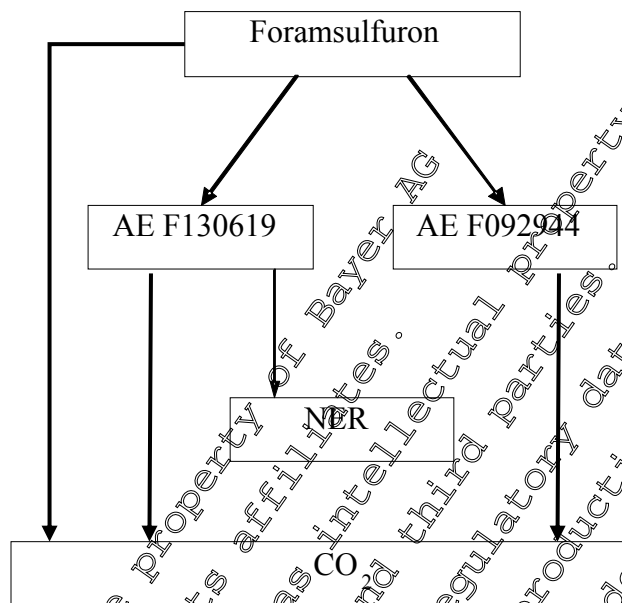


Figure 7.1.2.1.1-2: Compartment model for the degradation of pyrimidine-<sup>14</sup>C-labelled foramsulfuron in aerobic soil



## II. Results and Discussion

Following application of the parent substance foramsulfuron an 'unusual' metabolic pattern with time was observed, in particular for metabolite AE F092944 in a number of soils coming from a first rapid increase which was followed by a decline to low residues. This was followed by another increase to result in a second peak. However, testing of various hypotheses was inconclusive and did not result in a mechanistic explanation for the observations made. Consequently, evaluations were based of the compartment model as shown in Figure 7.1.2.1.1-1 and Figure 7.1.2.1.1-2 resulting in the consequence that fits could not be optimised to the observed metabolite data.

Formation fractions for metabolites AE F130619, AE F153745 and AE F092944 from studies with parent compound:

Only few formation fractions for the metabolites could be derived because the fits of the full pathway models only seldom led to acceptable results for the transformation products. The values obtained are compiled in Table 7.2.1.13. For AE F130619, sufficient number of three values for different soils could be obtained, while for AE F092944 it was only two values. For AE F153745 not a single formation fraction was determined. However, in case of AE F130619 one of the values is very low compared to the others and is rather considered an outlier. Because of this scarce data situation it is proposed to use the following formation fractions in environmental fate simulations:

- AE F130619: ff = 0.92 (maximum of three values)
- AE F153745: ff = 0.22 (estimated from ff of AE F092944)
- AE F092944: ff = 0.22 (maximum of three values)

In all cases as conservative assumption the highest observed value was chosen. AE F153745 can only be formed parallel to AE F092944. AE F153745 and AE F092944 are the two products of the cleavage



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of the sulfonylurea bound and should thus be formed with the same rate. Therefore the formation fraction of AE F153745 was assumed to be equal to that of AE F092944.

Calculation of non-normalised DT<sub>50</sub>-values:

For the parent compound foramsulfuron the kinetic evaluation of soil degradation tests using the SFO approach did not result in acceptable fits to the experimental data. For all but two data sets the evaluation resulted in FOMC to be the optimal fit to describe the degradation data. Instead, the two tests failing the FOMC fit could be described best by the DFOP model. For modelling purposes and for use as non-normalised data prior to normalisation to reference conditions, the DT<sub>50</sub>-values were back-calculated from the corresponding value of the DT<sub>90</sub> derived either by the FOMC or the DFOP fit. The results are summarised in Table 7.1.2.1.1-4. For purposes of evaluation against persistence triggers, the non-normalised values for DT<sub>50</sub>- and the DT<sub>90</sub> derived are summarised in Table 7.1.2.1.1-5.

Normalisation of DT<sub>50</sub>-values:

For the use in environmental modelling the degradation half-lives were normalised to reference conditions of 100 % field capacity regarding soil moisture and 20°C for the temperature. The parameters used in the laboratory tests and the respective correction factors calculated are summarised in Table 7.1.2.1.1-6. The values of half-lives resulting from normalisation are summarised in Table 7.1.2.1.1-7.

**Table 7.1.2.1.1-3: Formation fractions of metabolites AE F092944 and AE F130619 from application of parent compound foramsulfuron to aerobic soil under laboratory conditions**

Soil (Origin)	Label position	Formation fraction for process	
		Foramsulfuron AE F130619	Foramsulfuron to AE F092944
Orainville, 20°C (2000a)	phenyl	1.0	-
Orainville, 20°C (2000a)	pyrimidyl	0.84	-
	Mean Orainville	0.92	-
Chantepie, 20°C (2000a)	phenyl	0.85	-
Shuttleworth, 20°C (2000a)	phenyl	0.14	-
Chantepie, 20°C (2000a)	pyrimidyl	-	0.07
Shuttleworth, 10°C (2000b)	pyrimidyl	-	0.22
<b>Mean (arithmetic)</b>		<b>0.64 *</b>	<b>0.15</b>

\* Arithmetic mean calculated from average values for single soils

No formation fraction could be derived for AE F153745. An upper limit of 10% was estimated as the difference between 100% and the formation fraction of AE F130619



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Table 7.1.2.1.1-4: Non-normalised DT<sub>50</sub>-values for parent compound foramsulfuron in aerobic soils under laboratory conditions for modelling evaluation

Soil (Origin)	Label position	DT <sub>50</sub> (days)	Model
Iowa, 25°C (██████████, 1999)	phenyl	43.3	FOMC
Iowa, 25°C (██████████, 1999)	pyrimidyl	30.9	FOMC
North Carolina, 25°C (██████████, 1999)	phenyl	67.0	FOMC
North Carolina, 25°C (██████████, 1999)	pyrimidyl	28.0	FOMC
Shuttleworth, 20°C (██████████, 2000a)	phenyl	15.6	FOMC
Shuttleworth, 20°C (██████████, 2000a)	pyrimidyl	19.6	FOMC
Orainville, 20°C (██████████, 2000a)	phenyl	3.5	FOMC
Orainville, 20°C (██████████, 2000a)	pyrimidyl	3.1	FOMC
Chantepie, 20°C (██████████, 2000a)	phenyl	10.6	FOMC
Chantepie, 20°C (██████████, 2000a)	pyrimidyl	10.5	FOMC
Shuttleworth, 10°C (██████████, 2000b)	phenyl	56.7	DFOP
Shuttleworth, 10°C (██████████, 2000b)	pyrimidyl	85.6	DFOP

Table 7.1.2.1.1-5: Non-normalised DT<sub>50</sub>-values for parent compound foramsulfuron in aerobic soils under laboratory conditions for trigger evaluation

Soil (Origin)	Label position	DT <sub>50</sub> (days)	DT <sub>90</sub> (days)	Model
Iowa, 25°C (██████████, 1999)	phenyl	7.1	143.8	FOMC
Iowa, 25°C (██████████, 1999)	pyrimidyl	9.9	222.4	FOMC
<b>Mean (geometric)</b>		8.1	178.8	
North Carolina, 25°C (██████████, 1999)	phenyl	7.0	102.6	FOMC
North Carolina, 25°C (██████████, 1999)	pyrimidyl	6.7	93.0	FOMC
<b>Mean (geometric)</b>		6.9	97.7	
Shuttleworth, 20°C (██████████, 2000a)	phenyl	7.3	51.8	FOMC
Shuttleworth, 20°C (██████████, 2000a)	pyrimidyl	11.5	65.1	FOMC
<b>Mean (geometric)</b>		9.2	58.1	
Orainville, 20°C (██████████, 2000a)	phenyl	1.2	11.6	FOMC
Orainville, 20°C (██████████, 2000a)	pyrimidyl	1.0	10.3	FOMC
<b>Mean (geometric)</b>		1.1	10.9	
Chantepie, 20°C (██████████, 2000a)	phenyl	3.5	35.2	FOMC
Chantepie, 20°C (██████████, 2000a)	pyrimidyl	3.5	34.9	FOMC
<b>Mean (geometric)</b>		3.5	35.0	
<hr/>				
Shuttleworth, 10°C (██████████, 2000b)	phenyl	18.5	188.2	DFOP
Shuttleworth, 10°C (██████████, 2000b)	pyrimidyl	20.5	287.5	DFOP
<b>Mean (geometric)</b>		19.5	232.6	



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Table 7.1.2.1.1-6: Study conditions and correction factors used for moisture and temperature normalisation

Study	Soil	Texture class (USDA)	Gravimetric water content		Actual moisture in test **	Reference moisture pF2 *	T [°C]	Corr. Factor	
			MHWC [%m/m]	0.33 bar [%m/m]				Moisture [-]	Temp. [°C]
1999	North Carolina	Loamy sand	-	9	18.5	14	25	0.60	1.6
	Iowa	Clay loam	-	25	18.75	28	25	0.76	1.61
2000a	Shuttleworth	Sandy loam	27	-	10.8	-	20	0.67	1.00
	Orainville	Clay loam	32	-	12.3	28	20	0.58	1.00
	Chantepie	Clay loam	32	-	12.8	28	20	0.58	1.00
2000b	Shuttleworth	Sandy loam	40	10.9	10.9	-	17	0.52	0.39
2000c	Illinois	Sandy loam	52.3	19.7	20.9	-	20	1.04	1.00
	Shuttleworth	Sand	44.7	8.1	17.5	-	20	0.74	1.00
	Orainville	Loam	54.3	23	21.7	-	20	0.96	1.00
	Chantepie	Loam	56.3	16.3	21.8	-	20	0.90	1.00
DAR, 2006	Collombes	Loamy sand	44.2	-	17.7	14	20	1.18	1.00
	Spover 2.2	Loamy sand	53.4	-	17.7	14	20	1.18	1.00
	Les Evouettes	Loam	44.3	-	21.4	25	20	0.90	1.00
2011	Porterville	Sandy loam	27.1	-	14.9	13.9***	20	1.05	1.00
	Springfield	Silt loam	46.8	-	25.7	32.4***	20	0.85	1.00
	Pikeville	Loamy sand	26.9	-	14.8	10.2***	20	1.30	1.00
	Sanger	Loamy sand	30.5	-	16.8	14.4***	20	1.11	1.00

\* Calculated values according to FOONIS, 2006

\*\* 75% of 0.33 bar or at 40% (35%) of MHWC

\*\*\* Values given in study report

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Soil (Origin)	Label position	DT <sub>50</sub> (days)	Model
Iowa (██████████, 1999)	phenyl	53.0	FOMC
Iowa (██████████, 1999)	pyrimidyl	82.0	FOMC
<b>Mean (geometric)</b>		<b>65.9</b>	
North Carolina (██████████, 1999)	phenyl	29.8	FOMC
North Carolina (██████████, 1999)	pyrimidyl	27.0	FOMC
<b>Mean (geometric)</b>		<b>28.4</b>	
Orainville (██████████, 2000a)	phenyl	2.0	FOMC
Orainville (██████████, 2000a)	pyrimidyl	1.8	FOMC
<b>Mean (geometric)</b>		<b>1.9</b>	
Chantepie (██████████, 2000a)	phenyl	7.1	FOMC
Chantepie (██████████, 2000a)	pyrimidyl	6.1	FOMC
<b>Mean (geometric)</b>		<b>6.6</b>	
Shuttleworth (██████████, 2000a)	phenyl	10.5	FOMC
Shuttleworth (██████████, 2000a)	pyrimidyl	23.1	FOMC
Shuttleworth (██████████, 2000b)	phenyl	29.2	DFOP
Shuttleworth (██████████, 2000b)	pyrimidyl	44.6	DFOP
<b>Mean (geometric)</b>		<b>20.6</b>	
<b>Mean (geometric)</b>		<b>13.5</b>	

### III. Conclusion

The evaluation according to FOOCUS kinetic guidance resulted in half-lives of the parent compound foramsulfuron for use as inputs in environmental risk assessments. The various approaches for fitting with experimental data resulted in the use of the bi-phasic kinetic models FOMC and DFOP. For evaluation as input parameter in modelling, non-normalised values for the DT<sub>50</sub> were derived by back-calculation from the corresponding DT<sub>90</sub>-values for FOMC or from the smaller kinetic rate of DFOP. The non-normalised half-lives were then referenced for moisture (pF 2) and temperature (20°C).

The values derived from laboratory tests with two positions of radiolabel in three EU and two US soils are regarded as suitable and reliable for use in environmental exposure assessments. For the active substance foramsulfuron, a normalised half-life of 13.5 days was calculated as modelling endpoint.

For evaluation against persistence triggers, geometric mean values of non-normalised half-lives were calculated for each soil and position of radiolabel tested as a result from best fits to measured data. The mean half-lives range from 1.1 days for soil Orainville to 9.2 days for soil Shuttleworth while values for the DT<sub>90</sub> ranged from 10.9 days for soil Orainville to 178.8 days for soil Iowa. For tests performed at 10°C, the corresponding values for the DT<sub>50</sub> and DT<sub>90</sub> were 19.5 days and 232.6 days in soil Shuttleworth.

For the formation fraction of active substance to metabolite AE F130619 a mean value of 0.64 was calculated while for the formation of AE F092944 from the active substance a value of 0.22 was derived. For metabolite AE F153745, no formation fraction could be derived. Since AE F153745 and AE F092944 are the two products of the cleavage of the sulfonylurea bound and should thus be formed with the same rate, the formation fraction of AE F153745 was assumed to be equal to that of AE F092944.



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CA 7.1.2.1.2 Aerobic degradation of metabolites, breakdown and reaction products

<b>Report:</b>	[REDACTED]; [REDACTED]; [REDACTED]; 2009; M-185910-01
<b>Title:</b>	Degradation of (U- <sup>14</sup> C-phenyl) and (2- <sup>14</sup> C-pyrimidyl)-AE F130360 in three European soils under laboratory aerobic conditions at 20 degrees C. Code: AE F130360
<b>Report No:</b>	C003294
<b>Document No(s):</b>	Report includes Trial Nos.: 522CF M-185910-01-1
<b>Guidelines:</b>	PMRA: T-1-255; SETAC: 1.1; USEPA (=EPA): Section N 162-1; Deviation not specified
<b>GLP/GEP:</b>	Yes

<b>Report:</b>	[REDACTED]; [REDACTED]; 1999; M-186637-01
<b>Title:</b>	Degradation of (U- <sup>14</sup> C-phenyl) and (2- <sup>14</sup> C-pyrimidyl)-AE F130360 in two U.S. soils under laboratory aerobic conditions at 25 degrees C. Code: AE F130360
<b>Report No:</b>	C003704
<b>Document No(s):</b>	Report includes Trial Nos.: 513CF M-186637-01-1
<b>Guidelines:</b>	EU (=EC): 99/6 7.1.1; PMRA: T-255; SETAC: 1999; USEPA (=EPA): N 162-1; Deviation not specified
<b>GLP/GEP:</b>	Yes

<b>Report:</b>	[REDACTED]; [REDACTED]; 2000; M-238314-01
<b>Title:</b>	Degradation of [(U- <sup>14</sup> C-phenyl) and (2- <sup>14</sup> C-pyrimidyl)] AE F130360 in a European soil under laboratory aerobic conditions at 15 C: AE F130360
<b>Report No:</b>	B00256
<b>Document No(s):</b>	Report includes Trial Nos.: CF97E523 M-238314-01-2
<b>Guidelines:</b>	USEPA (=EPA): 162-1; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[REDACTED]; [REDACTED]; [REDACTED]; 2000; M-238440-02; Amended: 2000-03-23
<b>Title:</b>	Degradation of [(U- <sup>14</sup> C-phenyl) and (2- <sup>14</sup> C-pyrimidyl)]-AE F130619 in four soils under laboratory aerobic conditions at 15 C: AE F130619
<b>Report No:</b>	B00270
<b>Document No(s):</b>	Report includes Trial Nos.: CF99E548 F99E548A M-238440-02
<b>Guidelines:</b>	PMRA: T-255; SETAC: 1.1; USEPA (=EPA): 162-1; Deviation not specified
<b>GLP/GEP:</b>	Yes

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<b>Report:</b>	[REDACTED]; [REDACTED]; 2000; M-238491-01
<b>Title:</b>	Kinetic Evaluation of the Aerobic Degradation of AE F130360 and its Metabolites in Five Different Soils using TopFit 2.0
<b>Report No:</b>	B002763
<b>Document No(s):</b>	Report includes Trial Nos.: CF00E578 M-238491-01-2
<b>Guidelines:</b>	Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[REDACTED]; [REDACTED]; 2012; M-425904-01
<b>Title:</b>	[Phenyl-UL-14C]foramsulfuron sulfonamide: Aerobic soil metabolism in four US soils
<b>Report No:</b>	MEFSL008
<b>Document No:</b>	M-425904-01-1
<b>Guidelines:</b>	<b>OECD: Guideline 307; Aerobic and Anaerobic Transformation of Soil, April 24, 2002</b> <b>OPPTS 835.4100, Aerobic Soil Metabolism, US EPA, October 2008; The sterilization of the soil conducted at FTSI was not conducted under GLP but GMP. The kinetics modeling was not conducted under GEP.</b>
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[REDACTED]; [REDACTED]; 2006; M-469999-01
<b>Title:</b>	Study summary - <sup>14</sup> C-ADM. Degradation in three soils incubated under aerobic conditions. Extract of draft assessment report (DAR) - Public version - Initial risk assessment provided by the rapporteur member state United Kingdom for the existing active substance nicosulfuron of the third stage (part A) of the review programme referred to in article 8 (2) of council directive 91/414/EEC - Volume 3, Annex , B.8
<b>Report No:</b>	384480
<b>Document No:</b>	M-469999-01-1
<b>Guidelines:</b>	Deviation not specified
<b>GLP/GEP:</b>	n.a.

<b>Report:</b>	[REDACTED]; [REDACTED]; 2013; M-453563-02;
<b>Title:</b>	Kinetic evaluation of laboratory aerobic soil degradation of foramsulfuron and its metabolites according to Focus
<b>Report No:</b>	EnSa-12-0246
<b>Document No:</b>	M-453563-02-1
<b>Guidelines:</b>	not applicable; not applicable
<b>GLP/GEP:</b>	no

In the evaluations for Annex I inclusion information on rate of degradation of foramsulfuron metabolites in aerobic soil was derived from the following set of laboratory tests:

- 3 soils under standard conditions of 20°C and moisture at 40 % maximum water holding capacity, MWHC, following application of phenyl-UL-<sup>14</sup>C- and pyrimidyl-2-<sup>14</sup>C- labeled active substance (KCA 7.1.2.1.1 /01);
- 2 soils at 25°C and 75% moisture of the field capacity at 0.33 bar following application of UL-<sup>14</sup>C- phenyl- and pyrimidyl-2-<sup>14</sup>C- labeled active substance (KCA 7.1.2.1.1 /02);
- 1 soil at 10°C and moisture at 40 % MWHC following application of phenyl-UL-<sup>14</sup>C- and pyrimidyl-2-<sup>14</sup>C- labeled active substance (KCA 7.1.2.1.1 /03);
- 4 soils under standard conditions of 20°C and moisture at 40 % MWHC following application of phenyl-UL-<sup>14</sup>C- and pyrimidyl-2-<sup>14</sup>C- labeled metabolite AE F130619 (KCA 7.1.2.1.2 /04).



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The data sets from laboratory tests were kinetically re-evaluated in document (KCA 7.1.2.1.2 /05).

The evaluations had been addressed under Point 7.1.1.2.1.3 of the Dossier and evaluated within the process of evaluation for Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments.

In order to generate robust half-lives for degradation of metabolite AE F153745 in aerobic soil, a new study was performed following dosing of phenyl-UL-<sup>14</sup>C AE F153745 to four aerobic soils at 20°C and moisture at 55% of MWHC (KCA 7.1.2.1.2 /06).

Additional information on the rate of degradation in three aerobic soils (20°C, 40% MWHC moisture) has been derived for metabolite AE F092944 from publicly available data (KCA 7.1.2.1.2 /07).

Following latest guidance on kinetic evaluation and thus interpretation (FOCUS, 2006) the data of existing studies have been re-evaluated therefore superseding the existing kinetic evaluations (KCA 7.1.2.1.2 /08).

<b>Report:</b>	[REDACTED]; 2012 M-425904-01
<b>Title:</b>	[Phenyl-UL- <sup>14</sup> C]foramsulfuron sulfonamide: Aerobic soil metabolism in four US soils
<b>Report No:</b>	MEFS008
<b>Document No:</b>	M-425904-01-1
<b>Guidelines:</b>	<b>OECD: Guideline 307; Aerobic and Anaerobic Transformation in Soil, April 24, 2002</b> <b>OPPTS 835.4100, Aerobic Soil Metabolism, US EPA, October 2008; The sterilization of the soil conducted at FTSI was not conducted under GLP but GMP. The kinetics modeling was not conducted under GLP.</b>
<b>GLP/GEP:</b>	yes

**Executive Summary**

The degradation of [phenyl-UL-<sup>14</sup>C]foramsulfuron sulfonamide (AE F153745) was investigated in four US soils, under aerobic conditions by incubation in the dark at 20 °C and a soil moisture of 55% of MWHC for 26 days in maximum.

The test was performed at a test concentration of 0.21 mg [<sup>14</sup>C]foramsulfuron sulfonamide/kg soil. The test concentration reflected a ten-fold exaggerated rate when being based on a field rate of 90 g a.s./ha and a maximum occurrence of 7% AR in route studies with the active substance to ensure analytical sensitivity.

Recovery of radioactivity was 102.2% ± 2.0% of AR for soil Porterville, 101.7% ± 1.4% for soil Springfield, 99.0% ± 4.4% of AR for soil Pikeville and 102.0% ± 1.2% for soil Sanger. Total extractable radioactivity decreased from 98.9% by day zero to 18.0% by day 23 for soil Porterville, from 99.8% by day zero to 8.4% by day 26 for soil Springfield, from 102.1% by day zero to 12.5% by day 26 for soil Pikeville and from 101.5% by day zero to 8.8% by day 26 for soil Sanger. The decrease of extractable radioactivity was accompanied by the formation of non-extractable residues (NER) to account for 80.1% AR after 23 days in soil Porterville, 94.3% after 26 days in soil Springfield, 83.8% after 26 days in soil Pikeville and 93.2% after 26 days in soil Sanger.

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Mineralisation was moderate in all soils to account for 1.2 to 1.6% of AR determined as <sup>14</sup>C-carbon dioxide by days 23 to 26. Formation of other organic volatile components was insignificant (< 0.1% AR).

As a result of biotransformation in soil the formation of the single metabolite foramsulfuron aminosulfonamide (AE F148003) was observed at maximum values of 30.7% AR (day 1, soil Porterville), 66.2% (day 1, soil Springfield), 41.5% (day 2, soil Pikeville) and 67.2% (day 1, soil Sanger) in the course of the study. Considering a maximum occurrence of 8.7% for precursor metabolite AE F153745 in studies performed with the parent substance (see KCA 7, P.I. 1/02) the maximum occurrence of 67.2% for AE F148003 would translate to maximum value of 5.9% AR for the parent study in theory. However AE F148003 occurred at trace level in studies performed with the active substance foramsulfuron thus underlining its transient character. Considering its transient nature and overall low occurrence in the total metabolic pathway, the compound was not triggered for take up into the residue definition for environmental risk assessment.

Other unidentified components occurred at trace levels of 0.5% to 0.8% in all soils in the course of the study.

The biotic character of degradation of foramsulfuron-sulfonamide (AE F153745) in aerobic soil was indicated by the formation of metabolite foramsulfuron-aminosulfonamide (AE F148003) and non-extractable (bound) residues and the formation of <sup>14</sup>C-carbon dioxide to a moderate, but marked extent.

The degradation of foramsulfuron sulfonamide in four aerobic soils was fast to result in half-lives ranging from 0.1 to 3.3 days.

**K. Material and Methods****A. Materials**

- 1. Test Material:** [Phenyl-<sup>14</sup>C]foramsulfuron sulfonamide (AE F153745)  
Specific radioactivity: 4.32 MBq/mg (ca. 259232 dpm/μg, 31.68 μCi/mg)  
Radiochemical purity: 100% (HPLC)  
Chemical purity: 99% (HPLC-UV)  
Sample ID: KML 9049
- 2. Soil:** The soils were freshly collected from the field followed by sieving to 2 mm. The physico-chemical characteristics are summarised in Table 7.1.2.1.2-1.

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Table 7.1.2.1.2-1: Characteristics of test soils

Soil	Porterville	Springfield	Pikeville	Sanger
Geographic Location (City / State / Country)	██████ / CA / US	██████ / NE / US	██████ / NC / US	██████ / CA / US
GPS coordinates	██████	██████	██████	██████
Pesticide use history	No use for previous 3 years	No pesticide use for previous 6 years		
Collection procedures	Sample taken with shovel/soil auger and transport in bucket			
Sampling depth	0 – 6 inches (0 – 15 cm)	0 – 8 inches (0 – 20 cm)	0 – 6 inches (0 – 15 cm)	0 – 6 inches (0 – 15 cm)
Storage conditions	Refrigerator @ 3.9°C			
Storage length	14 to 20 days in maximum			
Soil preparation	Sieved (2 mm)			
Soil Series / Taxonomic name (USDA)	Fine-loamy, mixed, superactive, thermic Typic Durixeralfs	Marshall fine- silty mixed, superactive, mesic Typic Hapludolls	Norfolk fine- loamy, kaolinitic, thermic typic kandiudults	Hanford fine- sandy loam, gravelly substrate
Texture Class (USDA)	sandy loam	silt loam	loamy sand	loamy sand
Sand [50 µm - 2 mm] (%)	67.8	13.2	79.2	80.3
Silt [2 µm - 50 µm] (%)	27.7	62.4	17.5	14.6
Clay [< 2 µm] (%)	6.5	24.4	3.3	5.1
pH, saturated paste	7.1	6.7	6.4	7.2
pH in water	7.3	6.9	6.1	7.3
pH in CaCl <sub>2</sub> (0.01 M)	7.2	6.4	5.4	6.7
Organic Matter <sup>A</sup> (%)	0.53	0.2	1.6	0.77
Organic Carbon (%)	0.31	1.8	0.75	0.45
Microbial biomass (mg microbial C/kg dw soil)				
Day 0 (start)	88	506	99	165
Day 14 (middle)	4	433	81	140
Day 41 (final, duplicates)	63 / 66	437 / 433	63 / 63	140 / 147
CEC (meq/100 g)	9.1	5.2	4.2	5.7
55% of MWHC (g/100 g)	14.5	25.7	14.8	16.8
MWHC (g water/100 g soil)	27.1	46.9	26.9	30.5
Moisture at 0.1 bar = pF 2.0 (g water/100 g soil)	13.9	22.4	10.2	14.4
Moisture at 0.33 bar = pF 2.5 (g water/100 g soil)	8.3	24.3	7.7	8.7
Bulk density (sieved) (g/mL)	1.28	1.02	1.35	1.27

<sup>A</sup>) % organic matter = % organic carbon × 1.724;

CEC: Cation exchange capacity; MWHC: Maximum Water Holding Capacity; n.d.: not determined



## B. Study design

**1. Experimental conditions:** Samples of 50 g dry weight of soil each were filled into glass incubation flasks and pre-equilibrated prior to treatment at approximate study conditions (darkness, 20 °C, moisture content of 55% MWHC) for 13 days. At start, each sample received 0.21 mg test substance/kg soil, a dose representing a ten-fold exaggerated rate on the basis of a field rate of 90 g a.s./ha and a maximum occurrence of 8.7% AR in tests on route of degradation with the active substance. Following application the samples were attached to flow-through systems with traps to collect <sup>14</sup>C-carbon dioxide and other volatile components. Samples were incubated at 20 ± 1 °C and a moisture content of 55% MWHC in the dark for 26 days in maximum.

In addition, samples containing untreated soil were incubated under the same conditions for determination of soil microbial activity at selected time points. In order to characterize the biotic nature of non-extractable residue formation, additional samples of sterilized (gamma irradiated) soil were incubated.

**2. Sampling:** Duplicate samples were removed for work-up after 0, 1, 2, 5, 7, 9 and 26 days of incubation for soils Springfield, Pikeville and Sanger. Duplicate samples were removed for work-up after 0, 1, 2, 5, 7, 9, 14 and 23 days of incubation for soil Porterville. Samples for determination of soil microbial biomass were investigated after 0, 14 and 41 days of incubation. Samples of sterilized soil were taken for analysis after 0, 6 and 24 days of incubation. The complete samples were immediately processed by extraction and HPLC analysis was usually performed the same day. Therefore no additional investigations of storage stability were necessary.

**3. Analytical procedures:** The entire soil sample in each test vessel was processed by a stepwise extraction procedure. The initial step was performed with 60 mL aqueous acetonitrile solution containing 0.1 M ammonium acetate (70:30:0.01, v/v) three times successively by shaking the soil/solvent mixture for 30 min. After separation by centrifugation the soil was extracted with aqueous methanol containing 0.1 M ammonium bicarbonate (70:30:0.01, v/v) three times successively heating in a microwave extractor at 70 °C for 10 min followed by centrifugation. Aliquots of microwave and ambient extracts were proportionately combined together for a total volume of 20 mL with phosphate buffer (pH 6) added for stability. The combined extracts were concentrated to a small volume prior to analysis.

The <sup>14</sup>C-material balance was established for each sample by extraction, analysis of volatiles and combustion of non-extractable residues. Following quantification of radioactivity in extracts by LSC, analysis was performed by reversed phase HPLC and <sup>14</sup>C-flow-through detection techniques. The determination of non-extractable residues (NER) was performed by combustion/LSC of aliquots of the air-dried extracted soil.

The LOQ of the HPLC analytical method was estimated to be 0.5% AR on the basis of the LOD of the radio detector and based on the smallest peak observed in various chromatograms in the course of the study.

**C. Determination of degradation kinetics:** Degradation data were kinetically evaluated by use of the software KinGut version 1.1. Following calculations of fits with kinetic models SFO, FOMC and DFOP, the best fit was evaluated by visual assessment and the error of chi-square ( $\chi^2$ ) to be a minimum in the significance test.



II. Results and Discussion

A. Data: The results of aerobic biotransformation of [phenyl-UL-<sup>14</sup>C]foramsulfuron sulfonamide after incubation in four US soils are summarised in Tables 7.1.2.1.2-2 to Table 7.1.2.1.2-5.

Table 7.1.2.1.2-2: Degradation of [phenyl-UL-<sup>14</sup>C]foramsulfuron sulfonamide in sandy loam soil Porterville under aerobic conditions (mean ± SD)

Component		Sampling interval (days)								
		0	1	2	7	9	14	23		
Foramsulfuron sulfonamide (AE F153745)	Mean*	98.9	82.7	62.7	37.7	24.3	15.6	10.6	3.1	
	SD	±4.6	±4.7	±1.0	±4.0	±2.7	±0.4	±4.3	±1.1	
Foramsulfuron amino= sulfonamide (AE F148003)	Mean*	0.0	3.5	26.4	30.5	30.7	30.5	21.8	14.4	
	SD	±0.0	±2.9	±0.8	±5.2	±0.0	±0.5	±2.6	±1.5	
Total other unidentified	Mean*	0.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	
	SD	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	±0.6	±0.0	
Total extractable radioactivity	Mean*	98.9	96.2	89.1	68.2	54.9	46.9	22.9	18.0	
	SD	±4.6	±1.2	±0.9	±2.1	±0.9	±0.9	±6.3	±0.4	
Non-extractable radioactivity	Mean*	0.0	3.7	13.9	33.6	50.0	54.3	70.5	80.1	
	SD	±3.5	±0.0	±1.8	±2.1	±1.1	±1.0	±13.3	±0.3	
<sup>14</sup> CO <sub>2</sub>	Mean*	0.0	0.0	0.0	0.4	0.4	0.7	0.7	1.2	
	SD	±0.0	±0.0	±0.0	±0.0	±0.0	±0.1	±0.0	±0.2	
Other volatiles	Mean*	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
	SD	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	
Total radioactivity (%)	Mean*	101.6	100.3	103.3	102.7	105.4	101.2	104.1	99.3	
	SD	±1.1	±1.8	±1.6	±1.7	±1.9	±0.2	±7.0	±0.1	

Values given as percentages of initially applied radioactivity  
SD = standard deviation, \* Mean values of two replicates

Table 7.1.2.1.2-3: Degradation of [phenyl-UL-<sup>14</sup>C]foramsulfuron sulfonamide in silt loam soil Springfield

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under aerobic conditions (mean ± SD)

Component		Sampling interval (days)						
		0	1	2	5	7	9	26
Foramsulfuron sulfonamide (AE F153745)	Mean*	97.7	3.4	0.7	0.3	0.0	0.0	0.0
	SD	±2.3	±0.3	±1.0	±0.4	±0.0	±0.0	±0.0
Foramsulfuron amino= sulfonamide (AE F148003)	Mean*	2.0	66.2	52.9	28.6	21.7	19.7	14.1
	SD	±0.5	±1.0	±1.7	±2.2	±3.1	±0.4	±0.2
Total other unidentified	Mean*	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	SD	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0
Total extractable radioactivity	Mean*	99.8	69.6	61.6	28.9	11.7	19.7	8.4
	SD	±1.9	±1.3	±0.7	±1.7	±3.1	±0.4	±0.2
Non-extractable radioactivity	Mean*	0.5	31.6	41.5	72.5	70.6	81.0	94.3
	SD	±0.0	±1.9	±0.2	±0.5	±3.5	±1.0	±0.2
<sup>14</sup> CO <sub>2</sub>	Mean*	0.0	0.1	0.4	0.9	1.0	1.2	1.6
	SD	±0.0	±0.2	±0.0	±0.0	±0.1	±0.0	±0.0
Other volatiles	Mean*	0.0	0.1	0.0	0.0	0.0	0.0	0.0
	SD	±0.0	±0.1	±0.0	±0.0	±0.0	±0.0	±0.0
Total radioactivity (%)	Mean*	100.3	101.4	101.5	102.3	100.3	101.9	104.3
	SD	±1.8	±0.5	±0.6	±1.2	±0.6	±0.6	±0.4

Values given as percentages of initially applied radioactivity  
SD = standard deviation; \* Mean values of two replicates

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Table 7.1.2.1.2-4: Degradation of [phenyl-UL-<sup>14</sup>C]foramsulfuron sulfonamide in loamy sand soil Pikeville under aerobic conditions (mean ± SD)

Component		Sampling interval (days)							
		0	1	2	5	7	9	26	
Foramsulfuron sulfonamide (AE F153745)	Mean*	102.1	45.1	28.7	11.2	9.1	8.0	2.7	
	SD	±0.6	±1.4	±0.4	±0.6	±0.6	±0.6	±0.1	
Foramsulfuron amino=Sulfonamide (AE F148003)	Mean*	0.0	41.3	41.5	32.0	24.7	11.2	9.1	
	SD	±0.0	±0.3	±2.0	±2.3	±0.5	±0.5	±1.1	
Total other unidentified	Mean*	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
	SD	±0.0	±0.0	±0.0	±1.2	±0.0	±0.0	±1.0	
Total extractable radioactivity	Mean*	102.1	86.4	70.2	43.9	33.8	29.2	12.5	
	SD	±0.6	±1.6	±1.6	±0.7	±0.7	±0.4	±0.0	
Non-extractable radioactivity	Mean*	0.0	0.0	19.9	56.6	62.0	60.9	83.8	
	SD	±0.0	±0.2	±0.0	±5.0	±3.0	±1.4	±7.2	
<sup>14</sup> CO <sub>2</sub>	Mean*	0.0	0.5	0.6	0.6	0.9	0.9	1.5	
	SD	±0.0	±0.0	±0.0	±0.0	±0.0	±0.1	±0.0	
Other volatiles	Mean*	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
	SD	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	
Total radioactivity (%)	Mean*	102.2	103.9	100.7	101.1	96.6	91.0	97.6	
	SD	±0.6	±1.4	±1.6	±0.5	±0.5	±1.7	±7.2	

Values given as percentages of initially applied radioactivity  
SD = standard deviation; \* Mean values of two replicates

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Table 7.1.2.1.2-5: Degradation of [phenyl-UL-<sup>14</sup>C]foramsulfuron sulfonamide in loamy sand soil Sanger under aerobic conditions (mean ± SD)

Component		Sampling interval (days)							
		0	1	2	5	7	9	26	
Foramsulfuron sulfonamide (AE F153745)	Mean*	100.2	8.1	2.3	0.0	0.8	0.0	0.0	
	SD	±1.8	±0.4	±0.0	±0.0	±1.1	±0.0	±0.0	
Foramsulfuron amino= sulfonamide (AE F148003)	Mean*	1.2	67.2	51.4	20.6	17.0	17.7	8.8	
	SD	±0.3	±1.1	±0.2	±0.7	±2.8	±0.0	±0.1	
Total other unidentified	Mean*	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
	SD	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	
Total extractable radioactivity	Mean*	101.3	75.3	53.7	24.6	17.8	17.7	8.8	
	SD	±1.4	±1.5	±0.1	±0.7	±1.0	±0.0	±0.1	
Non-extractable radioactivity	Mean*	0.1	26.1	48.1	77.2	84.2	81.3	93.2	
	SD	±0.0	±1.1	±2.0	±0.9	±10.9	±4.0	±1.6	
<sup>14</sup> CO <sub>2</sub>	Mean*	0.0	0.3	0.6	0.0	0.0	0.0	4.6	
	SD	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	±0.2	
Other volatiles	Mean*	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
	SD	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	
Total radioactivity (%)	Mean*	101.4	101.7	102.4	102.4	102.8	100.0	103.6	
	SD	±1.4	±0.4	±1.8	±1.0	±9.2	±4.7	±1.4	

Values given as percentages of initially applied radioactivity. SD = standard deviation. \*Mean values of two replicates.

**B. Mass balance:** The total material balances of radioactivity showed a complete recovery to range from 100.0 – 102.8% AR for the four soils investigated. The results are summarised in more detail in Table 7.1.2.1.2-6. Conclusively there were no signs for losses of radioactivity from sample work-up and processing.

Table 7.1.2.1.2-6: Total material balances of radioactivity of <sup>14</sup>C-AE F153745 in four US soils

Soil	Porterville	Springfield	Pikeville	Sanger
Total Recovery (% AR)	99.3 – 105.4	100.3 – 104.3	91.0 – 103.9	100.0 – 103.6
Mean (% AR)	102.2	101.7	99.0	102.0
Ref. standard deviation	2.0	1.4	4.4	1.2

Values given as percentages of initially applied radioactivity

**C. Bound and extractable residues:** Values of extractable radioactivity decreased rapidly with time accompanied by significant formation of non-extractable residues as summarised in Table 7.1.2.1.2-7. Starting from a complete extractability given by day zero (98.9% for soil Porterville, 99.8% for Springfield, 102.1% for Pikeville and 101.3% for Sanger soil) values decreased to 18.0% (Porterville), 8.4% (Springfield), 12.5% (Pikeville) and 8.8% (Sanger) after a maximum incubation period of 23 days (soil Porterville) or 26 days (soils Springfield, Pikeville and Sanger).



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In turn, values for non-extractable radioactivity (NER) were low by day zero (2.7% for soil Porterville, 0.5% for Springfield, 0.1% for Pikeville and 0.1% for Sanger soil) to show a significant increase to 80.1% (Porterville), 94.3% (Springfield), 83.8% (Pikeville) and 93.2% (Sanger) at the last sampling intervals of 23 days (soil Porterville) or 26 days (soils Springfield, Pikeville and Sanger).

In comparison, results from work-up of samples with sterilized soil indicated significantly lower levels of NER formed when the potential for biotic conversion of the test substance is inhibited or, at least delayed, i.e. 21.5% (Porterville), 75.9% (Springfield), 35.9% (Pikeville) and 73.9% (Sanger) after a maximum of 24 days of incubation.

Table 7.1.2.1.2-7: Extractable and non-extractable residues of <sup>14</sup>C-AE F153745 in four US soils (mean ± SD)

Soil	Extractable residues (%)		Non-extractable residues (%)	
	Day 0	Day 23/26	Day 0	Day 23/26
Porterville	98.9 ±4.6	18.0 ±0.4	2.7 ±3.5	80.1 ±0.3
Springfield	99.8 ±0.4	0.4 ±0.2	0.5 ±0.0	94.3 ±0.2
Pikeville	102.1 ±0.6	12.5 ±0.0	0.1 ±0.0	83.8 ±7.2
Sanger	101.3 ±1.4	0.8 ±0.1	0.1 ±0.0	93.2 ±1.6

Values given as percentages of initially applied radioactivity.

**D. Volatile radioactivity:** The extent of mineralization to <sup>14</sup>C-carbon dioxide was moderate to account for 1.2% AR (soil Porterville), 1.6% (Springfield), 1.3% (Pikeville) and 1.6% (Sanger) at study end (days 23 or 26, respectively). Formation of other volatile radioactivity was insignificant for all soils at any sampling interval (0.1% AR).

**E. Transformation of test substance:** The formation of a single compound, foramsulfuron aminosulfonamide (AE F148003) was observed at maximum values of 30.7% AR (day 7, Porterville), 66.2% AR (day 1, Springfield), 41.5% AR (day 2, Pikeville) and 67.2% AR (day 1, Sanger) in the course of the study.

Metabolite AE F148003 was also observed at trace level in the studies on aerobic route performed with the parent substance (see K/A 7.1.1.1/02). Considering its overall low occurrence in the total metabolic pathway, the compound was not triggered for take up into the residue definition for environmental risk assessment.

Other unidentified components occurred only at trace level below 1.0% in all soils in the course of the study.

The biotic character of degradation of foramsulfuron sulfonamide in aerobic soil is underlined by the formation of non-extractable (bound) residues *via* minor metabolites and the formation of <sup>14</sup>C-carbon dioxide to a moderate, but marked extent. The biotic character of bound residue formation is supported by the results of separate samples indicating a lower level of formation for sterilized soils.

**F. Degradation kinetics:** The evaluation of degradation kinetics was performed by fitting of data to the three kinetic models SFO, FOMC (Gustafson-Holden) and DFOP<sup>1</sup> for the test substance only with the quality of fits assessed according to FOCUS kinetic guidance. The initial concentration at time zero was

<sup>1</sup> SFO = Single first order; FOMC = First order multi compartment; DFOP = Double first order in parallel

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included in the parameter optimisation. All data points were weighted equally. For optimal goodness of fit, the initial value was also allowed to be estimated by the model. The best-fit kinetic model was selected by applying the criteria for chi-square ( $\chi^2$ ) scaled-error to be a minimum and on the basis of visual assessment. The results of the kinetic evaluation are provided in Table 7.1.2.1.2-8.

The fits describing degradation of foramsulfuron sulfonamide in the four soils resulted in low chi-square ( $\chi^2$ ) errors for all models applied with overall ranges of  $\chi^2$ -errors being marginal for all but one soil (exception for SFO in soil Pikeville). When including results of visual assessment best fits were found to follow the FOMC (DFOP for soil Porterville) and thus bi-phasic kinetic model for all soils. For soil Porterville FOMC was also chosen due to the identical fit obtained compared to the FOMC approach. The degradation half-lives of foramsulfuron sulfonamide were estimated to 3.3 days (DFOP soil Porterville), 0.1 days (FOMC, Springfield), 0.8 days (FOMC, Pikeville) and 0.2 days (FOMC, Sanger). The associated DT<sub>90</sub>-values were 13.0 days (soil Porterville), 0.5 days (Springfield), 6.2 days (Pikeville) and 0.9 days (Sanger).

**Table 7.1.2.1.2-8: Kinetics of aerobic degradation of foramsulfuron sulfonamide in four soils at 20°C**

Soil	Kinetic model	DT <sub>50</sub> (days)	DT <sub>90</sub> (days)	Chi <sup>2</sup> Err (%)	Visual assessment
Porterville	SFO	3.5	11.7	4.5	+
	FOMC	3.3	12.0	3.7	+
	<b>DFOP</b>	<b>3.3</b>	<b>13.0</b>	<b>3.7</b>	+
Springfield	SFO	0.2	0.7	1.0	+
	<b>FOMC</b>	<b>0.1</b>	<b>0.5</b>	<b>0.5</b>	+
	DFOP	0.2	0.4	0.7	+
Pikeville	SFO	1.0	3.5	15.8	o
	<b>FOMC</b>	<b>0.8</b>	<b>6.2</b>	<b>2.0</b>	+
	DFOP	0.9	6.6	4.2	+
Sanger	SFO	0.3	0.9	3.4	+
	<b>FOMC</b>	<b>0.2</b>	<b>0.9</b>	<b>1.4</b>	+
	DFOP	0.2	0.9	1.7	+

Best fits according to the criteria set are marked bold.

Visual assessment: + good; o medium; - bad

**III. Conclusion**

The degradation of foramsulfuron sulfonamide in four aerobic soils was fast to result in half-lives ranging from 0.1 to 3.3 days.

The degradation kinetics was also revisited in a supplemental evaluation report (see KCA 7.1.2.1.2/08) to derive input parameters for modeling purposes in environmental exposure assessments.

In the following additional degradation data in aerobic soil are presented for metabolite AE F092944. AE F092944 is a common metabolite of the active substances foramsulfuron and nicosulfuron. The study had been subject to evaluation within the Annex I inclusion process of the active substance nicosulfuron and it was therefore included into the publicly available version of the Draft Assessment Report of this existing active substance prepared by RMS UK dated June 2006.

This separate study performed with <sup>14</sup>C-labelled AE F092944 thus generated information on the degradation in aerobic soil independent from their parent molecules.

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<b>Report:</b>	[REDACTED];2006;M-469999-01
<b>Title:</b>	Study summary - 14C-ADMP: Degradation in three soils incubated under aerobic conditions - Extract of draft assessment report (DAR) - Public version - Initial risk assessment provided by the rapporteur member state United Kingdom for the existing active substance nicosulfuron of the third stage (part A) of the review programme referred to in article 8(2) of council directive 91/414/EEC - Volume 3, Annex 2.8
<b>Report No:</b>	384480
<b>Document No:</b>	M-469999-01-1
<b>Guidelines:</b>	<b>Deviation not specified</b>
<b>GLP/GEP:</b>	n.a.

**Executive Summary**

The degradation of pyrimidine-<sup>14</sup>C-2-amino-4,6-dimethoxy pyrimidine (ADMP, AE F092944) was investigated in the three EU soils Collombey (loamy sand, Switzerland), Speyer 2.2 (loamy sand, Germany) and Les Evouettes (loam, Switzerland) for a maximum period of 104 days. The soil samples were treated at 0.08 mg/kg dry weight equivalent to a field rate of 60 g/ha. Following incubation at 20±1°C and 40 % maximum water capacity (MWC) in the dark, samples were worked up to establish a full material balance by determination of radioactivity in extracts, extracted soil and traps for volatile components.

The amount of AE F092944 extractable from soil declined from 90.8% of AR (soil Collombey), 93.7% (soil Speyer 2.2) and 91.4% (soil Les Evouettes) by day zero to 0.8, 4.7 and 8.3% by day 104, respectively. Following 104 days of incubation the degradation of AE F092944 was accompanied by the formation of non-extractable residues (NER, range 29.6 to 39.4%) and significant mineralisation to <sup>14</sup>CO<sub>2</sub> (48.5 to 56.9%).

Application of non-linear regression using the SFO kinetic model resulted in values for the DT<sub>50</sub> of 2.9 days (soil Collombey), 6.1 days (soil Speyer 2.2) and 11.1 days (soil Les Evouettes). The corresponding values for the DT<sub>90</sub> were 9.5 days, 20.4 days and 37.7 days, respectively.

**I. Material and Methods****A. Materials****1. Test Material**

pyrimidine-<sup>14</sup>C-ADMP (AE F092944)

Specific radioactivity: not reported

Radiochemical purity: 95.0%

**2. Soil:**

The degradation of AE F092944 was studied in two Swiss soils and a German soil. All soils were sieved to 2 mm prior to use with physico-chemical characteristics summarised in Table 7.2.1.2.9.

Table 7.1.2.1.2-9: Characteristics of test soils

Soil	Collombey Switzerland	Speyer 2.2 Germany	Les Evouettes Switzerland
Texture class	loamy sand	loamy sand	loam
Sand [50µm – 2 mm] (%)	83.1	89.3*	47.3
Silt [2-50 µm] (%)	15.8	5.6*	43.4
Clay [<2 µm] (%)	1.1	5.1*	9.3
pH (KCl)	7.6	6.0	6.3
Organic carbon (%)	0.58	2.294	1.96
CEC (meq/100g)	9.7	9.1	10.4
Max. water holding capacity (%)	44.2	44.3	33.4
Biomass (mg C/100g soil)			
Start	48.3	50.3	80.3
Completion of incubation	34.4	44.8	57.4

\* International classification following slightly different distribution of soil particles into sand [50µm – 2 mm], silt [2-20 µm] while being the same for clay [<2µm].

**B. Study design**

Samples of 100 g dry weight of soil each were treated at 0.08 mg test substance/kg soil, a dose equivalent to a field rate of 60 g/ha. Following application the samples were incubated under flow-through conditions including traps for volatile radioactivity at 20 ± 1 °C and a moisture content of 40% MWHC in the dark for 104 days in maximum. Samples were removed for work-up after 0, 1, 3, 7, 14, 28, 56 and 104 days of incubation. Samples containing untreated soil were incubated under the same conditions for determination of soil microbial biomass and investigated at day zero and after completion of incubation. The soil samples were processed by stepwise extraction. The initial step was performed with aqueous acetonitrile mixture as solvent three to four times successively at ambient temperature. This was followed by a Soxhlet extraction step using aqueous acetone (1:9, v/v). The <sup>14</sup>C material balance was established for each sample by extraction, analysis of volatiles and combustion of non-extractable residues. Following quantitation of radioactivity in extracts, analysis was performed by TL using at least two solvent systems. The determination of non-extractable residues (NER) was performed by combustion/LSC of aliquots of the air-dried extracted soil. Volatile radioactivity was determined by measuring aliquots of the solvents used for adsorption in traps.

The degradation data were kinetically evaluated by use of SFO as kinetic model.

**II. Results and Discussion**

The total recoveries of radioactivity in samples ranged from 91.0-98.1% of AR for soil Collombey, 94.2-99.7% for soil Speyer 2.2 and from 97.0-100.5% for soil Les Evouettes.

Following 104 days of incubation, values of non-extractable radioactivity ranged from 29.6 to 39.4% AR accompanied by the formation of <sup>14</sup>CO<sub>2</sub> amounting to 48.6 to 56.9%.

While no values were reported for total extractable residues, the amount of AE F092944 extracted from soil declined from 90.8% of AR (soil Collombey), 93.7% (soil Speyer 2.2) and 91.4% (soil Les Evouettes) by day zero to 0.8%, 4.7% and 8.3% after 104 days of incubation. The results in terms of AE F092944 determined at the various time points are summarised in Table 7.1.2.12- 10.



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Small amounts of at least 7 other unidentified components were observed in soil extracts. The largest fraction was represented by two polar components being below 4.2% of AR in all soils. None of the other components exceeded 2.6% of AR in the course of the study.

Table 7.1.2.1.2-10: Degradation of [pyrimidine-<sup>14</sup>C]AE F092944 in three aerobic soils

Sampling interval (days)	Collombey	Speyer 2.2	Les Evouettes
0	90.8	93.7	91.4
1	69.9	70.0	85.2
3	45.1	58.5	69.9
7	14.7	39.1	51.8
14	6.1	20.7	32.8
28	3.7	11.5	19.0
56	3.6	5.0	12.5
104	0.8	1.7	3.0

The resulting DT<sub>50</sub> and DT<sub>90</sub> values of AE F092944 following SFO kinetic evaluation are summarised in Table 7.1.2.12- 11.

Table 7.1.2.1.2-11: DT<sub>50</sub> and DT<sub>90</sub> values of AE F092944 in three aerobic soils

	DT <sub>50</sub> (days)	DT <sub>90</sub> (days)	r <sup>2</sup>
Collombey	2.9	9.3	0.995
Speyer 2.2	6.1	20.4	0.980
Les Evouettes	11.3	37.7	0.970

III. Conclusion

The degradation of AE F092944 was shown to proceed rapidly to result in half-lives ranging from 2.9 to 11.3 days.

Results of kinetic evaluation of this study were considered in report KCA 7.1.2.1.2 /08 in order to derive input parameters for modeling use in environmental exposure assessments and for comparison with EU trigger endpoints.

Report:	[redacted]; 2013;M-453563-02;
Title:	Kinetic evaluation of laboratory aerobic soil degradation of foramsulfuron and its metabolites according to Focus
Report No:	Ensi-12-0246
Document No:	M453563-02-1
Guidelines:	not applicable; not applicable
GLP/GEP:	no



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Foramsulfuron****Executive Summary**

For the active substance foramsulfuron the kinetic re-evaluation was summarised under Point CA 7.1.2.1.1.

For metabolites AE F092944, AE F130619 and AE F153745 the kinetic re-evaluation was performed with data from tests with the active substance (KCA 7.1.2.1.1 /01 to KCA 7.1.2.1.1 /03), amended by soil degradation data from separate tests with AE F130619 (KCA 7.1.2.1.2 /04) and AE F153745 (KCA 7.1.2.1.2 /06). Finally, the kinetic evaluation included data publicly available for metabolite AE F092944 (KCA 7.1.2.1.2 /07).

The kinetic re-evaluation according to FOCUS Guidance resulted in normalised values (20°C, pF2 moisture) for use as modeling inputs in environmental exposure assessments and in non-normalised half-lives for comparison against trigger endpoints.

The degradation of the active substance foramsulfuron and its metabolites AE F092944, AE F130619 and AE F153745 in aerobic soil under laboratory conditions was investigated in a total of six studies including two positions of radiolabel following application of the active substance or its metabolite AE F130619. For metabolite AE F130619 this resulted in twelve reliably evaluable data sets (n=12) from four soils. For metabolite AE F153745, it was four data sets evaluable (n=4) derived from four different soils. For metabolite AE F092944, it was finally five data sets (n=5) to result in a reliable half-life.

For the calculation of normalised half-lives in soil for use in modeling, a stepwise approach was made. The initial step consisted of fitting the SFO kinetic model to the measured data. In case of unacceptable fits according to the criteria set bi-phasic models (i.e. FOMC or DFOP) were applied.

The procedure resulted in SFO fits for metabolite AE F130619 for all (i.e. twelve) data sets that could be evaluated. For metabolite AE F153745, use of the SFO model was acceptable for three data sets (soils) while a bi-phasic fit (FOMC) was taken for one soil. The value for the DT<sub>50</sub> from this soil was back-calculated from the DT<sub>90</sub>. Finally, the evaluation resulted in SFO best fits for AE F092944 from three data sets while FOMC was more appropriate for the additional two sets evaluable. Again, the DT<sub>50</sub>'s for these two sets were back-calculated from the corresponding DT<sub>90</sub>-values or, from the smaller degradation rate in case of DFOP respectively.

In a next step, non-normalised half-lives were normalised to reference conditions (20°C, pF2 moisture) with results summarised in Table 7.1.2.1.2-12 for the three compounds under assessment.

For use as modeling endpoint, an overall geometric mean of normalised half-lives of 25.9 days was calculated for AE F092944, 2.5 days for AE F130619 and 0.85 days for AE F153745.

For comparison with trigger values, non-normalised values of the DT<sub>50</sub> and the DT<sub>90</sub> were derived as described during the process for modeling purposes. The results are summarised for the three compounds under assessment in Table 7.1.2.1.2-12.

For metabolite AE F092944, a non-normalised worst case half-life of 254 days was derived from data of soil Chantepie while the worst case DT<sub>90</sub> was 845 days from the same soil.

For metabolite AE F130619 a non-normalised worst case half-life of 14.7 days was calculated for soil Illinois associated with a DT<sub>90</sub> of 48.7 days from the same soil.

For metabolite AE F153745, a non-normalised worst case half-life of 3.5 days was derived for soil Porterville associated with a DT<sub>90</sub> of 11.6 days from the same soil.

Table 7.1.2.1.2-12: Summary of results of kinetic evaluation of degradation of metabolites AE F092944, AE F130619 and AE F153745 in aerobic soil in the laboratory for use as modelling input parameters in environmental exposure assessments and for comparison against EU triggers

Compound	AE F092944	AE F130619	AE F153745
Modelling input parameters			
Normalised DT <sub>50</sub> , range (days)	3.4 – 147.6	0.1 – 15.2	0.2 – 3.7
<b>Geometric mean DT<sub>50</sub></b> (days)	25.9	2.3	1.85
Trigger evaluation			
Non-normalised DT <sub>50</sub> , range (days)	2.9 – 254.4	0.1 – 14.7	0.2 – 3.5
<b>Worst case DT<sub>50</sub></b> (days)	254	14.7	3.5
Non-normalised DT <sub>90</sub> , range (days)	9.6 – 844.6	0.7 – 48.7	0.7 – 11.6
<b>Worst case DT<sub>90</sub></b> (days)	845	48.7	11.6

### I. Material and Methods

The degradation data resulting from tests with the active substance and from separate tests with metabolites AE F130619, AE F153745 and AE F092944 were kinetically evaluated following FOCUS guidance with the software KinGUI, version 2.

The measured values were taken into account as reported and thus treated as individual replicates. All sets with their data points were weighted equally. The concentration at time zero was included in the parameter optimisation with the initial value being allowed to be estimated by the model.

In cases where the radioactive residues in soil were below the limit of detection (LOD) the respective values were set to 0.5 LOD for the evaluation for time points before or after which a value above LOD was determined. For some studies no LOD was given in the original report. In these cases no values were added.

In some cases degradation products of the applied substance were already detected at time zero. In such cases the respective percentages were added to the parent values and the values for the metabolite were set to zero.

All radioactive residues in soil were used for the kinetic evaluation. For some of the studies performed for very long periods of up to one year the evaluations for deriving modelling endpoints used only data measured up to day 120 days which is the maximum recommended duration for laboratory studies according to OECD Guideline 307 (2002).

For fits of compounds under evaluation, SFO kinetics was tested first due to its simplicity and its nearly exclusive use in environmental exposure models.

In general, also the use of other kinetic model approaches is possible as proposed by FOCUS. The evaluation thus considered also the model approaches first order multiple-compartment (FOMC), dual first order in parallel (DFOP) and Hockey Stick (HS), in principle, following the scheme for identification of the appropriate kinetic model as proposed by FOCUS.

To check the parameters for their significance a single-sided t-test was used. The probability of t should be low or equal to zero as this probability can be assumed to be higher the more uncertain a parameter is. In general, a value of 0.05 for the probability of t is considered as appropriate with degradation parameters being regarded as significant at this level.

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The  $DT_{50}$ -values derived were normalised to standard reference temperature 20 °C and soil moisture 100 % field capacity in order to obtain standardised input parameters for predictions of environmental concentrations. This normalisation was conducted according to the standard approach by FOCUS.

The application of foramsulfuron to aerobic soil results in the predominant formation (> 80%) of non-extractable residues as degradation products. Similar results were obtained for tests with metabolites AE F130619 and AE F153745 following their separate application to soil.

The results suggest that the amino group at the phenyl ring of AE F130619 is responsible for such irreversible binding to the soil matrix. The lower portion of bound residues found after application of pyrimidyl labelled AE F130619 can be explained by cleavage of the sulfonylurea bridge as structural element thus losing the respective amino-phenyl containing residues.

As a result of formation of AE F153745 metabolite AE F148003 can be formed as a transient compound since this molecule also contains the amino-phenyl structural element that is subject to irreversible binding to soil in the following. Since AE F148003 was observed at trace level only it had not been included in the kinetic evaluations.

The overall importance of the bound residues was considered by introduction as a separate compartment into the kinetic evaluations for those studies following application of the parent compound foramsulfuron. This resulted in compartmental models as shown in Figure 7.1.2.1.1-4 (phenyl-label) and Figure 7.1.2.1.1-2 (pyrimidyl-label). The inclusion of bound residues into the model optimisation resulted in an improvement of certainty for the parameter determination since more experimental information had been considered.

Studies with metabolites directly applied to soil were considered as pure degradation studies with degradation of the applied substance evaluated by using a simple model (i.e. SFO) from which the transformation to a 'sink' is considered. Rate studies like those performed with AE F130619 may be also interpreted as route study serving as information for further metabolites. However, metabolite formation was very low in all but one case. This result again suggests that binding of AE F130619 to organic matter of soil was quantitative.

## IV Results and Discussion

Following application of the parent substance foramsulfuron an 'unusual' metabolic pattern with time was observed for a number of soils. A first rapid increase was followed by a decline to low residues. This was followed by another increase to result in a second peak. The test of various hypotheses did not result in a mechanistic explanation for this observation. Consequently evaluations were based of the compartment model as shown in Figure 7.1.2.1.1-1 and Figure 7.1.2.1.1-2 with the consequence that fits could not be optimised to the observed metabolite data.

### Calculation of non-normalised $DT_{50}$ -values:

For metabolites AE F130619 and AE F092944 the kinetic evaluation of soil degradation tests using the SFO approach did not result in acceptable fits to the experimental data. For all but two data sets the evaluation resulted in FOMC to be the optimal fit to describe the degradation data. Instead, the two tests failing the FOMC fit could be described best by the DFOP model. For use as non-normalised data prior to normalisation to reference conditions, the  $DT_{50}$ -values were back-calculated from the corresponding



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value of the DT<sub>90</sub> derived either by the FOMC or the DFOP fit. The results are summarised for AE F130619, AE F153745 and AE F092944 in Table 7.1.2.1.2-13 to Table 7.1.2.1.2-18, respectively.

Normalisation of best-fit DT<sub>50</sub>-values:

For the use in environmental modeling the degradation half-lives were normalised to reference conditions of 100% field capacity regarding soil moisture and 20°C for the temperature. The parameters used in the laboratory tests and the respective correction factors calculated are summarised in Table 7.1.2.1.1-6 (see Section CA 7.1.2.1.1).

The values of half-lives resulting from normalisation are summarised for AE F130619, AE F153745 and AE F092944 in Table 7.1.2.1.2-19 to Table 7.1.2.1.2-21, respectively.

**Table 7.1.2.1.2-13: Non-normalised DT<sub>50</sub>-values for metabolic AE F092944 in aerobic soil under laboratory conditions for modelling evaluation**

Soil	Label position	DT <sub>50</sub> (Days)	Model
Shuttleworth (Study 1)	phenyl	-	-
Shuttleworth (Study 1)	pyrimidyl	141	SFO
Orainville (Study 1)	phenyl	-	-
Orainville (Study 1)	pyrimidyl	-	-
Chantepie (Study 1)	phenyl	-	-
Chantepie (Study 1)	pyrimidyl	254.4	SFO
Illinois (Study 2)	phenyl	-	-
Illinois (Study 2)	pyrimidyl	-	-
Shuttleworth (Study 2)	phenyl	-	-
Shuttleworth (Study 2)	pyrimidyl	-	-
Orainville (Study 2)	phenyl	-	-
Orainville (Study 2)	pyrimidyl	-	-
Chantepie (Study 2)	phenyl	-	-
Chantepie (Study 2)	pyrimidyl	-	-
Collombey (Study 3)	pyrimidyl	2.9	SFO
Speyer 2.2 (Study 3)	pyrimidyl	10.5	FOMC
Les Evouettes (Study 3)	pyrimidyl	21.8	FOMC

Study 1: KCA 7.1.2.1.1 /04; Study 2: KCA 7.1.2.1.2 /01; Study 3: KCA 7.1.2.1.2 /03

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Table 7.1.2.1.2-14: Non-normalised DT<sub>50</sub>-values for metabolite AE F092944 in aerobic soil under laboratory conditions for trigger evaluation

Soil	Label position	DT <sub>50</sub> (days)	DT <sub>90</sub> (days)	Model
Shuttleworth (Study 1)	phenyl	-	-	-
Shuttleworth (Study 1)	pyrimidyl	141.7	470.4	SFO
Orainville (Study 1)	phenyl	-	-	-
Orainville (Study 1)	pyrimidyl	-	-	-
Chantepie (Study 1)	phenyl	-	-	-
Chantepie (Study 1)	pyrimidyl	254.4	844.6	SFO
Illinois (Study 2)	phenyl	-	-	-
Illinois (Study 2)	pyrimidyl	-	-	-
Shuttleworth (Study 2)	phenyl	-	-	-
Shuttleworth (Study 2)	pyrimidyl	-	-	-
Orainville (Study 2)	phenyl	-	-	-
Orainville (Study 2)	pyrimidyl	-	-	-
Chantepie (Study 2)	phenyl	-	-	-
Chantepie (Study 2)	pyrimidyl	-	-	-
Collombey (Study 3)	pyrimidyl	2.9	9.6	SFO
Speyer 2.2 (Study 3)	pyrimidyl	4.9	34.8	FOMC
Les Evouettes (Study 3)	pyrimidyl	9.0	72.4	FOMC
Overall worst case		54	845	

Study 1: KCA 7.1.2.1.1 /01; Study 2: KCA 7.1.2.1.2 /01; Study 3: KCA 7.1.2.1.2 /03

Table 7.1.2.1.2-15: Non-normalised DT<sub>50</sub> values for metabolite AE F130619 in aerobic soil under laboratory conditions for modelling evaluation

Soil	Label position	DT <sub>50</sub> (days)	Model
Shuttleworth (Study 1)	phenyl	6.5	SFO
Shuttleworth (Study 1)	pyrimidyl	-	-
Orainville (Study 1)	phenyl	-	SFO
Orainville (Study 1)	pyrimidyl	0.9	SFO
Chantepie (Study 1)	phenyl	0.2	SFO
Chantepie (Study 2)	pyrimidyl	-	-
Illinois (Study 2)	phenyl	8.7	SFO
Illinois (Study 2)	pyrimidyl	24.7	SFO
Shuttleworth (Study 2)	phenyl	2.0	SFO
Shuttleworth (Study 2)	pyrimidyl	1.8	SFO
Orainville (Study 2)	phenyl	1.4	SFO
Orainville (Study 2)	pyrimidyl	1.7	SFO
Chantepie (Study 2)	phenyl	1.5	SFO
Chantepie (Study 2)	pyrimidyl	1.6	SFO

Study 1: KCA 7.1.2.1.1 /01; Study 2: KCA 7.1.2.1.2 /01



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Table 7.1.2.1.2-16: Non-normalised DT<sub>50</sub>-values for metabolite AE F130619 in aerobic soil under laboratory conditions for trigger evaluation

Soil	Label position	DT <sub>50</sub> (days)	DT <sub>90</sub> (days)	Model
Shuttleworth (Study 1)	phenyl	6.5	21.6	SFO
Shuttleworth (Study 1)	pyrimidyl	-	-	
Worst case		6.5	21.6	
Shuttleworth (Study 2)	phenyl	2.0	6.6	SFO
Shuttleworth (Study 2)	pyrimidyl	1.8	6.0	SFO
Mean (geometric)		1.9	6.3	
Orainville (Study 1)	phenyl	0.7	2.3	SFO
Orainville (Study 1)	pyrimidyl	0.9	3.0	SFO
Mean (geometric)		0.8	2.8	
Orainville (Study 2)	phenyl	1.4	4.6	SFO
Orainville (Study 2)	pyrimidyl	1.7	5.6	SFO
Mean (geometric)		1.5	5.1	
Chantepie (Study 1)	phenyl	0.2	0.7	SFO
Chantepie (Study 1)	pyrimidyl	-	-	
Worst case		0.2	0.7	
Chantepie (Study 2)	phenyl	1.5	5.3	SFO
Chantepie (Study 2)	pyrimidyl	1.3	4.3	SFO
Mean (geometric)		1.5	5.1	
Illinois (Study 2)	phenyl	8.7	28.9	SFO
Illinois (Study 2)	pyrimidyl	24.7	80.0	SFO
Mean (geometric)		17	48.7	
Overall worst case		4.7	48.7	

Study 1: KCA 7.1.2.1.2/01; Study 2: KCA 7.1.2.1.2/02

Table 7.1.2.1.2-10: Non-normalised DT<sub>50</sub>-values for metabolite AE F153745 in aerobic soil under laboratory conditions for modelling evaluation

Soil	Label position	DT <sub>50</sub> (days)	Model
Porterville (Study 1)	phenyl	3.5	SFO
Springfield (Study 1)	phenyl	0.2	SFO
Pikeville (Study 1)	phenyl	1.9	FOMC
Sanger (Study 1)	phenyl	0.3	SFO

Study 1: KCA 7.1.2.1.2/03

Table 7.1.2.1.2-18: Non-normalised DT<sub>50</sub>-values for metabolite AE F153745 in aerobic soil under laboratory conditions for trigger evaluation

Soil	Label position	DT <sub>50</sub> (days)	DT <sub>90</sub> (days)	Model
Porterville (Study 1)	phenyl	3.5	11.6	SFO
Springfield (Study 1)	phenyl	0.2	0.7	SFO
Pikeville (Study 1)	phenyl	1.9	6.2	FOMC
Sanger (Study 1)	phenyl	0.3	1.0	SFO
Overall worst case		3.5	11.6	

Study 1: KCA 7.1.2.1.2/03



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Table 7.1.2.1.2-19: Normalised DT<sub>50</sub>-values for metabolite AE F092944 in aerobic soil under laboratory conditions for use as modelling input parameters in environmental exposure assessments

Soil	Label position	DT <sub>50</sub> (days)	Model
Shuttleworth (Study 1)	phenyl	-	-
Shuttleworth (Study 1)	pyrimidyl	94.9	SFO
Shuttleworth (Study 2)	phenyl	-	-
Shuttleworth (Study 2)	pyrimidyl	-	-
Orainville (Study 1)	phenyl	-	-
Orainville (Study 1)	pyrimidyl	-	-
Orainville (Study 2)	phenyl	-	-
Orainville (Study 2)	pyrimidyl	-	-
Chantepie (Study 1)	phenyl	-	-
Chantepie (Study 1)	pyrimidyl	147.6	SFO
Chantepie (Study 2)	phenyl	-	-
Chantepie (Study 2)	pyrimidyl	-	-
Illinois (Study 2)	phenyl	-	-
Illinois (Study 2)	pyrimidyl	-	-
Collombey (Study 3)	pyrimidyl	3.4	SFO
Speyer 2.2 (Study 3)	pyrimidyl	12.4	FOMC
Les Evouettes (Study 3)	pyrimidyl	19.6	FOMC
<b>Mean</b> (geometric)		7.9	

Study 1: KCA 7.1.2.1.1 /01; Study 2: KCA 7.1.2.1.2 /01; Study 3: KCA 7.1.2.1.2 /04

Table 7.1.2.1.2-20: Normalised DT<sub>50</sub>-values for metabolite AE F130619 in aerobic soil under laboratory conditions for use as modelling input parameters in environmental exposure assessments

Soil	Label position	DT <sub>50</sub> (days)	Model
Shuttleworth (Study 2)	phenyl	4.4	SFO
Shuttleworth (Study 1)	pyrimidyl	-	-
Shuttleworth (Study 2)	phenyl	3.3	SFO
Shuttleworth (Study 2)	pyrimidyl	3.1	SFO
<b>Mean</b> (geometric)		3.6	
Orainville (Study 2)	phenyl	0.4	SFO
Orainville (Study 1)	pyrimidyl	0.5	SFO
Orainville (Study 2)	phenyl	1.3	SFO
Orainville (Study 2)	pyrimidyl	1.6	SFO
<b>Mean</b> (geometric)		0.8	
Chantepie (Study 1)	phenyl	0.1	SFO
Chantepie (Study 1)	pyrimidyl	-	-
Chantepie (Study 2)	phenyl	1.4	SFO
Chantepie (Study 2)	pyrimidyl	1.4	SFO
<b>Mean</b> (geometric)		0.6	
Illinois (Study 2)	phenyl	9.0	SFO
Illinois (Study 2)	pyrimidyl	25.7	SFO
<b>Mean</b> (geometric)		15.2	
<b>Mean</b> (geometric)		2.3	

Study 1: KCA 7.1.2.1.1 /01; Study 2: KCA 7.1.2.1.2 /01



Table 7.1.2.1.2-21: Normalised DT<sub>50</sub>-values for metabolite AE F153745 in aerobic soil under laboratory conditions for use as modelling input parameters in environmental exposure assessments

Soil	Label position	DT <sub>50</sub> (days)	Model
Porterville (Study 1)	phenyl	3.7	SFO
Springfield (Study 1)	phenyl	0.2	SFO
Pikeville (Study 1)	phenyl	2.5	FOMC
Sanger (Study 1)	phenyl	0.3	SFO
<b>Mean</b> (geometric)		0.85	

Study 1: KCA 7.1.2.1.2 /03

### III. Conclusion

Normalised (pF2 moisture, 20°C) half-lives were derived according to FOCUS kinetic guidance for foramsulfuron soil metabolites AE F130619, AE F092944 and AE F153745 for use as inputs in environmental risk assessments.

In addition, non-normalised half-lives and associated values of the DT<sub>90</sub> were derived for comparison against trigger endpoints for the same compounds.

The evaluations for metabolites AE F130619 and AE F153745 resulted in data sets from four different soils. For metabolite AE F092944 reliable half-lives could be derived for five data sets.

For the calculation of normalised half-lives in soil for use in modeling, the stepwise approach according to FOCUS resulted in SFO best fits for metabolite AE F130619 for all (i.e. twelve) data sets that could be evaluated. For metabolite AE F153745, use of the SFO model was acceptable for three data sets (soils) while a bi-phasic fit (FOMC) was taken for one soil. The value for the DT<sub>50</sub> for this soil was back-calculated from the DT<sub>90</sub>. Finally, the evaluation resulted in SFO best fits for AE F092944 for three data sets while FOMC was more appropriate for additional two sets evaluable. For the two sets a back-calculation of the corresponding DT<sub>90</sub> values was performed followed by normalization to reference conditions (20°C, pF2 moisture).

For use as modelling endpoint, an overall normalised mean half-life of 25.9 days was calculated for AE F092944, 2.3 days for AE F130619 and 0.85 days for AE F153745.

For comparison with trigger values, non-normalised half-lives of AE F092944 range from 2.9 days for soil Collombey to 254 days for soil Chantepie while values for the DT<sub>90</sub> range from 9.6 to 845 days for the same soils, respectively.

For metabolite AE F130619, non-normalised half-lives range from 0.8 days for soil Chantepie to 14.7 days for soil Illinois while values for the DT<sub>90</sub> range from 2.6 days to 48.7 days for the same soils.

For metabolite AE F153745, non-normalised half-lives range from 0.2 days for soil Springfield to 3.5 days for soil Porterville while values for the DT<sub>90</sub> range from 0.7 days to 11.6 days for the same soils.





**CA 7.1.2.1.3 Anaerobic degradation of the active substance**

Report:	[REDACTED]; [REDACTED]; [REDACTED]; 2000;M-238343-02; Amended: 2000-02-29
Title:	Degradation of [U-14C-phenyl] and [2-14C-pyrimidyl] AE F130360 in a European soil under laboratory anaerobic conditions at 20°C: AE F130360
Report No:	B002603
Document No(s):	Report includes Trial Nos.: CF97E524 CF97E524A M-238343-02-1
Guidelines:	EU (=EEC): Annex II Point 7.1.1.2; PMR T-1-255; US EPA (=EPA): 62-2; Deviation not specified
GLP/GEP:	yes

The rate of degradation was calculated within the respective study on route of degradation in anaerobic soil (KCA 7.1.2.1.3/ 01).

The data requirement had been addressed under Point 7.1.2.1.4 of the Dossier submitted and evaluated within the process of Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments. Consequently there is no detailed description of this existing data in this update.

The evaluation revealed that foramsulfuron degraded slowly under the conditions of anaerobic soil degradation testing in the laboratory to result in half-lives of 165 days (SFO model) or 230 days (bi-phasic, Hockey Stick model). Both kinetic models are able to describe the experimental data adequately in terms of the quality of fits. This half-life is also reported in the List of Endpoints (SANCO/10324/2002-Final of Nov 2002).

**CA 7.1.2.1.4 Anaerobic degradation of metabolites, breakdown and reaction products**

The data requirement had been addressed under Point 7.1.2.1.5 of the Dossier submitted and evaluated within the process of Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments.

The evaluation revealed that the pathway for degradation of foramsulfuron under aerobic and anaerobic conditions is the same. However, the low level of metabolites formed resulting in scattering data did not allow for kinetic evaluation to determine degradation rates under anaerobic conditions. However, the transient character of metabolites could be demonstrated under the conditions of aerobic testing. Foramsulfuron is intended for use in corn where anaerobic conditions in soil do not prevail for extended time periods and usually not on a full field plot scale. Metabolites formed under anaerobic conditions will be degraded when the soil turns back to aerobic conditions after a period of low oxygen content. This will prevent accumulation of metabolites in the soil. For these reasons specific studies on anaerobic degradation of relevant metabolites, degradation and reaction products in soil are not required.



**CA 7.1.2.2 Field studies**

**CA 7.1.2.2.1 Soil dissipation studies**

<b>Report:</b>	[REDACTED];2000;M-238506-02
<b>Title:</b>	Dissipation of AE F130360 and AE F122006 in soil following application of AE F130360 WDG and AE F122006 WDG to a bare plot at the maximum proposed rates, USA and Canada, 1997 (report on the decline of AE F130360): AE F130360 WDG WG50 A107;
<b>Report No:</b>	B004767
<b>Document No(s):</b>	Report includes Trial Nos.: CF97R003 M-238506-02-1
<b>Guidelines:</b>	USEPA (=EPA): 164-1; Data not specified
<b>GLP/GEP:</b>	yes

The data requirement was addressed under Point 7.1.2.2 of the Dossier submitted and evaluated within the process of Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments. Consequently there is no detailed description of this existing data in this update.

The study was performed to fulfill specific US data registration requirements. Within the EU Annex I inclusion process it was regarded as supportive data with no consideration for environmental risk assessments. The evaluation revealed that the DT<sub>50</sub>-values of the active substance were less than the specified triggers, i.e. 60 days at 20°C and 90 days at 10°C with moisture being in the range of pF 2 to pF 2.5. Since both the active substance was degraded fast and the principal soil metabolite AE F130619 showing transient character, field dissipation studies were not required nor conducted in the EU.

Field dissipation studies with foramsulfuron are not triggered also when following re-calculations of aerobic soil degradation rates in the laboratory under Point CA 7.1.2.1.

**CA 7.1.2.2.2 Soil accumulation studies**

The data requirement was addressed under Point 7.1.1.2.3 of the Dossier submitted and evaluated within the process of Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments.

The evaluation revealed that the values for the DT<sub>90</sub> of foramsulfuron from laboratory tests were all significantly below one year thus with no indication for accumulation of foramsulfuron in the soil environment. The conclusion is justified also in view of actual re-calculations of soil degradation rates in the laboratory under Point CA 7.1.2.1.

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CA 7.1.3 Adsorption and desorption in soil

CA 7.1.3.1 Adsorption and desorption

CA 7.1.3.1.1 Adsorption and desorption of the active substance

Report:	██████████; 2000; M-141563-02; Amended: 2000-03-08
Title:	The adsorption/desorption of ( <sup>14</sup> C)-AE F130360 on five soils Code: AE F130360
Report No:	A57846
Document No(s):	Report includes Trial Nos.: 514CF CF96E514A M-141563-02-1
Guidelines:	OECD: 106; USEPA (=EPA): BAG-N 103-1; Deviation not specified
GLP/GEP:	yes

The adsorption of the active substance foramsulfuron to soil was investigated under conditions of the laboratory in:

- 5 soils under standard conditions of batch equilibrium tests at 20°C following application of phenyl-UL-<sup>14</sup>C- labeled active substance (KCA 7.1.3.1.101).

The data requirement had been addressed under Point 7.1.2.1 of the Dossier submitted and evaluated within the process of Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments. Consequently there is no detailed description of this existing data in this update.

The evaluation revealed that the active substance foramsulfuron was weakly adsorbed to soil. Values for the adsorption K<sub>oc</sub> ranged from 31 to 151 mL/g while values for Freundlich coefficients 1/n were from 0.82 to 0.96. The data have been summarised in Table 7.1.3.1.1-1.

Table 7.1.3.1.1-1: Sorption behaviour of foramsulfuron (AE F130360) in 5 soils

Soil	%OC	% Clay	pH (CaCl <sub>2</sub> )	CEC	Ads K <sub>F</sub> (mL/g)	Ads K <sub>oc</sub> (mL/g)	Ads 1/n
Maquoketa, US (EFS-16)	1.73	29.5	7.2	16.2	2.61	151	0.96
Pikeville, US (EFS-21)	0.47	4.8	6.2	2.2	0.42	89	0.82
Münster, D (EFS-22)	1.80	6.7	5.5	5.6	0.91	51	0.86
Shuttleworth, UK (EFS-24)	0.81	6.0	6.4	3.7	0.31	38	0.86
Chantepie F (EFS-25)	1.84	40.0	5.4	10.0	1.17	63	0.87

CEC = Cation Exchange Capacity

The data for K<sub>F</sub>, K<sub>oc</sub> and 1/n as presented above were also published in SANCO/10324/2002-Final as of Nov 2002, along with the conclusion that adsorption is independent from pH of soil.



**CA 7.1.3.1.2 Adsorption and desorption of metabolites, breakdown and reaction products**

<b>Report:</b>	[REDACTED];1999;M-238339-01
<b>Title:</b>	Adsorption and desorption of [ <sup>14</sup> C]-AE F153475 in US and European soils
<b>Report No:</b>	B002593
<b>Document No(s):</b>	Report includes Trial Nos.: CF99E547 XBL99031 M-238339-01-2
<b>Guidelines:</b>	EU (=EEC): oint7.1.2; OECD: 106; USEPA (EPA): 163-1; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[REDACTED];2000;M-238202-01
<b>Title:</b>	The adsorption/desorption of [ <sup>14</sup> C]-AE F130619 in US and European soils:
<b>Report No:</b>	B002457
<b>Document No(s):</b>	Report includes Trial Nos.: CF99E546 M-238202-01-2
<b>Guidelines:</b>	OECD: 106; USEPA (EPA): 163-1; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[REDACTED];1992;M-136973-01
<b>Title:</b>	Adsorption/Desorption of 2-Amino-4,6-dimethoxypyrimidine (a.e. 092944) in the system soil/water
<b>Report No:</b>	A48097
<b>Document No:</b>	M-136973-01-1
<b>Guidelines:</b>	Deviation not specified
<b>GLP/GEP:</b>	yes

The adsorption of the metabolite AE F153745 to soil was investigated under conditions of the laboratory in:

- 4 soils under standard conditions of batch equilibrium tests following application of phenyl-UL-<sup>14</sup>C-labeled test substance (KCA 7.1.3.1.2 (04)).

The point was addressed under Point 7.1.2.2 of the Dossier submitted and evaluated within the process of Annex C inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments. Consequently there is no detailed description of this existing data in this update.

The evaluation revealed that metabolite AE F153745 was weakly adsorbed to soil to result in values for the adsorption  $K_{F,OC}$  to range from 47 to 63 mL/g. Values for Freundlich coefficients 1/n were from 0.92 to 1.00. The data have been summarised in Table 7.1.3.1.2-1.

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Table 7.1.3.1.2-1: Sorption behaviour of AE F153745 in 4 soils

Soil	%OC	% Clay	pH (CaCl <sub>2</sub> )	CEC	Ads K <sub>F</sub> (mL/g)	Ads K <sub>oc</sub> (mL/g)	Ads 1/n
Shuttleworth, US	0.81	6.0	6.9	3.67	0.51	63	0.92
Chantepie, F	4.09	37.2	6.2	13.77	1.43	35	0.97
Wonderpark, US	3.0	6.0	7.7	19	1.49	50	0.92
Pikeville, US	2.07	19.8	5.1	10.6	0.99	48	1.00

CEC = Cation Exchange Capacity

The adsorption of the metabolite AE F130619 to soil was investigated under conditions of the laboratory in:

- 4 soils under standard conditions of batch equilibrium tests following application of phenyl-UL-<sup>14</sup>C-labeled test substance (KCA 7.1.3.1.2 /02).

The point was addressed under Point 7.1.2.2 of the Dossier submitted and evaluated within the process of Annex I inclusion as published in the corresponding Monograph of FMS Germany (April 01, 2001) and its amendments. Consequently there is no detailed description of this existing data in this update.

The evaluation revealed that metabolite AE F130619 was weakly adsorbed to soil with values for the adsorption K<sub>F,OC</sub> to range from 0.36 to 1.44 mL/g. Values for Freundlich coefficients 1/n were from 0.90 to 0.94. The data have been summarised in Table 7.1.3.1.2-2.

Table 7.1.3.1.2-2: Sorption behaviour of AE F130619 in 4 soils

Soil	%OC	% Clay	pH (CaCl <sub>2</sub> )	CEC	Ads K <sub>F</sub> (mL/g)	Ads K <sub>oc</sub> (mL/g)	Ads 1/n
Wonderpark, US	3.0	6.0	7.2	19	1.90	63	0.93
Shuttleworth, US	0.81	6.0	6.4	3.67	0.36	44	0.93
Orainville, F	1.99	32.3	7.4	7.99	0.79	40	0.90
Pikeville, US	2.07	19.8	4.5	10.61	2.98	144	0.94

CEC = Cation Exchange Capacity

The data for K<sub>F</sub>, K<sub>F,OC</sub> and 1/n for AE F130619 as presented above were also published in SANCO/10324/2002-Final as of Nov 2002.

The adsorption of metabolite AE F092944 to soil was investigated under conditions of the laboratory in:

- 8 soils under standard conditions of batch equilibrium tests following application of non-labeled test substance (KCA 7.1.3.1.2 /03).



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The point was addressed under Point 7.1.2.2 of the Dossier submitted and evaluated within the process of Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments. Consequently there is no detailed description of this existing data in this update.

The evaluation revealed that metabolite AE F092944 was found to be strongly adsorbed to soil with values for the adsorption  $K_{F,OC}$  to range from 89 to 11289 mL/g. Values for Freundlich coefficients  $1/n$  were from 0.52 to 0.86. The data have been summarised in Table 7.1.3.1.2-2.

Table 7.1.3.1.2-2: Sorption behaviour of AE F092944 in 8 soils

Soil	%OC	% Clay	pH (CaCl <sub>2</sub> )	CEC	Ads $K_F$ (mL/g)	Ads $K_{OC}$ (mL/g)	Ads $1/n$
S 2.1, D	1.17	3.50	5.0	3.5	2.47	20	0.69
LS 2.2, D	2.91	5.70	4.7	10.59	2.59	89	0.65
SL 2.3, D	1.32	8.20	4.7	4.5	8.25	62	0.65
Arizona A, US	0.16	8.75	8.0	3.39	1.05	663	0.52
Arizona B, US	0.26	19.4	9.5	10.7	1.82	696	0.63
SLV, D	1.04	11.60	6.1	6.60	4.11	395	0.78
SL 2, US	0.72	18.1	7.6	16.10	8.30	11289	0.58
Kanada, Canada	1.80	56.47	7.7	30.54	16.50	917	0.62

CEC = Cation Exchange Capacity

The data for  $K_F$ ,  $K_{OC}$  and  $1/n$  for AE F092944 as presented above were also published in SANCO/10324/2002 Final as of Nov 2002.

**CA 7.1.3.2 Aged sorption**

Being a new data point for the optional submission of data this had not been addressed in the existing Dossier or evaluation within the process of Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments.

Aged sorption studies with the active substance were not performed.

Sorption data available as Freundlich adsorption coefficient normalised for organic carbon ( $K_{F,OC}$ ) from batch equilibrium tests allow for a conservative approach regarding the use as input parameter for environmental risk assessment. The potential effects of ageing of foramsulfuron residues in soil and their use in terms of desorption parameters reflect a potential higher tier option which was not considered in current risk assessments.



**CA 7.1.4 Mobility in soil**

**CA 7.1.4.1 Column leaching studies**

**CA 7.1.4.1.1 Column leaching of the active substance**

Column leaching studies with the active substance foramsulfuron were not performed. This data requirement had been addressed under Point 7.1.3.1.1 of the Dossier submitted and evaluated within the process of Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments.

The evaluation revealed that instead of performing a column leaching study, the mobility in soil is assessed by data on their persistence (e.g. half-lives) under aerobic conditions in the laboratory, and by the adsorption to soil. These data allow for an adequate description of the behaviour of the parent compound in soil in environmental risk assessments. A column leaching study with parent compound is therefore regarded as not necessary.

**CA 7.1.4.1.2 Column leaching of metabolites, breakdown and reaction products**

Column leaching studies with soil metabolites of foramsulfuron were not performed. This data requirement had been addressed under Point 7.1.3.1.2 of the Dossier submitted and evaluated within the process of Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments.

The evaluation revealed that instead of performing a column leaching study, the mobility of metabolites AE F130619, AE F153745 and AE F092944 in soil can be adequately assessed by data on their persistence (e.g. half-lives) under aerobic conditions and the adsorption to soil. These data allow for a description of the mobility of soil-borne residues in environmental risk assessments. Column leaching studies with metabolites are therefore regarded as not necessary.

**CA 7.1.4.2 Lysimeter studies**

<b>Report:</b>	[REDACTED]; [REDACTED]; [REDACTED]; 2000;M-194838-01
<b>Title:</b>	( <sup>14</sup> C- <sup>2</sup> -RIMIDYL)-AE F130360: Leaching in outdoor Lysimeters [2-4C- <sup>2</sup> -PYRIMIDYL]-AE F130360
<b>Report No.:</b>	C00906
<b>Document No(s):</b>	Report includes final No. ENVI/1010/M-194838-01-1
<b>Guidelines:</b>	BBA: Part IV 4-3 1990; Deviation not specified
<b>GLP/GEP:</b>	

<b>Report:</b>	[REDACTED]; [REDACTED]; [REDACTED]; 2001;M-207434-01
<b>Title:</b>	( <sup>14</sup> C-pyrimidyl)-AE F130360 leaching in outdoor lysimeter
<b>Report No.:</b>	C014862
<b>Document No.:</b>	M-207434-01-1
<b>Guidelines:</b>	BBA: Part IV 4-3 1990; EU (=EEC): 91/414; Deviation not specified
<b>GLP/GEP:</b>	yes



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The leaching of foramsulfuron under semi-field outdoor conditions was investigated in:

- 1 soil in two lysimeters following application of pyrimidyl-2-<sup>14</sup>C-labeled active substance (KCA 7.1.4.2 /01).

This data requirement had been addressed under Point 7.1.3.3 of the Dossier submitted and evaluated within the process for Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments. Consequently there is no detailed description of this study in this update.

The evaluation revealed that even under realistic worst case conditions for leaching, neither the active substance foramsulfuron nor any of its soil metabolites were found to leach at concentrations that could pose a risk to ground water.

The leaching of foramsulfuron under semi-field outdoor conditions was also investigated in another study with the same soil in two lysimeters and following application of the active substance with the same position of radiolabel (i.e. pyrimidyl-2-<sup>14</sup>C, KCA 7.1.4.2 /02). The study is regarded as supplementary data amending the existing information.

<b>Report:</b>	[REDACTED]; [REDACTED]; [REDACTED]	2001; M-207434-01
<b>Title:</b>	(2- <sup>14</sup> C-pyrimidyl)-AE F130360 leaching in outdoor lysimeter	
<b>Report No:</b>	G014861	
<b>Document No:</b>	M-207434-01-1	
<b>Guidelines:</b>	BBA Part IV 4-3 1990; E/C-EEC: 91/404; Deviation not specified	
<b>GLP/GEP:</b>	yes	

**Executive Summary**

The fate and mobility of pyrimidyl-2-<sup>14</sup>C-labelled foramsulfuron in soil was investigated under semi-field conditions in two outdoor lysimeters following good agricultural practice in the EU for three years in total. Two applications each at nominal rates of 4 g a.s./ha (four weeks interval) were made in spring to both lysimeters, while one lysimeter received two further applications at the same rate (four weeks interval) in spring of the next growing season.

The radioactive residues in soil, plants grown on lysimeters and leachates were determined. Leachates were collected regularly on a monthly basis and analysed by HPLC chromatographic methods.

The annual average concentration for any single component including parent compound foramsulfuron and its metabolites in the leachates did not exceed 0.03 µg a.s.-equiv./L. The remainder of radioactivity in leachates was composed of multiple components of UV-associated organic material that showed the same elution behavior as observed for the soil matrix.

The study demonstrated that even under realistic worst case conditions for leaching, neither the active substance foramsulfuron nor any of its soil metabolites were found to leach at concentrations that could pose a risk to ground water.

**Material and Methods:**

The fate and mobility of pyrimidyl-2-<sup>14</sup>C-labelled foramsulfuron (AE F130360) was investigated under conditions of actual use in an outdoor study performed in two lysimeters (L22 and L25). The lysimeters





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had been collected from agricultural land and consisted of undisturbed sandy soil monoliths. Following collection the soil cores were installed in a specially constructed underground test facility. The soil was characterized as a loamy sand containing >70% sand with a low organic matter content. The soil had been selected for its uniformity throughout the profile and to conform to BBA Guideline requirements for lysimeter soils. The soil characteristics were summarised in Table 7.1.4.2-1.

Table 7.1.4.2-1: Soil characteristics of lysimeter soil horizons

Soil horizon	Depth (cm)	Particle size*						pH (water)	Cation exchange capacity (mEq/100g)	Org carbon (%)
		Sand (%)				Silt (%)	Clay (%)			
		600 µm - 2 mm	212- 600 µm	106- 212 µm	106 µm - 63 µm					
Ap	0-23	0.72	61.33	29.15	1.14	3.20	4.46	2.7	0.6	
Bw/Cu	23-81	0.17	77.60	18.84	0.94	0.91	2.07	1.1	0.9	
Cu	81-129	0.46	68.05	26.83	0.48	1.15	3.04	0.6	0.05	

\* ADAS classification scheme.

The applications of [<sup>14</sup>C]-AE F130360 at a target rate of 2 x 45 g/ha were made to the intended crop (maize), together with the non-labelled safener compound AE F122906 (Isxadifen). Treatments of the first season were made on June 17 and July 19, 1997 to each of the two lysimeters. L22 was treated again in the following growing season, i.e. on July 2 and August 7, 1998, by application of the same rates. The radiochemical purity of [2-<sup>14</sup>C-pyrimidyl]-AE F130360 applied to the lysimeters was > 95% on each occasion. The radio-labelled compound was diluted with non-labelled AEO 130360 to result in a specific radioactivity of 100 µCi/mg (about 4.876 MBq/mg).

Within one week after the first treatment potassium bromide (5g of dissolved in 0.5L of water) was applied as a tracer to each of the two lysimeters.

On L25, maize was grown in the first season (sown May 19, 1997) followed by winter wheat (sown November 24, 1997) and spring wheat (sown February 9, 1998), followed by winter wheat (November 20, 1998) and spring wheat (March 15, 1999) due to partial crop failure. Final crop was winter wheat sown on October 7, 1999.

On L22, maize was grown in the first season (sown May 19, 1997) followed by maize in the next season (sown May 19, 1998) which was followed by winter wheat (sown November 20, 1998) and spring wheat (March 15, 1999) due to partial crop failure. Final crop was winter wheat sown on October 7, 1999.

Plants of the final crops of both lysimeters were harvested immature on 12th August 2000. Maize and all subsequent crops in the following years were maintained and harvested according to Good Agricultural Practice (GAP) as far as possible on the small plot size. The surrounding area was cultivated with the same crop in order to avoid edge effects and to achieve an identical microclimate consistent with the field situation.

Crops harvested from the lysimeters were analysed for total radioactive residues (TRR) by combustion followed by LSC.

Rainfall was recorded daily and supplemental irrigation carried out to ensure that the total precipitation received was ca. 800 mm/year. Irrigation was also carried out for agronomic reasons as required. An additional lysimeter, L20, served as control being a source for untreated leachates.

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Leachate from each lysimeter was continuously collected by gravity into containers. The amount of leachate was usually checked twice a week between September and April, and following significant rainfall events. Generally, a collection of leachate was made when more than two litres had accumulated in the leachate container. Collections were also made when less than two litres had accumulated on particular outside of the usual leaching period from September to April. In general, leachates were further characterized by analysis when total radioactivity as determined by LSC exceeded 0.1 µg a.s.-equiv./L. Samples containing >0.1 a.s.-equiv./L were concentrated and analysed by high performance liquid chromatography (HPLC). Prior to concentration aliquots of the leachates were pooled on a calendar monthly basis.

From each lysimeter soil cores were removed up to a depth of 15 cm at the end of each growing season (1997, 1998 and 1999). The soil cores were sectioned, extracted and the extracts analysed by HPLC.

At the end of the third experimental year (August 2000) lysimeters were removed from the facility and the soil cores were segmented into 10 cm layers. The total amount of radioactivity in each segment was determined by combustion/LSC followed by extraction of the top three layers and their analysis for AE F130360 and degradation products.

**Results and discussion**Radioactivity in soil:

After three experimental years the majority of radioactive residues was located in the top 30 cm of the soil amounting ca. 40% of AR in maximum (41.9% for L22, 38.1% for L25). Radioactivity was below the limit of quantification (1.4% of AR) in soil below 30 cm (L25) and 40 cm (L22).

Analysis of soil-extractable radioactivity in the top 30 cm of the soil was found to consist of AE F092944 as the largest component (<1.5% of AR). The parent compound foramsulfuron (<0.2% of AR), metabolite ADF099095 (<0.6% of AR) and AEF130619 (<0.2% of AR) were detected as additional minor components.

Leachates:

During the first experimental year (June 17, 1997 to August 8, 1998) leachates amounted to 46% of the total precipitation and supplementary irrigation for each of the two lysimeters L22 and L25. During the second year (August 9, 1998 to August 14, 1999) leachates amounted to 38% (L22) and 39% (L25) of the total precipitation and supplementary irrigation. For the third experimental year (August 15, 1999 to August 14, 2000) corresponding leachates amounted to 62% (L22) and 65% (L25).

Total radioactivity in leachates:

The concentrations of total radioactive residues in leachates in terms of annual averages and their associated % of AR are summarised in Table 7.1.4.2-2.

Total radioactivity cumulated in leachates after three experimental years was 4.91% (L25) and 3.85% of AR (L22).

For lysimeter L25 radioactivity exceeded 0.1 µg a.s.-equiv./L in all individual leachates collected from July 1997 to August 2000 on a monthly basis. For L22 this was true for all leachates collected from November 1997 to August 2000. For L22, the radioactivity in the leachate of October 1997 was additionally investigated.

Annual average concentrations of total radioactive residues in leachates were virtually the same for both lysimeters in the first experimental year (0.428 µg a.s.-equiv./L for L25 and 0.374 µg a.s.-equiv./L for L22).



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Due to treatments of L22 in the second experimental year, radioactive residues in leachates doubled (0.678 µg a.s.-equiv./L) in comparison to L25 (0.347 µg a.s.-equiv./L). The same applies for the last experimental year with radioactive residues of 0.517 µg a.s.-equiv./L for L22 and 0.335 µg a.s.-equiv./L for L25.

Table 7.1.4.2-2: Total radioactivity in leachates of lysimeters L25 and L22

Year	Lysimeter 25				Lysimeter 22			
	Total precipitation & irrigation (mm)	Total leachates (mm)	Leachate		Precipitation & irrigation (mm)	Total leachates (mm)	Leachate	
			Total radioactivity				Total radioactivity	
			Cumulative % of AR <sup>1</sup>	Mean concentration (µg a.s.-equiv./L)			Cumulative % of AR <sup>2</sup>	Mean concentration (µg a.s.-equiv./L)
Application: Treatment 1: June 17, 1997 (45.0 g/ha) Treatment 2: July 19, 1997 (45.0 g/ha)	Application Year 1: Treatment 1: June 17, 1997 (45.0 g/ha) Treatment 2: July 19, 1997 (45.0 g/ha)				Application Year 2: Treatment 1: July 2, 1998 (45.0 g/ha) Treatment 2: August 7, 1998 (45.0 g/ha)			
1	951.1	433.5	2.931	0.438	951.1	438.5	0.948	0.374
2	963.8	380.3	3.542	0.347	956.7	359.0	2.278	0.678
3	854.9	551.5	4.910	0.246	854.9	532.0	3.847	0.527
Total	2769.9	1365.3	4.910	0.335	2762.0	1329.5	3.847	0.517

<sup>1</sup> Based on total AR applied to L25 in 1997.

<sup>2</sup> Based on total AR applied to L22 in 1997 and 1998.

Analysis of radioactive residues in leachates

The radioactivity in leachates could be separated by HPLC/fraction collection/LSC into characteristic profiles distributed in a broad range along the whole chromatographic run with retention times from less than 5 to about 88 min. These profiles did not change in the course of the study and they were accompanied by a strong and typical profile of UV-absorbing material in all leachates. This was confirmed by investigations of leachates from an untreated control lysimeter during the same time thus enabling to derive the elution profile of water-soluble organic material originating from the same soil. Radioactive residues eluted in leachates therefore consisted of multiple components rather than to show a defined peak elution behavior being characteristic for single compounds.

The results of HPLC analysis including fraction collection/LSC are summarised in Table 7.1.4.2-3 (L25) and Table 7.1.4.2-4 (L22). The values are shown in terms of mean annual average concentrations for the various components and regions separated.



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Table 7.1.4.2-3: Lysimeter L25: Distribution of radioactivity in leachates; annual average concentrations [µg a.s.-equiv./L]

Year	AE F130360	AE F130619	Early eluting	Region A	Region B	Region C	Region D	Peak 2*	Others*
1	0.005	0.003	0.137	0.160	0.094	0.035	0.020	0.016	0.001-0.004
2	nd	0.0001	0.095	0.126	0.061	0.019	0.014	0.017	0.0001-0.002
3	nd	nd	0.070	0.073	0.028	0.040	0.007	0.042	0.0001-0.002

nd = not detected

\* Note: Region D (62 to 70 min) is included in Region C, while Peak 2 (20 to 21 min) is included in Region A. Finally, 'Others' consist of radioactivity assigned to distinct peaks detected in Regions A and B.

Table 7.1.4.2-4: Lysimeter L22: Distribution of radioactivity in leachates; annual average concentrations [µg a.s.-equiv./L]

Year	AE F130360	AE F130619	Early eluting	Region A	Region B	Region C	Region D*	Peak 2*	Others*
1	nd	0.003	0.160	0.21	0.075	0.032	0.026	0.002	0.0001-0.003
2	nd	0.003	0.260	0.208	0.104	0.051	0.024	0.009	0.0003-0.003
3	nd	0.003	0.171	0.172	0.083	0.030	0.021	0.028	0.0001-0.004

nd = not detected

\* Note: Region D (62 to 70 min) is included in Region C, while Peak 2 (20 to 21 min) is included in Region A. Finally, 'Others' consist of radioactivity assigned to distinct peaks detected in Regions A and B.

The overall metabolic profiles of radioactive residues in leachates were fairly the same for both lysimeters as reflected by their elution characteristics. The results serve additionally as an indication for the fact that residues in leachates consisted of multiple components rather than to be the result from defined compounds and their peaks.

The total radioactivity observed in HPLC runs was separated into known compounds (i.e. parent foramsulfuron, AE F130619), unknown compounds ('Peaks 1 to 7') and at least into four regions 'Early eluting' (1 to 8 min), 'Region A' (8 to 34 min), 'Region B' (34 to 54 min) and 'Region C' (54 to 88 min).

For both lysimeters and for defined single compounds, the mean annual average concentration in leachates did not exceed 0.03 µg a.s. equiv./L.

The radioactivity in leachates as characterized by chromatographic analyses showed a typical pattern:

Lysimeter L25:

The concentration of parent compound **foramsulfuron** was 0.005 µg/L based on the annual average for the first experimental year to be below the limit of detection (LOD) for the second and third year. For **metabolic AE F130619**, the corresponding concentration was 0.003 µg/L in the first year, followed by 0.0001 µg/L in the second year and with no detection in the third year. For L22 no parent compound foramsulfuron was found in the leachates of the first, second or third experimental year on the annual

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average basis. For metabolite AE F130619, the concentration in leachates was each 0.003 µg/L in the first, second and third experimental year.

The radioactivity in **region 'Early eluting'** consisted of the most polar components.

For L25, the total concentration of these components in leachates was 0.137 µg a.s.-equiv./L (year 1), 0.095 µg a.s.-equiv./L (year 2) and 0.070 µg a.s.-equiv./L (year 3). For L22, the total concentration of these components in leachates was 0.160 µg a.s.-equiv./L (year 1), 0.260 µg a.s.-equiv./L (year 2) and 0.171 µg a.s.-equiv./L (year 3).

The radioactivity in **'Region A'** was polar and found nearly evenly distributed over a broad range of retention times in the HPLC profile. For L25, the total concentration of the components was 0.160 µg a.s.-equiv./L (year 1), 0.126 µg a.s.-equiv./L (year 2) and 0.073 µg a.s.-equiv./L (year 3). For L22, the total concentration of these components in leachates was 0.221 µg a.s.-equiv./L (year 1), 0.208 µg a.s.-equiv./L (year 2) and 0.172 µg a.s.-equiv./L (year 3).

'Region A' can be characterized in total as a 'smear' that was interrupted by small peaks (i.e. Peak 3, 4 and 7) serving as an indication for single compounds. The values were clearly below 0.1 µg a.s.-equiv./L each for Peaks 1 to 3 and Peak 7. Unknown component 'Peak 2' eluted within 'Region A' as the largest single component (Table 7.1.4.2-2 and Table 7.1.4.2-4). For L25, the mean annual concentration of 'Peak 2' was 0.016 µg a.s.-equiv./L (year 1), 0.017 µg a.s.-equiv./L (year 2) and 0.012 µg a.s.-equiv./L (year 3). For L22, the concentration was 0.002 µg a.s.-equiv./L (year 1), 0.009 µg a.s.-equiv./L (year 2) and 0.028 µg a.s.-equiv./L (year 3).

The radioactivity in **'Region B'** was found distributed over the less polar retention times from 34 to 54 min. For L25, the total concentration of the components was 0.094 µg a.s.-equiv./L (year 1), 0.061 µg a.s.-equiv./L (year 2) and 0.028 µg a.s.-equiv./L (year 3). For L22, the total concentration of these components in leachates was 0.073 µg a.s.-equiv./L (year 1), 0.104 µg a.s.-equiv./L (year 2) and 0.083 µg a.s.-equiv./L (year 3).

Again, radioactivity was found to be nearly evenly distributed along the chromatographic run. As for Region B, the resulting smear was interrupted by a number of small peaks, and values were below 0.1 µg a.s.-equiv./L for single components like for Peak 6.

Finally, total radioactivity in **'Region C'**, distributing from 74 to 88 min, was below 0.1 µg a.s.-equiv./L for L25 and L22 and for all experimental years. As a sub-region of 'Region C', **'Region D'** was assigned to components eluting from 62 to 70 min. Region C included the minor and known non-polar single compounds AE F130619 and the parent compound foramsulfuron.

Following chromatographic characterization the total mean annual average concentration of radioactivity in leachates was higher than 0.1 µg a.s.-equiv./L for a number of regions observed in chromatographic profiles. In trend, this total radioactivity and its associated annual average concentration was highest in the first experimental year to show a decline in the successive years. Values of mean annual averages were also higher following repeated treatment in the next experimental year with values again showing a decline in the next growing season. In the first experimental year, total concentration of radioactivity in regions was very similar for both lysimeters while for L22 the concentrations doubled in the second year following the two additional treatments.

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Further efforts were consequently made in order to demonstrate that radioactivity in regions all consisted of multiple components:

Selected samples were re-analysed by HPLC/fraction collection and fractions were re-chromatographed using ion-exchange chromatography. This method resulted in a distribution of radioactive components into a large number of unresolved peaks. None of these peaks co-eluted with reference materials available and no individual component exceeded 0.1 µg a.s.-equiv./L on an annual average basis.

The remainder of the radioactivity in leachates was thus found to be composed of highly polar components or material that co-eluted with UV associated organic material. This was demonstrated by analysis of leachates from an untreated control lysimeter applying the same chromatographic method. Analysis showed the same typical natural profile of components that were distributed all over the chromatographic run in the same regions as observed for leachates from treated lysimeters.

This is in line with findings within laboratory investigations into the route of degradation of foramsulfuron in aerobic soil showing that foramsulfuron is rapidly transformed via metabolite AE F130619 to become part of soil organic matter. Organic matter of soil can be distributed into the fractions humic acids, humins and fulvic acids. Fulvic acids are known to be water soluble due to their lower molecular weight than that of the other fractions.

Investigation of leachates of treated as well as of untreated control lysimeters strongly suggest that radioactivity in leachates consisted of multiple components originating from bound residues. This conclusion can be derived from the various indications given in their qualitative and quantitative form during the investigations of leachates generated outdoors as well as from laboratory investigations. The results also support the conclusion that no single component was observed in leachates at a mean annual average concentration of more than 0.1 µg a.s.-equiv./L in the course of the test.

**Overall Conclusion:**

The annual average concentration in the leachates did not exceed 0.03 µg a.s.-equiv./L for any single component including parent compound foramsulfuron and its metabolites.

The remainder of the radioactivity in leachates was composed of highly polar components that showed the same elution behavior as observed for UV-associated organic material of the soil matrix from an untreated control lysimeter.

The data from two studies performed with a total of four lysimeters are well consistent. The investigations demonstrated that neither parent compound foramsulfuron nor any of its major residues in soil do pose a risk to ground water under realistic worst case conditions of leaching.

**CA 7.1.4.3 Field leaching studies**

Field leaching studies with the active substance foramsulfuron were not performed.

This data requirement had been addressed under Point 7.1.3.3 of the Dossier submitted and evaluated within the process of Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments.



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The evaluation revealed that the potential for mobility of foramsulfuron residues to ground water can be adequately assessed by the simulation of vulnerable scenarios representative for the EU. The simulations are able to cover a range of worst cases rather than to be limited to soil and climatic conditions reflected by field leaching studies.

Separate field leaching studies with foramsulfuron are therefore regarded as not necessary.

**CA 7.2 Fate and behaviour in water and sediment**

**CA 7.2.1 Route and rate of degradation in aquatic systems (chemical and photochemical degradation)**

**CA 7.2.1.1 Hydrolytic degradation**

<b>Report:</b>	[REDACTED] 4; [REDACTED] 2600.M-238210-01
<b>Title:</b>	The hydrolysis of [ <sup>14</sup> C]-AE F130360 in aqueous buffer at pH 4, 5, 7, and 9: AE F130360
<b>Report No:</b>	B002464
<b>Document No(s):</b>	Report includes Trial Nos. CF97E5, M-238210-01-2
<b>Guidelines:</b>	OECD: 116; USEP (=EP): 161.1; Deviation in specified
<b>GLP/GEP:</b>	yes

The abiotic hydrolysis of foramsulfuron was investigated in a study with:

- sterile aqueous buffer at pH 4, 5, 7 and 9 following application of phenyl-UL-<sup>14</sup>C- and pyrimidyl-<sup>2-14</sup>C-labeled active substance following incubation at 25 °C and 40 °C in the dark (KCA 7.2.1.1 / 01).

The data requirement was addressed under Points 2.9.4 and 7.2.1.1 of the Dossier submitted and evaluated within the process for Annex D inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments. Consequently there is no detailed description of this existing data in this update.

The evaluation revealed that the hydrolytic behavior of foramsulfuron is well understood with no additional studies on hydrolysis therefore deemed necessary. The half-lives of foramsulfuron under conditions of sterile aqueous buffer hydrolysis were summarised in Table 7.2.1.1-1.

Hydrolysis of foramsulfuron was shown to be dependent on pH resulting in half-lives of 3.7 days at pH 4 and 10.1 days at pH 5 to increase to values of 128 days (pH 7) and 132 days (pH 9) at 25 °C.

**Table 7.2.1.1-1: Half-lives of foramsulfuron in sterile aqueous buffer at 25 °C and 40 °C**

pH	Half-life (days)	
	25 °C	40 °C
4	3.7	0.41
5	10.1	1.1
7	128	19.4
9	132	36.3

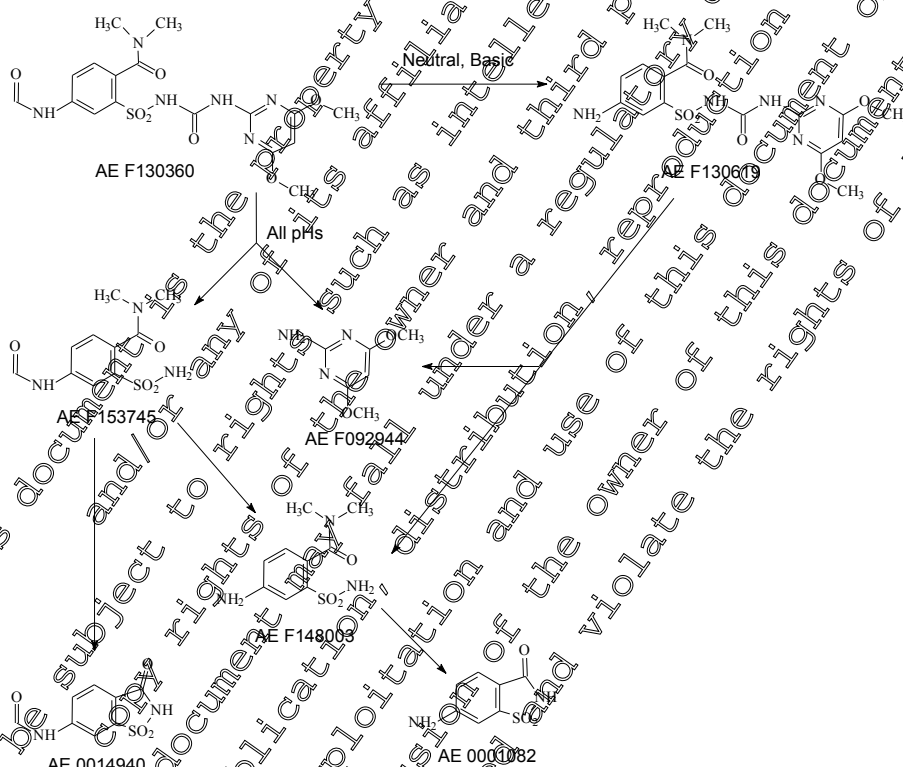
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Dependent therefore on pH foramsulfuron was found to be susceptible to hydrolysis to form AE F092944 and AE F153745 as major (i.e. >10% AR) hydrolysis products at 83.3% AR (pH 5, day 30, 25°C) and 71.3% (pH 5, day 30, 25°C) in the course of the study accompanied by the formation of AE F130619, AE F148003, AE 0014940 and AE 0001082 as minor (i.e. <10% AR) hydrolysis products.

Following current data requirements the compounds AE F092944 and AE F153745 are therefore to be considered in surface water risk assessments.

The proposed hydrolysis pathway of foramsulfuron in sterile aqueous buffer was summarised in Figure 7.2.1.1-1.

Figure 7.2.1.1-1: Proposed hydrolysis pathway of foramsulfuron in sterile aqueous buffer



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## CA 7.2.1.2 Direct photochemical degradation

<b>Report:</b>	[REDACTED]; 1999;M-194828-01
<b>Title:</b>	Aqueous photolysis under laboratory conditions Code: (U- <sup>14</sup> C-phenyl)-AE F12360
<b>Report No:</b>	C006901
<b>Document No:</b>	M-194828-01-1
<b>Guidelines:</b>	OECD: Guidance on Phototransf.; USEPA (=EPA): 161-2; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[REDACTED]; 2012;M-425561-01
<b>Title:</b>	Phototransformation of [ <sup>14</sup> C]foramsulfuron in aqueous pH 7 buffer
<b>Report No:</b>	MEFSL011
<b>Document No:</b>	M-425561-01-1
<b>Guidelines:</b>	EU Commission Directive 94/37/EC amending Council Directive 91/414/EEC, July 29, 1994 EU Commission Directive 95/36/EC amending Council Directive 91/414/EEC, July 14, 1995 US EPA Fate, Transport and Transformation Test Guidelines OPPTS 835.2240, Photodegradation in Water, US EPA, October 2008 Japanese JMAFF New Test Guidelines, 2000 Canada PMRA DACO Number 8.2.3.32; none
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[REDACTED]; 2013;M-460124-01
<b>Title:</b>	Foramsulfuron: Determination of the quantum yield and assessment of the environmental half-life of the direct photo-degradation in water
<b>Report No:</b>	EnSa 13-030
<b>Document No:</b>	M-460124-01-1
<b>Guidelines:</b>	Commission Regulation (EU) No 283/2013 in accordance with Regulation (EC) No 1107/2009, 2013 OECD Test Guideline 101, 1981 OECD Test Guideline 316, 2008; not specified
<b>GLP/GEP:</b>	yes

The direct photolysis of foramsulfuron was investigated in a study with:

- sterile aqueous buffer at pH 7 following application of phenyl-UL-<sup>14</sup>C-labeled active substance and irradiation with artificial sunlight (xenon light, 290 nm cutoff) at 25°C (KCA 7.2.1.2 /01).

The point was addressed under Points 2.9.2 and 7.2.1.2 of the Dossier submitted and evaluated within the process for Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments. Consequently there is no detailed description of this existing data in this update.

The evaluation revealed that photolytic degradation of foramsulfuron was negligible to result in photolytic half-lives of 500 days (Suntest I) or 538 days (Suntest II) when being referenced to natural sunlight and considering a 12 hours day/night interval.

Consequently, formation of photo-degradation products was poor as represented by the minor compound 'M1' found at 3.9% AR in maximum in the course of the study.

Photolysis was therefore regarded not to contribute significantly to the elimination of foramsulfuron from the aquatic environment.



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However, new information generated and presented under Point CA 7.2.1.3 later indicated that foramsulfuron may undergo indirect photochemical degradation in natural water. The results were thus in some contradiction to the existing data in sterile aqueous buffer.

New data were therefore generated by re-investigation of the behavior of foramsulfuron in sterile aqueous buffer (KCA 7.2.1.2 /02) at lower test concentration than submitted previously under KCA 7.2.1.2 /01.

In view of the observations made in the new photolysis study, the quantum yield was determined in addition as submitted under KCA 7.2.1.2 /03.

<b>Report:</b>	MEFSL011; 2012;M-425561-01
<b>Title:</b>	Phototransformation of [ <sup>14</sup> C]foramsulfuron in aqueous pH 7 buffer
<b>Report No:</b>	MEFSL011
<b>Document No:</b>	M-425561-01-1
<b>Guidelines:</b>	EU Commission Directive 94/37/EC amending Council Directive 91/414/EEC, July 29, 1994 EU Commission Directive 95/36/EC amending Council Directive 91/414/EEC, July 14, 1995 US EPA Fate, Transport and Transformation Test Guidelines OPPTS 835.2240, Photodegradation in Water, US EPA, October 2008 Japanese JMaff New Test Guidelines, 2000 Canada PMRA DACO Number 8.2.3.3.2:none
<b>GLP/GEP:</b>	yes

**Executive Summary**

The photolysis of phenyl-UL-<sup>14</sup>C- and pyrimidyl-<sup>14</sup>C-labeled foramsulfuron was investigated in sterile aqueous buffer solution at pH 7 at a concentration of 10 mg a.s./L. Samples were continuously irradiated at 25 ± 2 °C with artificial sunlight (< 290 nm cut-off filter) for 6.0 days (144 experimental hours, phenyl-label) or 7.0 days (168 hours, pyrimidine-label) equivalent to 18 or 21 environmental days of light intensity at summer solstice (June) at Arizona, US<sup>2</sup>.

The mean recovered radioactivity was above 97% for all samples of both label positions investigated. In irradiated samples phenyl-labeled foramsulfuron decreased from 99.0% of AR at time zero to 17.0% after 6.0 days. Pyrimidine-labeled foramsulfuron decreased from 100.3% of AR at time zero to 21.4% after 7.0 days

For phenyl-labeled foramsulfuron two major degradation products were identified to be 4-formamido-N-methylbenzamide (FMB, BCS-CW90756) and 4-amino-N-methylbenzamide (AMB, BCS-CV29520) at maximum values of 16.6% of AR (day 4.97) and 10.2% (day 6.0), respectively. For pyrimidine-labeled foramsulfuron two major degradation products were identified to be foramsulfuron sulfamic acid (FSA, BCS-AW41401) and the pyrimidine urea AE F099095 at maximum values of 14.2% of AR (days 6.0 and 7.0) and 35.2% (day 6.0), respectively. Formation of other minor degradation products was extensive amounting to 19 components (phenyl-label) or 15 components (pyrimidine-label) with none of these components exceeding 6.9% (phenyl-label) or 6.5% (pyrimidine-label) in the course of the study. In dark controls, no significant degradation of the <sup>14</sup>C-test substances was observed resulting in insignificant formation of degradation products.

Values of the DT<sub>50</sub> and DT<sub>90</sub> for the photolytic degradation of foramsulfuron were determined according to the recommendations of the FOCUS work group. Following simple first order (SFO) kinetics the results are summarised in Table 7.2.1.2-1.

<sup>2</sup> Irradiation was equivalent to 28.3 days (phenyl-label) or 33.0 days (pyrimidine-label) for light conditions at Athens, Greece.

Table 7.2.1.2-1: Kinetics of photo-transformation of foramsulfuron in sterile aqueous buffer at pH 7

System	Kinetic Model	Chi <sup>2</sup> error	Experimental days		Environmental days Athens, Greece	
			DT <sub>50</sub>	DT <sub>90</sub>	DT <sub>50</sub>	DT <sub>90</sub>
Irradiated Phenyl Label	SFO	n.a.	2.46	8.17	11.6	38.6
Irradiated Pyridyl Label	SFO	n.a.	3.16	10.50	14.9	49.5

\* Calculation of DT-values for environmental conditions: 2086 Suntest hours were equivalent to 1 day of natural sunlight intensity (environmental day) at Athens, Greece  
n.a. = not applicable since experimental half-lives were determined from net transformation rates of irradiated samples minus dark controls

## I. Material and Methods

### A. Materials

#### 1. Test Material: [Phenyl-UL-<sup>14</sup>C] Foramsulfuron (label 1)

Specific radioactivity: 4.44 MBq/mg (54.29 mCi/mmol; 266386 dpm/μg)

Radiochemical purity: 98.1%

Chemical purity: not reported

Sample ID: C-P138

[Pyrimidine-2-<sup>14</sup>C] Foramsulfuron (label 2)

Specific radioactivity: 4.51 MBq/mg (55.13 mCi/mmol; 270606 dpm/μg)

Radiochemical purity: 100%

Chemical purity: not reported

Sample ID: C-P145

#### 2. Buffer system

A 0.01 M aqueous phosphate buffer solution was prepared from dissolving potassium dihydrogen phosphate in water and by adjustment to pH 7 with sodium hydroxide solution. Before start of irradiation the corresponding <sup>14</sup>C treated buffer was passed through a sterile filter into the sterilized test vessels. The aqueous test solution in the test vessels was re-oxygenised.

### B. Study design

**1. Experimental conditions:** The test was performed with phenyl-UL-<sup>14</sup>C- (label 1) and pyrimidine-2-<sup>14</sup>C]foramsulfuron (label 2) at an initial concentration of 1.00 mg/L (label 1) and 1.02 mg/L (label 2). The test vessels consisted of quartz glass vessels without traps for volatile components with each sample containing 20 mL of the sterile test solution. The test solutions contained 0.11% acetonitrile as co-solvent. Duplicate samples were continuously irradiated in a <sup>®</sup>Suntest system at 25 ± 1 °C with simulated sunlight (xenon burner, range of wave length spectrum 290 – 3000 nm, i.e. spectral distribution similar to that of natural sunlight) providing a light intensity of 680 W/m<sup>2</sup> with cut-off of UV radiation < 290 nm by the use of filters (Suprax). In parallel, samples were incubated at the same temperature in the dark in a temperature-controlled chamber thus serving as dark controls. Based on intensity measurements a continuous light exposure of 6.0 days (144 experimental hours, phenyl-label) or 7.0 days (168 hours, pyrimidine-label) was equivalent to 18 or 21 environmental days when being compared to light conditions at Arizona, USA in June (summer solstice). For a transfer to light

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conditions of Athens, Greece, 30 environmental days were reached after 152.6 experimental (Suntest) hours.

Duplicates of irradiated samples containing phenyl-UL-<sup>14</sup>C-foramsulfuron were removed for analysis after 0, 1.00, 1.42, 2.00, 3.00, 4.01, 4.97 and 6.00 days of irradiation.

Single samples of dark controls containing phenyl-UL-<sup>14</sup>C-foramsulfuron were removed for analysis after 0, 0.42, 1.00, 2.00, 3.00, 4.00, 5.15, 6.10, 7.00, 8.00, 9.00 and 10.00 days of incubation.

Duplicates of irradiated samples and of dark controls treated with pyrimidine-2-<sup>14</sup>C-foramsulfuron were removed for analysis after 0, 0.33, 1.00, 1.92, 3.00, 4.00, 5.00, 6.00 and 7.00 days of irradiation.

The pH and sterility was determined for irradiated samples and dark controls at each sampling interval.

**2. Analytical procedures:** Samples were analysed directly with no additional steps for extraction, clean-up, or sample concentration using LSC for determination of total radioactivity. Reversed-phase HPLC with <sup>14</sup>C-flow-through detection techniques was used as primary chromatographic method for the separation and quantitation of products formed. Analysis was performed within one day after work up. Representative samples were additionally investigated by HPLC-MS-MS as confirmatory method and for identification of transformation products.

Based on a visual assessment of diluted samples of day zero, the LOD was estimated to be 0.11% of AR and the corresponding LOQ set to approximately 0.23% of AR.

**3. Kinetic evaluation:** The kinetic evaluation of foramsulfuron degradation data was performed with the software KinGui, Version 1.1 by using the three models SFO, FOMC<sup>3</sup> and DFOP<sup>3</sup> for fitting. Values for half-lives and DT90 were calculated for each set of data originating from the <sup>14</sup>C-phenyl- and <sup>14</sup>C-pyrimidine-labeled test substances, respectively. The quality of fits was evaluated by visual assessment and comparison to result in a minimum of Chi<sup>2</sup> errors.

## H. Results and Discussion

The total irradiation time of 6.0 days (144 experimental hours) for the phenyl-label and 7.0 days (168 hours) for the pyrimidine-label corresponded to 18 environmental days (phenyl-label) or 21 days (pyrimidine-label) under light conditions of Arizona in June to reflect a worst-case approach.

Sterility of samples was confirmed throughout the whole testing period. The pH of aqueous buffer was shown to be constant at 6.98 to 7.02 in the course of the experiment. The temperature was maintained at 25 ± 1 °C for irradiated samples and dark controls during the test.

For phenyl-labelled foramsulfuron, the mean material balances were 97.7% ± 2.9% AR for irradiated samples while material balances were 100.4% ± 1.2% for dark controls. The results including material balances and distribution of radioactivity are summarised in Table 7.2.1.2-2 for irradiated samples and the corresponding dark controls. Additional sampling intervals of dark controls with no corresponding interval for irradiated samples are summarised in Table 7.2.1.2-3.

For pyrimidine-labelled foramsulfuron, the mean material balances were 100.4% ± 1.3% AR for irradiated samples and 100.9% ± 1.0% for dark controls. The results including material balances and distribution of radioactivity are summarised in Table 7.2.1.2-4 for irradiated samples and the associated dark controls.

The complete material balances indicate no significant losses of radioactivity from samples in the course of the test including processing till analysis.

<sup>3</sup> SFO = Single First Order; FOMC = First Order Multi Compartment; DFOP = Double First Order in Parallel

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Experiences from other tests had shown that no formation of  $^{14}\text{C}$ -carbon dioxide or other volatile components had to be expected with therefore no determination during this test. This was again confirmed by the complete recoveries found.

In irradiated samples, phenyl-labelled foramsulfuron showed a decrease from 99.0% AR at time zero to 17.0% after 6.0 days. No significant degradation of phenyl-labelled foramsulfuron was observed in dark controls as it is documented by values of 97.6% AR at time zero to 95.0% after 6.1 days of incubation. A prolongation of sterile incubation in the dark up to 10.0 days did not result in higher degradation with 89.0% phenyl-labelled foramsulfuron still present at this time point.

In irradiated samples, pyrimidine-labelled foramsulfuron showed a decrease from 100.3% AR at time zero to 21.4% after 7.0 days. Degradation of pyrimidine-labelled foramsulfuron was again insignificant in dark controls as documented by values of 100.4% AR at time zero to 99.5% after 7.0 days of incubation.

Irradiation resulted in a complex pattern of transformation products for both radiolabels investigated with formation of at least 19 minor components (phenyl-labelled foramsulfuron) or 15 components (pyrimidine-label) in maximum with individual peaks amounting to 6.9% in maximum (phenyl-label) or 6.5% (pyrimidine-label). This large number of components detected as minor fractions added up to a maximum value of 53.4% for the phenyl-label after 6.0 days or 21.6% for the pyrimidine-label after 7.0 days (Table 7.2.1.2-2 and Table 7.2.1.2-4).

In addition, label-specific transformation products were identified. Irradiation of phenyl-labelled foramsulfuron resulted in the two major products 4-formamido-N-methylbenzamide (FMB, BCS-CW90756) and 4-amino-N-methylbenzamide (AMB, BCS-CV29520) formed at maximum values of 16.6% (day 4.97) and 10.2% (day 6.0) in the course of the study.

Irradiation of pyrimidine-labelled foramsulfuron resulted in foramsulfuron sulfamic acid (FSA, BCS-AW41401) and the pyrimidinyl urea compound (AE F099095) found as major products at maximum values of 14.2% (days 6.0 and 7.0) and 35.2% (day 6.0) in the course of the study. 2-Amino-4,6-dimethoxypyrimidine (AE F092944) was observed as a minor product at 6.5% AR in maximum (day 7.0).

The major and distinct transformation products observed requiring further assessment in environmental exposure assessments are summarised in Table 7.2.1.2-5.

The resulting proposed photolytic pathway is summarised in Figure 7.2.1.2-1.

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Table 7.2.1.2-2: Phototransformation of [phenyl-UL-<sup>14</sup>C]foramsulfuron in sterile aqueous buffer, expressed as percentage of total applied radioactivity

Component		Sampling interval (days)							
		0.00	1.00	1.42	2.00	3.00	4.01	4.97	6.00
	Irradiated	0.00	1.00	-	2.00	3.00	4.00	5.15	6.10
	Dark control	0.00	1.00	-	2.00	3.00	4.00	5.15	6.10
Foramsulfuron (Parent compound)	Irradiated	99.0 ± 0.0	75.1 ± 0.7	64.8 ± 5.8	57.6 ± 5.9	38.0 ± 0.3	31.7 ± 6.7	25.3 ± 2.8	17.0 ± 1.0
	Dark control	97.6	99.0	-	96.0	94.9	97.0	97.8	97.0
4-Formylamido-N-methylbenzamide (FMB)	Irradiated	0.0 ± 0.0	2.3 ± 3.3	6.9 ± 0.1	17.7 ± 2.3	11.7 ± 0.2	14.4 ± 0.0	16.6 ± 1.0	16.5 ± 0.0
	Dark control	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
4-Amino-N-methylbenzamide (AMB)	Irradiated	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	1.1 ± 1.5	3.2 ± 0.0	5.3 ± 0.2	7.2 ± 0.0	10.2 ± 0.5
	Dark control	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total unidentified radioactivity (each <7%)	Irradiated	1.7 ± 0.3	2.3 ± 3.3	1.6 ± 11.2	2.0 ± 2.0	38.2 ± 1.0	45.2 ± 5.0	50.7 ± 0.0	53.4 ± 0.4
	Dark control	2.2	3.0	2.2	2.2	0.0	0.9	7.0	7.7
Total number of individual unknown transformation products	Irradiated	8	8	13	14	18	15	19	18
	Dark control	3	4	-	-	-	-	9	6
Highest value for individual unknown transformation products	Irradiated	0.8	1.2	1.8	3.6	4.2	5.2	6.4	6.9
	Dark control	0.8	1.2	-	1.4	3.1	2.9	3.0	4.1
Total extractable	Irradiated	100.0 ± 0.3	97.7 ± 0.7	99.5 ± 0.1	99.4 ± 0.8	91.1 ± 0.7	96.7 ± 0.3	99.8 ± 0.3	97.1 ± 0.4
	Dark control	99.8	101.4	-	99.3	100.9	100.6	99.8	102.7
<sup>14</sup> C-Carbon dioxide	Irradiated	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	Dark control	n.d.	n.d.	-	n.d.	n.d.	n.d.	n.d.	n.d.
Volatile radioactivity	Irradiated	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	Dark control	n.d.	n.d.	-	n.d.	n.d.	n.d.	n.d.	n.d.
Total % recovery	Irradiated	100.2 ± 0.3	97.7 ± 0.7	99.5 ± 0.1	99.4 ± 0.8	91.1 ± 0.7	96.7 ± 0.3	99.8 ± 0.3	97.1 ± 0.4
	Dark control	99.8	101.4	-	99.3	100.9	100.6	99.8	102.7

Unless specified otherwise, mean values of duplicate sample analysis ± s.d., except for dark controls (single samples only), n.d. = not determined  
AMB / 4-amino-N-methylbenzamide = BCS-CV29520  
FMB / 4-formylamido-N-methylbenzamide = BCS-CW90756



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Table 7.2.1.2-3: Transformation of [phenyl-UL-<sup>14</sup>C]foramsulfuron in dark controls, expressed as percentage of total applied radioactivity

Component		Sampling interval (days)				
		Irradiated	-	-	-	-
	Dark control	0.42	7.00	8.00	9.00	10.00
Foramsulfuron (Parent compound)	Irradiated	-	-	-	-	-
	Dark control	97.7	92.9	92.2	91.8	89.0
4-Formylamido-N-methylbenzamide (FMB)	Irradiated	-	-	-	-	-
	Dark control	0.0	0.0	0.0	0.0	0.0
4-Amino-N-methylbenzamide (AMB)	Irradiated	-	-	-	-	-
	Dark control	0.0	0.0	0.0	0.0	0.0
Total unidentified radioactivity (each <7%)	Irradiated	-	-	-	-	-
	Dark control	3.0	8.0	8.0	8.0	7.0
Total number of individual unknown transformation products	Irradiated	-	-	-	-	-
	Dark control	0	0	0	0	0
Highest value for individual unknown transformation products	Irradiated	-	-	-	-	-
	Dark control	1.1	3.7	4.3	4.1	4.1
Total extractable	Irradiated	-	-	-	-	-
	Dark control	100.9	100.9	101.0	100.3	97.7
<sup>14</sup> C-Carbon dioxide	Irradiated	-	-	-	-	-
	Dark control	n.d.	n.d.	n.d.	n.d.	n.d.
Volatile radioactivity	Irradiated	-	-	-	-	-
	Dark control	n.d.	n.d.	n.d.	n.d.	n.d.
Total% recovery	Irradiated	-	-	-	-	-
	Dark control	100.8	100.9	101.0	100.3	97.7

Unless specified otherwise, mean values of duplicate sample analysis ± s.d., except for dark controls (single sample only); n.d. = not determined

AMB / 4-amino-N-methylbenzamide = BCS-CV29520

FMB / 4-formylamido-N-methylbenzamide = BCS-CW90756

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Table 7.2.1.2-4: Phototransformation of [pyrimidine-2-<sup>14</sup>C]foramsulfuron in sterile aqueous buffer, expressed as percentage of total applied radioactivity

Component		Sampling interval (days)					
		Irradiated	0.00	0.33	1.00	1.92	3.00
	Dark control	0.00	0.33	1.00	1.92	3.00	4.00
Foramsulfuron (Parent compound)	Irradiated	100.3 ± 0.9	92.5 ± 0.6	83.2 ± 3.0	67.9 ± 2.4	53.7 ± 0.1	42.8 ± 4.9
	Dark control	100.4 ± 0.1	100.2 ± 0.1	99.3 ± 0.1	98.9 ± 0.2	98.0 ± 0.1	96.0 ± 0.4
Foramsulfuron sulfamic acid (FSA)	Irradiated	0.0 ± 0.0	1.4 ± 0.1	3.9 ± 0.8	6.7 ± 0.6	9.8 ± 0.5	10.4 ± 0.0
	Dark control	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0
Pyrimidinyl urea (AE F099095)	Irradiated	0.0 ± 0.0	4.3 ± 0.5	8.8 ± 0.7	16.9 ± 0.9	27.0 ± 1.6	29.2 ± 4.4
	Dark control	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0
2-Amino-4,6-dimethoxypyrimidine (AE F092944)	Irradiated	0.3 ± 0.1	0.7 ± 0.2	1.7 ± 0.1	2.8 ± 0.0	4.1 ± 0.1	4.7 ± 0.0
	Dark control	0.0 ± 0.0	0.4 ± 0.0	0.5 ± 0.1	0.6 ± 0.1	0.8 ± 0.1	1.0 ± 0.0
Total unidentified radioactivity (each <7%)	Irradiated	0.2 ± 0.0	1.5 ± 0.2	3.3 ± 0.5	6.7 ± 0.7	11.5 ± 0.6	13.3 ± 0.4
	Dark control	0.1 ± 0.1	0.0 ± 0.0	1.0 ± 0.0	1.5 ± 0.2	2.7 ± 0.2	2.7 ± 0.2
Total number of individual unknown transformation products	Irradiated	1	2	7	11	11	13
	Dark control	2	0	2	2	2	2
Highest value for individual unknown transformation products	Irradiated	0.2	0.7	1.7	2.8	4.1	4.7
	Dark control	0.1	0.9	0.9	1.4	2.3	2.7
Total extractable	Irradiated	100.8 ± 0.6	100.7 ± 0.7	101.5 ± 0.7	100.9 ± 0.7	100.5 ± 0.5	100.5 ± 0.1
	Dark control	100.8 ± 0.0	100.7 ± 0.1	100.9 ± 0.2	101.0 ± 0.1	101.4 ± 0.3	100.3 ± 1.3
<sup>14</sup> C-Carbon dioxide	Irradiated	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	Dark control	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Volatile radioactivity	Irradiated	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	Dark control	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Total% recovery	Irradiated	100.8 ± 0.6	100.2 ± 0.7	101.5 ± 0.7	100.9 ± 0.7	100.5 ± 0.5	100.5 ± 0.1
	Dark control	100.8 ± 0.0	100.7 ± 0.1	100.9 ± 0.2	101.0 ± 0.1	101.4 ± 0.3	100.3 ± 1.3

Unless specified otherwise, mean values ± s.d.; n.d. = not determined

FSA = foramsulfuron sulfamic acid = BCS-AW41401

ADMP / 2-amino-4,6-dimethoxypyrimidine = AE F092944



Document MCA: Section 7 Fate and behaviour in the environment  
ForamsulfuronTable 7.2.1.2-4: Continued: Phototransformation of [pyrimidine-2-<sup>14</sup>C]foramsulfuron in sterile aqueous buffer, expressed as percentage of total applied radioactivity.

Component		Sampling interval (days)		
		5.00	6.00	7.00
Foramsulfuron (Parent compound)	Irradiated	33.5 ± 5.0	23.6 ± 4.0	21.4 ± 2.7
	Dark control	99.5 ± 0.7	97.0 ± 1.5	99.5 ± 0.6
Foramsulfuron sulfamic acid (FSA)	Irradiated	12.8 ± 0.9	14.2 ± 0.7	14.2 ± 0.6
	Dark control	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0
Pyrimidyl urea (AE F099095)	Irradiated	31.5 ± 3.0	35.2 ± 1.0	33.3 ± 1.7
	Dark control	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0
2-Amino-4,6-dimethoxy-pyrimidine (AE F092944)	Irradiated	5.6 ± 0.3	6.1 ± 0.1	6.5 ± 0.8
	Dark control	1.0 ± 0.1	1.2 ± 0.0	1.4 ± 0.1
Total unidentified radioactivity (each <7%)	Irradiated	17.5 ± 1.0	20.8 ± 1.3	21.6 ± 2.0
	Dark control	0.0 ± 0.0	0.4 ± 0.0	0.0 ± 0.0
Total number of individual unknown transformation products	Irradiated	14	14	15
	Dark control	1	1	0
Highest value for individual unknown transformation products	Irradiated	5.6	6.1	6.5
	Dark control	0.3	0.4	0.0
Total extractable	Irradiated	100.8 ± 0.7	100.1 ± 1.8	98.0 ± 2.8
	Dark control	100.9 ± 0.7	98.6 ± 1.5	101.4 ± 0.3
<sup>14</sup> C-Carbon dioxide	Irradiated	n.d.	n.d.	n.d.
	Dark control	n.d.	n.d.	n.d.
Volatile radioactivity	Irradiated	n.d.	n.d.	n.d.
	Dark control	n.d.	n.d.	n.d.
Total% recovery	Irradiated	100.8 ± 0.7	100.0 ± 1.8	98.0 ± 2.8
	Dark control	100.9 ± 0.7	98.6 ± 1.5	101.4 ± 0.3

Unless specified otherwise, mean values ± s.d.; n.d. = not determined

FSA = foramsulfuron/sulfamic acid = BCS-AW41401

ADMP / 2-Amino-4,6-dimethoxypyrimidine = AE F092944

Document MCA: Section 7 Fate and behaviour in the environment  
ForamsulfuronTable 7.2.1.2-5: Products of phototransformation of <sup>14</sup>C-foramsulfuron in sterile aqueous buffer

Label	Label position	Component	Maximum fraction (% AR)	Maximum occurrence after days*
1	phenyl	4-Formamido-N-methylbenzamide (FMB, BCS-CW90756)	16.6	4.97
	phenyl	4-Amino-N-methylbenzamide (AMB, BCS-CV29520)	10.2	6.0
2	pyrimidine	Foramsulfuron sulfamic acid (FSA, BCS-AWA1401)	14.2	6.0 and 7.0
	pyrimidine	Pyrimidinyl urea (AE F099095)	35.2	6.0

\* Total duration was 6.0 days (144 hours) for phenyl-label and 7.0 days (168 hours) for pyrimidine-label

The experimental DT<sub>50</sub>-values for foramsulfuron in irradiated and in dark samples were calculated by applying a simple first order kinetic model.

For phenyl-labelled foramsulfuron the experimental half-life was determined to 2.39 days for irradiated samples while degradation was slow in dark controls showing a DT<sub>50</sub> of 83 days. Following determination of the 'net' phototransformation rate thus excluding biotic degradation processes the experimental DT<sub>50</sub> has been calculated to 2.46 days (Table 7.2.1.2-6). When transferring this result to outdoor conditions considering the (lower) light intensities of natural sunlight, half-lives were 7.5 days (Phoenix, USA) or 11.6 days (Athens, Greece).

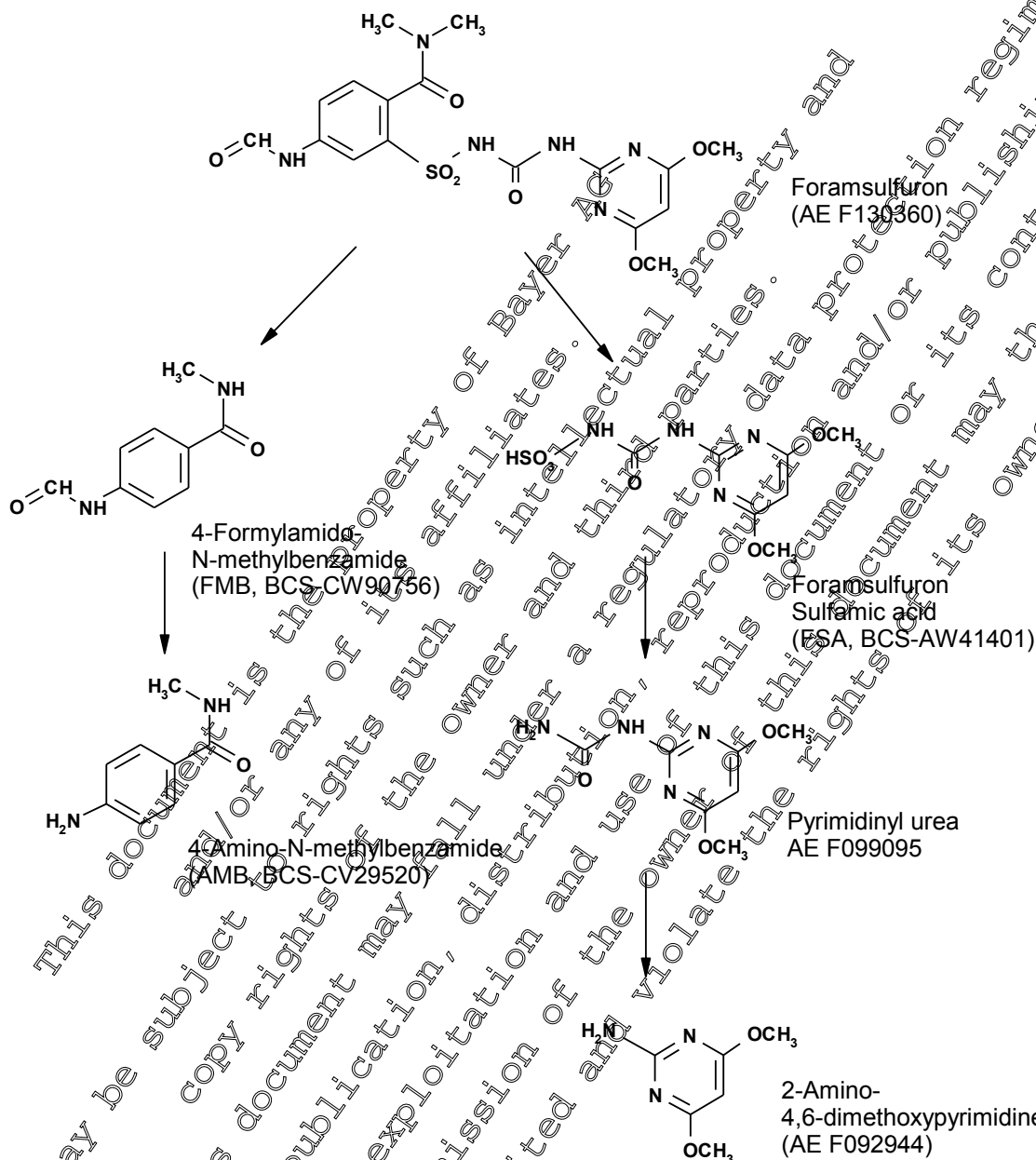
For pyrimidine-labelled foramsulfuron the experimental half-life was determined to 3.12 days for irradiated samples while degradation was again slow in dark controls (DT<sub>50</sub> of 253 days). Considering the net phototransformation rate thus excluding biotic degradation processes resulted in an experimental DT<sub>50</sub> of 3.16 days (Table 7.2.1.2-6). The transfer of this result to outdoor conditions considering light intensities of natural sunlight resulted in half-lives of 9.6 days (Phoenix, USA) or 14.9 days (Athens, Greece).

Table 7.2.1.2-6: Kinetics of photolysis of foramsulfuron in sterile aqueous buffer at pH 7

Single First Order Model				Calculated for natural light conditions at			
Test system	Experimental DT <sub>50</sub> (days)	Rate constant (days <sup>-1</sup> )	Chi <sup>2</sup> Err	Phoenix, USA		Athens, Greece	
				DT <sub>50</sub> (days)	DT <sub>90</sub> (days)	DT <sub>50</sub> (days)	DT <sub>90</sub> (days)
Irradiated, phenyl	2.39	0.2898	2.6157	7.28	24.19	-	-
Dark control, phenyl	83.0	0.0084	0.8285	n.a.	n.a.	n.a.	n.a.
'Net' transformation rate *	2.46	0.2814	-	7.5	24.9	11.6	38.6
Irradiated, pyrimidine	3.12	0.2224	5.3319	9.49	31.52	-	-
Dark control, pyrimidine	253	0.0027	0.8976	n.a.	n.a.	n.a.	n.a.
'Net' transformation rate *	3.16	0.2197	-	9.6	31.9	14.9	49.5

\* (k<sub>irradiated</sub>) minus (k<sub>dark</sub>)

Figure 7.2.1.2-1: Photolysis of foramsulfuron in sterile aqueous buffer solution



### III. Conclusion

The photolytic degradation of foramsulfuron in sterile aqueous buffer solution was moderate to result in photolytic half-lives of 14.9 days when being referenced to natural light conditions of Athens, Greece, and considering 12 hours day/night intervals.

Irradiation of phenyl-<sup>14</sup>C-labeled foramsulfuron resulted in formation of the major photo-degradation products 4-formamido-N-methylbenzamide (FMB, BCS-CW90756) and, 4-amino-N-methylbenzamide (AMB, BCS-CV29520) observed at maximum values of 16.6% and 10.2% of AR in the course of the study.

**Document MCA: Section 7 Fate and behaviour in the environment  
Foramsulfuron**

Irradiation of pyrimidine-2-<sup>14</sup>C-labeled foramsulfuron resulted in formation of major photo-degradation products sulfamic acid (BCS-AW41401) and the pyrimidinyl urea compound AE F099095 observed at maximum values of 14.2% and 35.2% of AR in the course of the study.

Direct photolysis may therefore contribute to a limited extent to the overall elimination of foramsulfuron from the aquatic environment.

<b>Report:</b>	9; 2013;M-460124-01
<b>Title:</b>	Foramsulfuron: Determination of the quantum yield and assessment of the environmental half-life of the direct photo-degradation in water
<b>Report No:</b>	EnSa-13-0305
<b>Document No:</b>	M-460124-01-1
<b>Guidelines:</b>	Commission Regulation (EU) No 283/2013 in accordance with Regulation (EC) No 1107/2009, 2013 OECD Test Guideline 101, 1981 OECD Test Guideline 316, 2008; not specified
<b>GLP/GEP:</b>	yes

**Executive Summary**

The quantum yield for the direct photo-degradation in water was determined in order to allow for the calculation of the environmental half-life of foramsulfuron in surface water according to the ECETOC method<sup>4</sup>. The method is based on light absorption data of foramsulfuron in aqueous solution as determined by UV/VIS spectrometry. After irradiation of foramsulfuron in pure aqueous solution with polychromatic light the decline in concentration was measured to result in a value of  $6.18 \times 10^{-4}$  for the quantum yield  $\Phi$ .

Dependent on season and latitude environmental half-lives of foramsulfuron were calculated to range from 48.7 to 2286 days according to the computer software GC SOLAR and from 58 to 14000 days for the model of [REDACTED]

The results of quantum yield determination and associated estimations of direct photo-transformation in aqueous solution indicate slow transformation by photolytic processes and thus a negligible contribution of this potential route of degradation to the overall elimination of foramsulfuron from the aquatic environment. The assessment does not consider further potential indirect mechanisms influencing photo-transformation in a natural aquatic environment like, for example, the influence of photosensitisers.

**1. Material and Methods****A. Materials**

**1. Test Material:** Company code: Foramsulfuron (AE F130360)

Chemical purity: 98.2%

Sample ID: AZ16639, Batch AE F130360 00 1B 99 0003

**2. Solutions:** Solutions of 1.3 mg Foramsulfuron/L were prepared for determination of UV/VIS spectra in 0.01 M aqueous buffer solutions of pH 7 (phosphate buffer) and pH 9 (borate buffer).

A solution containing 5.2 mg Foramsulfuron/L was prepared in pure water for irradiation experiments.

<sup>4</sup> Synopsis in German BBA Guideline Phototransformation of Chemicals in Water, Part A, Umweltbundesamt, Berlin, Germany, December 1992.



**B. Study design**

**1. Experimental conditions:** The UV-VIS adsorption spectra for solutions of foramsulfuron in purified water and the corresponding buffer solutions were recorded by a spectrophotometer. A solution of foramsulfuron in purified water was irradiated in a merry-go-round device for 500 minutes. The concentration in the aqueous solution was determined at various time points of irradiation by HPLC analysis using UV detection. From a decrease in concentration the degradation rate constant was calculated by use of single first order kinetics. In addition, the intensity of irradiation was determined by actinometry. All determinations were performed in duplicate.

**II. Results and Discussion**

**A. UV-VIS absorption spectrum:** The UV-VIS absorption spectra of foramsulfuron were very similar in pure and the various aqueous buffer solutions. One adsorption maximum was found at 249 nm, thus resulting in no significant overlap of adsorption with the spectrum of visible sunlight, i.e. within the environmentally relevant range of wave length starting at 290 nm to approximately 800 nm. The possibility for a direct interaction of light photons in aqueous solution is therefore limited. This assessment does not consider indirect mechanisms of interaction as it is enabled, for example, by the presence of photosensitizers in natural water.

Moreover, the molar extinction coefficient  $\epsilon$  of foramsulfuron in pure water was determined to 2257 L/mol x cm at a wave length of 290 nm and 1899 L/mol x cm at 295 nm.

**B. Photodegradation:** A decline of approximately 12 to 14% was found for foramsulfuron in aqueous solutions in the course of the quantum yield determination experiments.

**C. Quantum yield:** The actinometric determination of light intensity resulted in a mean value of  $6.18 \times 10^{-4}$  for the quantum yield  $\Phi$ .

**D. Half-lives:** Based on the value determined for the quantum yield and the molar extinction coefficients determined for wave lengths in the range of 295 to 490 nm, values for environmental half-lives were derived by use of the software GC SOLAR (Table 7.2.1.2-7). The results from computations according to the approach by [redacted] are presented in Table 7.2.1.2-8.

**Table 7.2.1.2-8: Environmental half-lives for the direct photolytic degradation of foramsulfuron according to the software GC SOLAR**

Season	Environmental DT <sub>50</sub> (days)			
	30 <sup>th</sup> degree latitude	40 <sup>th</sup> degree latitude	50 <sup>th</sup> degree latitude	60 <sup>th</sup> degree latitude
Spring	58.6	71.9	93.9	129
Summer	48.7	53.3	61.0	72.8
Fall	87.4	130	233	522
Winter	138	264	647	2280

\* Conditions: Pure surface water of 0 to 5 cm depth, 10<sup>th</sup> degree longitude, clear sky, typical concentrations of ozone in the atmosphere, half-lives integrated for the entire day. The column given for 50<sup>th</sup> degree latitude is typical for conditions of region central Europe.



Table 7.2.1.2-8: Environmental half-lives for the direct photolytic degradation of foramsulfuron according to the model of FRANK and KLOEPFFER\*

Month	Photolysis constant (1/sec)	Environmental DT <sub>50</sub> (days)		
		Minimum	Mean	Maximum
January	0.482 x 10 <sup>-8</sup>	790	1700	600
February	0.117 x 10 <sup>-7</sup>	330	680	3000
March	0.279 x 10 <sup>-7</sup>	150	290	1290
April	0.552 x 10 <sup>-7</sup>	81	150	880
May	0.775 x 10 <sup>-7</sup>	65	100	410
June	0.925 x 10 <sup>-7</sup>	59	87	350
July	0.841 x 10 <sup>-7</sup>	64	95	320
August	0.784 x 10 <sup>-7</sup>	68	100	340
September	0.411 x 10 <sup>-7</sup>	110	200	700
October	0.188 x 10 <sup>-7</sup>	230	430	1900
November	0.637 x 10 <sup>-8</sup>	550	1300	6300
December	0.288 x 10 <sup>-8</sup>	1300	2800	14000

\* Conditions: Pure static surface water of 0 to 5 cm depth, geographic and climatic conditions of Germany (50<sup>th</sup> degree latitude), no contribution of other mono- or bimolecular processes to elimination

### III Conclusion

The results of quantum yield determination and its associated estimation of direct photo-transformation in aqueous solution indicate a limited contribution of this potential route of degradation to the overall elimination of foramsulfuron in the environment. The assessment does not consider further potential indirect mechanisms of photo-transformation in a natural aquatic environment like, for example, the influence of photo-sensitisers.

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CA 7.2.1.3 Indirect photochemical degradation

<b>Report:</b>	[REDACTED]; [REDACTED];2009;M-346695-01
<b>Title:</b>	[Phenyl-UL-14C]foramsulfuron: Phototransformation in natural water
<b>Report No:</b>	MEFSU004
<b>Document No:</b>	M-346695-01-1
<b>Guidelines:</b>	Japanese MAFF New Test Guidelines for Supporting Registration of Chemical Pesticides 12 Nousan 8147, adopted November 24, 2000, amended March 31, 2008, Annex No. 2-6-2. US EPA Subdivision N, Section 161-2;not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[REDACTED]; [REDACTED];2008;M-327230-01
<b>Title:</b>	[Pyrimidine-2-14C] foramsulfuron: Phototransformation in natural water
<b>Report No:</b>	MEFSU001
<b>Document No:</b>	M-327230-01-1
<b>Guidelines:</b>	Japanese MAFF New Test Guidelines for Supporting Registration of Chemical Pesticides 12 Nousan 8147, adopted November 24, 2000, amended March 31, 2008, Annex No. 2-6-2. US EPA Subdivision N, Section 161-2;The certificates of analysis for two reference compounds were expired at the time of the study. However, identity was confirmed within the study and no quantitative comparisons were made. There is no effect on the study.
<b>GLP/GEP:</b>	yes

The indirect photolysis of foramsulfuron was investigated in:

- sterile natural water at pH 8.3 in two studies following application of phenyl-UL-<sup>14</sup>C- or pyrimidine-2-<sup>14</sup>C-labeled active substance and irradiation (xenon light, 290 nm cutoff) at 25°C under light conditions equivalent to Tokyo (KCA 7.2.1.3.01 and KCA 7.2.1.3.02).

Being a new potential data requirement this was not addressed in the original Dossier submitted and evaluated within the process for Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments.

The data are regarded as supplemental information since the tests had been performed in order to fulfill data requirements outside the EU, i.e. Japan. The new information is more detailed in the following.

<b>Report:</b>	[REDACTED]; [REDACTED];2009;M-346695-01
<b>Title:</b>	[Phenyl-UL-14C]foramsulfuron: Phototransformation in natural water
<b>Report No:</b>	MEFSU004
<b>Document No:</b>	M-346695-01-1
<b>Guidelines:</b>	Japanese MAFF New Test Guidelines for Supporting Registration of Chemical Pesticides 12 Nousan 8147, adopted November 24, 2000, amended March 31, 2008, Annex No. 2-6-2. US EPA Subdivision N, Section 161-2;not specified
<b>GLP/GEP:</b>	yes

Executive Summary



Document MCA: Section 7 Fate and behaviour in the environment  
Foramsulfuron

The photolysis of phenyl-UL-<sup>14</sup>C-labeled foramsulfuron was investigated in sterile natural water at pH 8.3 at a concentration of 1.0 mg a.s./L. Samples were continuously irradiated at 25 ± 2 °C with artificial sunlight (< 290 nm cut-off filter) for 5 days (118 experimental hours) equivalent to 34 environmental days of light intensity at summer solstice (June) at Tokyo, Japan.

The mean recovered radioactivity was above 96% for all samples of both label positions investigated. Values for foramsulfuron in irradiated samples decreased from 99.0% of AR at time zero to 17.0% after 5 days.

Three major degradation products were identified to be AE F130619 (foramsulfuron amine), 4-formamido-N-methylbenzamide (FMB, BCS-CW90756) and 4-amino-N-methylbenzamide (AMB, BCS-CV29520) at maximum values of 10.7% of AR (day 1), 29.7% (day 3) and 12.8% (day 4), respectively.

Formation of other minor degradation products was extensive amounting to 16 components with none of these components exceeding 7.6% in the course of the study.

In dark controls, no significant degradation of the <sup>14</sup>C-test substance was observed resulting in insignificant formation of degradation products.

Values of the DT<sub>50</sub> and DT<sub>90</sub> for the photolytic degradation of foramsulfuron were determined according to the recommendations of the FOCUS work group. Following simple first order (SFO) kinetics the results are summarised in Table 7.2.1.3-1.

Table 7.2.1.3-1: Kinetics of indirect photochemical degradation of (phenyl-UL-<sup>14</sup>C) foramsulfuron in sterile natural water

Single First Order Model, phenyl-label				Calculated for natural light conditions at			
Test system	Experimental DT <sub>50</sub> (days)	Rate constant (days <sup>-1</sup> )	Chi <sup>2</sup> Err	Tokyo, Japan		Athens, Greece*	
				DT <sub>50</sub> (days)	DT <sub>90</sub> (days)	DT <sub>50</sub> (days)	DT <sub>90</sub> (days)
Irradiated	2.1	0.3211	8.09	14.6	49.3	10.7	36.0
Dark control	92.4	0.0075	1.99	n.a.	n.a.	n.a.	n.a.

\* Values re-calculated from DT<sub>50</sub> and DT<sub>90</sub> for Tokyo light conditions

I. Material and Methods

A. Materials

1. Test Material: [Phenyl-UL-<sup>14</sup>C]Foramsulfuron  
Specific radioactivity: 216 MBq/mg (63.1 mCi/mmol; 309605 dpm/μg)  
Radiochemical purity: 97.8%  
Chemical purity: not reported  
Sample ID: C-1193

2. Test water

The natural water used for the test was freshly collected (0 to 15 cm depth) from a lake at ██████████, Kan US. Water samples were characterized as summarised in Table 7.2.1.3-2.





Table 7.2.1.3-2: Physico-chemical characteristics of unfiltered test water

Water	Olathe
pH	8.3
Dissolved oxygen concentration at collection (mg/L)	8.1
Calcium (mg/kg)	46
Magnesium (mg/kg)	11
Hardness (CaCO <sub>3</sub> -equiv.; mg/L)	162
Electrical conductivity (mmho/cm)	0.40
Total dissolved solids (mg/kg)	260
Total organic carbon (mg/kg)	3.8
Dissolved Organic Carbon (DOC, mg/L)	3.5
Total nitrogen (mg/L)	0.9
Total phosphorus (mg/L)	0.9

Before start of irradiation the corresponding <sup>14</sup>C-treated natural water was passed through a sterile filter into the sterilized test vessels.

## B. Study design

**1. Experimental conditions:** The test was performed with phenyl-<sup>14</sup>C-foramsulfuron at an initial concentration of 1.00 mg/L. The test vessels consisted of quartz glass vessels without traps for volatile components with each sample containing 20 mL of the sterile test solution. The test solutions contained 0.1% acetonitrile as co-solvent. Duplicate samples were continuously irradiated in a Suntest system at 25 ± 1 °C with simulated sunlight (xenon burner, range of wave length spectrum 290 – 3000 nm, i.e. spectral distribution similar to that of natural sunlight) providing a light intensity of 680 W/m<sup>2</sup> with cut-off of UV radiation < 290 nm by the use of filters (Suprax). In parallel, samples were incubated at the same temperature in the dark in a temperature-controlled chamber thus serving as dark controls. Based on intensity measurements a continuous light exposure of 5.6 days (118 experimental hours) was equivalent to 34 environmental days when being compared to light conditions at Tokyo, Japan, in June (summer solstice).

Duplicates of irradiated samples were removed for analysis after 0, 0.33, 1, 2, 3, 4 and 5 days of irradiation.

Duplicates of dark controls were removed for analysis after 0, 1, 2, 3 and 5 days of incubation.

The pH was determined for irradiated samples at each sampling interval while sterility was checked for dark controls after 0, 3 and 5 days of incubation.

**2. Analytical procedures:** Samples were analysed directly with no additional steps for extraction, clean-up, or sample concentration using LSC for determination of total radioactivity. Reversed-phase HPLC with <sup>14</sup>C-flow-through detection techniques was used as primary chromatographic method for the separation and quantitation of products formed accompanied by thin-layer chromatography (TLC) and <sup>14</sup>C-detection as confirmatory method. HPLC analysis was performed within one day after work-up. Representative samples were additionally investigated by HPLC-MS-MS for identification of transformation products.

Based on the lowest integrable peak within <sup>14</sup>C-flow-through detection, the LOD was estimated to be about 0.6% of AR.

**3. Kinetic evaluation:** The kinetic evaluation of foramsulfuron degradation data was performed with the software KinGui, Version 1.1 by using the SFO model<sup>5</sup> for fitting. Values for half-lives and  $t_{90}$  were calculated for each set of data. The quality of fit was expressed in terms of  $\text{Chi}^2$  error.

## II. Results and Discussion

The total irradiation time of 5.0 days (118 experimental hours) corresponded to 34 environmental days under light conditions of Tokyo, Japan in June to reflect a worst-case approach. Sterility of samples was confirmed throughout the whole testing period. The pH of aqueous buffer was shown to be in a narrow range from 7.85 to 8.25 in the course of the experiment. The temperature was maintained at  $25 \pm 2$  °C for irradiated samples and dark controls during the test.

The material balances and distribution of radioactivity are summarised for irradiated samples and dark controls in Table 7.2.1.3-3. The mean material balances were  $101.1\% \pm 0.9\%$  AR for irradiated samples and  $101.8\% \pm 2.0\%$  for dark controls. The complete material balances indicate no significant losses of radioactivity from samples in the course of the test including processing till analysis. Experiences from other tests had shown that no formation of  $^{14}\text{C}$ -carbon dioxide or other volatile components had to be expected with therefore no determination of volatiles during this test. This was again confirmed by the complete recoveries found.

In irradiated samples, foramsulfuron showed a decrease from 94.4% AR at time zero to 11.0% after 5 days while degradation of foramsulfuron was negligible in dark controls as it is documented by values of 94.4% AR at time zero to 89.7% after 5 days of incubation. Irradiation resulted in a complex pattern of transformation products with formation of at least 16 minor components in maximum with individual peaks amounting to 7.6% in maximum (day 3). This large number of components detected as minor fractions added up to a maximum values of 57.6% after 5 days (Table 7.2.1.3-3).

Following irradiation, AE F130619 (foramsulfuron-amine, BCS-AU59648), 4-formamido-N-methylbenzamide (FMB, BCS-CW90756) and 4-amino-N-methylbenzamide (AMB, BCS-CV29520) were formed as major products at maximum values of 10.7% (day 1), 19.7% (day 3) and 12.8% (day 4), respectively. Additionally, foramsulfuron sulfonic acid was found as a minor product at 6.7% AR in maximum (day 4).

The major and distinct transformation products observed requiring further assessment in environmental exposure assessments are summarised in Table 7.2.1.3-4.

The resulting photolytic pathway is summarised for both positions of radiolabel investigated in Figure 7.2.1.3-1.

<sup>5</sup> SFO = Single First Order



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Foramsulfuron

Table 7.2.1.3-3: Phototransformation of [phenyl-UL-<sup>14</sup>C]foramsulfuron in sterile natural water, expressed as percentage of total applied radioactivity

Component	Irradiated	Sampling interval (days)						
		0.0	0.33	1	2	3	4	5
	Dark control	0.0	-	1	2	3	-	5
Foramsulfuron (Parent compound)	Irradiated	94.4 ± 0.3	88.0 ± 0.7	72.6 ± 0.8	53.0 ± 0.5	46.9 ± 4.6	20.8 ± 1.2	11.0 ± 6.3
	Dark control	94.4 ± 0.3	-	95.4 ± 0.1	94.8 ± 0.9	95.9 ± 0.2	-	90.7 ± 1.0
AE F130619 (Foramsulfuron amine)	Irradiated	5.6 ± 0.2	7.1 ± 0.1	10.7 ± 1.3	12.2 ± 1.3	7.9 ± 1.1	5.9 ± 0.5	2.6 ± 3.7
	Dark control	5.6 ± 0.2	-	5.4 ± 0.4	5.9 ± 0.1	5.9 ± 0.3	-	6.2 ± 0.8
4-Formamido-N-methylbenzamide (BCS-CW90756)	Irradiated	0.0 ± 0.0	1.1 ± 0.2	3.6 ± 1.8	13.4 ± 0.7	19.7 ± 4.2	16.1 ± 1.6	14.4 ± 4.2
	Dark control	0.0 ± 0.0	-	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	-	0.0 ± 0.0
Foramsulfuron sulfonic acid*	Irradiated	0.0 ± 0.0	1.4 ± 0.2	3.2 ± 0.3	4.1 ± 0.3	5.5 ± 1.1	6.0 ± 0.4	6.0 ± 0.7
	Dark control	0.0 ± 0.0	-	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	-	0.0 ± 0.0
4-Amino-N-methylbenzamide (BCS-CV29520)	Irradiated	0.0 ± 0.0	0.0 ± 0.0	1.3 ± 1.8	4.6 ± 1.8	5.0 ± 0.8	12.8 ± 1.5	9.5 ± 8.5
	Dark control	0.0 ± 0.0	-	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	-	0.0 ± 0.0
Total unidentified radioactivity (each <8%)	Irradiated	0.0 ± 0.0	0.0 ± 0.0	2.9 ± 0.9	16.0 ± 0.8	14.8 ± 1.4	36.2 ± 6.9	57.6 ± 14.3
	Dark control	0.0 ± 0.0	-	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	-	0.0 ± 0.0
Total number of individual unknown transformation products	Irradiated	0	0	2	2	4	12	16
	Dark control	0	-	0	0	0	-	0
Highest value for individual unknown transformation products	Irradiated	0.6	3.8	2.0	8.0*	7.6	5.2	7.3
	Dark control	0.8	-	1.4	3.1	2.9	-	4.1
Total extractable	Irradiated	100.0 ± 0.4	101.1 ± 1.0	99.3 ± 0.2	100.3 ± 0.2	100.0 ± 0.4	98.4 ± 1.1	101.0 ± 1.5
	Dark control	100.0 ± 0.4	-	100.8 ± 0.3	100.7 ± 1.0	101.8 ± 0.1	-	96.7 ± 1.8
<sup>14</sup> C-Carbon dioxide	Irradiated	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	Dark control	n.d.	-	n.d.	n.d.	n.d.	-	n.d.
Volatile radioactivity	Irradiated	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	Dark control	n.d.	-	n.d.	n.d.	n.d.	-	n.d.
Total % recovery	Irradiated	100.0 ± 0.4	101.1 ± 1.0	99.3 ± 0.2	100.3 ± 0.2	100.0 ± 0.4	98.4 ± 1.1	101.0 ± 1.5
	Dark control	100.0 ± 0.4	-	100.8 ± 0.3	100.7 ± 1.0	101.8 ± 0.1	-	96.7 ± 1.8



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Unless specified otherwise, mean values of duplicate sample analysis ± SD; n.d. = not determined

\* Value for component 'K' shown to consist of multiple components being part of polar mixture

Please note: For consistency, the abbreviation FSA should be reserved for foramsulfuron sulfamic acid (BCS-AW41401) while there is no BCS code for the foramsulfuron sulfonic acid found here

**Table 7.2.1.3-4: Products of indirect photochemical degradation of phenyl-UL-<sup>14</sup>C-labeled foramsulfuron in sterile natural water**

Label	Label position	Component	Maximum fraction (% AR)	Maximum occurrence after days
1	phenyl	AE F1306 (Foramsulfuron amine)	90.7	1
		4-Formamido-N-methylbenzamide (BCS-GW90756, FMB)	19	4
		4-Amino-N-methylbenzamide (BCS-CV29520, AMB)	12.9	4

\* Total duration was 5 days (118 hours)

The experimental DT<sub>50</sub> values for foramsulfuron in irradiated and in dark control samples were calculated by applying a simple first order kinetic model.

For phenyl-labelled foramsulfuron the experimental half-life was determined to 21 days for irradiated samples while degradation was slow in dark control showing a DT<sub>50</sub> of 92.4 days. The experimental DT<sub>50</sub> has been calculated to 21 days (Table 7.2.1.3-5) with no correction for (insignificant) degradation processes in the dark. When transferring this result to outdoor conditions considering the (lower) light intensities of natural sunlight, half-lives were 14.6 days for Tokyo, Japan or, 10.7 days for Athens, Greece.

**Table 7.2.1.3-5: Kinetics of indirect photochemical degradation of phenyl-UL-<sup>14</sup>C-labeled foramsulfuron in sterile natural water**

Single First Order Model				Calculated for natural light conditions at			
Test system	Experimental DT <sub>50</sub> (days)	Rate constant (days <sup>-1</sup> )	Chi <sup>2</sup> Err	Tokyo, Japan		Athens, Greece*	
				DT <sub>50</sub> (days)	DT <sub>90</sub> (days)	DT <sub>50</sub> (days)	DT <sub>90</sub> (days)
Irradiated	21	0.3211	8.09	14.6	49.3	10.7	36.0
Dark control	92.4	0.0075	1.19	n.a.	n.a.	n.a.	n.a.

\* Values re-calculated from DT<sub>50</sub> and DT<sub>90</sub> for Tokyo light conditions

**III. Conclusion**

The indirect photolytic transformation of foramsulfuron in sterile natural water was moderate to result in a photolytic half-life of 10.7 environmental days when being referenced to natural light conditions of Athens, Greece.



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Application of phenyl-UL-<sup>14</sup>C-labeled foramsulfuron resulted in formation of major photo-degradation products AE F130619 (foramsulfuron amine), 4-formamido-N-methylbenzamide (FMB, BCS-CW90756) and 4-amino-N-methylbenzamide (AMB, BCS-CV29520) observed at maximum values of 10.7%, 19.7% and 12.8% AR in the course of the study.

Indirect photolysis may therefore contribute to a limited extent to the overall elimination of foramsulfuron from the aquatic environment.

<b>Report:</b>	[REDACTED]; [REDACTED] 2008;M-327230-01
<b>Title:</b>	[Pyrimidine-2- <sup>14</sup> C] foramsulfuron: Phototransformation in natural water
<b>Report No:</b>	MEFSU001
<b>Document No:</b>	M-327230-01-1
<b>Guidelines:</b>	Japanese MAFF New Test Guidelines for Supporting Registration of Chemical Pesticides 12 Nousan 8147, adopted November 24, 2000, amended March 31, 2008, Annex No. 2-6-2; US EPA Subdivision N, Section 161-2; The certificates of analysis for two reference compounds were expired at the time of the study. However, identity was confirmed within the study and no quantitative comparisons were made. There is no effect on the study.
<b>GLP/GEP:</b>	yes

**Executive Summary**

The photolysis of pyrimidine-2-<sup>14</sup>C-labeled foramsulfuron was investigated in sterile natural water at pH 8.3 at a concentration of 10 mg a.s./L. Samples were continuously irradiated at 25 ± 2 °C with artificial sunlight (< 290 nm cut-off filter) for 5 days (119 experimental hours) equivalent to 34 environmental days of light intensity at summer solstice (June) at Tokyo, Japan.

The mean recovered radioactivity was above 95% for all samples. Values for foramsulfuron in irradiated samples decreased from 97.5% of AR at time zero to 13.5% after 5 days.

Irradiation resulted in the formation of AE F099095 (foramsulfuron urea), foramsulfuron sulfamic acid (BCS-AW41401) and AE F092944 (foramsulfuron pyrimidinamine) at maximum values of 19.7% (day 5), 17.6% (day 5) and 26.5% (day 5), respectively. Additionally, AE F130619 (foramsulfuron amine) was found as a minor product at 6.1% AR in maximum (day 1).

Formation of other minor degradation products was extensive amounting to at least 13 components with none of these components exceeding 7.2% in the course of the study. In dark controls, no significant degradation of the <sup>14</sup>C-test substance was observed resulting in insignificant formation of degradation products.

Values of the DT<sub>50</sub> and DT<sub>90</sub> for the photolysis of foramsulfuron in sterile natural water were determined according to the recommendations of the FOCUS work group. Following simple first order (SFO) kinetics the results are summarised in Table 7.2.1.3-6.

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Table 7.2.1.3-6: Kinetics of indirect photolytic degradation of [pyrimidine-2-<sup>14</sup>C]foramsulfuron in sterile natural water

Single First Order Model, pyrimidine label				Calculated for natural light conditions at			
				Tokyo, Japan		Athens, Greece*	
Test system	Experimental DT <sub>50</sub> (days)	Rate constant (days <sup>-1</sup> )	Chi <sup>2</sup> Err	DT <sub>50</sub> (days)	DT <sub>90</sub> (days)	DT <sub>50</sub> (days)	DT <sub>90</sub> (days)
Irradiated	1.9	0.3618	5.18	13.2	14.4	13.6	22.0
Dark control	65.9	0.0105	2.11	n.a.	n.a.	n.a.	n.a.

\* Values re-calculated from DT<sub>50</sub> and DT<sub>90</sub> for Tokyo light conditions

### I. Material and Methods

#### A. Materials

- 1. Test Material:** [Pyrimidine-2-<sup>14</sup>C]foramsulfuron  
Specific radioactivity: 4.71 MBq/mg (35.2 mCi/mmol; 270,440 dpm/μg)  
Radiochemical purity: 100%  
Chemical purity: not reported  
Sample ID: C-1102

#### 2. Test water

The natural water used for the test was freshly collected (0 to 15 cm depth) from a lake at ██████████, KS, US. Water samples were characterized as summarised in Table 7.2.1.3-7.

Table 7.2.1.3-7: Physico-chemical characteristics of unfiltered test water

Water	Olathe
pH	7.9
Dissolved oxygen concentration at collection (mg/L)	4.1
Calcium (mg/kg)	31
Magnesium (mg/kg)	8.3
Hardness (CaCO <sub>3</sub> -equiv.; mg/L)	113
Electrical conductivity (μmho/cm)	0.40
Total dissolved solids (mg/kg)	126
Total organic carbon (mg/kg)	5.9
Dissolved Organic Carbon (DOC, mg/L)	4.8
Total nitrogen (mg/L)	0.9
Total phosphorus (mg/L)	1.1

Before start of irradiation the corresponding <sup>14</sup>C-treated natural water was passed through a sterile filter into the sterilized test vessels.

#### B. Study design

- 1. Experimental conditions:** The test was performed with pyrimidinyl-2-<sup>14</sup>C-foramsulfuron at an initial concentration of 1.00 mg/L. The test vessels consisted of quartz glass vessels without traps for volatile components with each sample containing 20 mL of the sterile test solution. The test solutions contained 0.1% acetonitrile as co-solvent. Duplicate samples were continuously irradiated in a <sup>®</sup>Suntest system at 25 ± 1 °C with simulated sunlight (xenon burner, range of wave length spectrum 290 – 3000 nm, i.e.



spectral distribution similar to that of natural sunlight) providing a light intensity of 680 W/m<sup>2</sup> with cut-off of UV radiation < 290 nm by the use of filters (Suprax). In parallel, samples were incubated at the same temperature in the dark in a temperature-controlled chamber thus serving as dark controls. Based on intensity measurements a continuous light exposure of 5.0 days (119 experimental hours) was equivalent to 34 environmental days when being compared to light conditions at Tokyo, Japan, in June (summer solstice).

Duplicates of irradiated samples were removed for analysis after 0, 0.33, 1, 2, 3, 4 and 5 days of irradiation.

Duplicates of dark controls were removed for analysis after 0, 1, 2, 3 and 5 days of incubation. The pH was determined for irradiated samples at each sampling interval while sterility was checked for dark controls after 0, 3 and 5 days of incubation.

**2. Analytical procedures:** Samples were analysed directly with no additional steps for extraction, clean-up, or sample concentration using LSC for determination of total radioactivity. Reversed-phase HPLC with <sup>14</sup>C-flow-through detection techniques was used as primary chromatographic method for the separation and quantitation of products formed accompanied by thin-layer chromatography (TLC) and <sup>14</sup>C-detection as confirmatory method. HPLC analysis was performed within one day after work-up. Representative samples were additionally investigated by HPLC-MS-MS for identification of transformation products.

Based on the lowest integrable peak within <sup>14</sup>C-flow-through detection the LOD was estimated to be about 0.6% of AR.

**3. Kinetic evaluation:** The kinetic evaluation of foramsulfuron degradation data was performed with the software KinGui, Version 1.1 by using the SFO<sup>6</sup> model<sup>6</sup> for fitting. Values for half-lives and DT90 were calculated for each set of data. The quality of fit was expressed in terms of Chi<sup>2</sup> error.

## II. Results and Discussion

The total irradiation time of 5.0 days (119 experimental hours) corresponded to 34 environmental days under light conditions of Tokyo, Japan in June to reflect a worst-case approach.

Sterility of samples was confirmed throughout the whole testing period. The pH of aqueous buffer was shown to be in a narrow range from 7.85 to 8.25 in the course of the experiment. The temperature was maintained at 25 ± 2 °C for irradiated samples and dark controls during the test.

The material balances and distribution of radioactivity are summarised for irradiated samples and dark controls in Table 7.2.1.3-8. The mean material balances were 100.8% ± 0.6% AR for irradiated samples and 99.8% ± 2.8% for dark controls. The complete material balances indicate no significant losses of radioactivity from samples in the course of the test including processing till analysis.

Experiences from other tests had shown that no formation of <sup>14</sup>C-carbon dioxide or other volatile components had to be expected with therefore no determination of volatiles during this test. This was again confirmed by the complete recoveries found.

In irradiated samples foramsulfuron showed a decrease from 97.5% AR at time zero to 13.5% after 5 days. Degradation of foramsulfuron was negligible in dark controls as it is documented by values of 97.5% AR at time zero to 92.8% after 5 days of incubation.

<sup>6</sup> SFO = Single First Order



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Irradiation resulted in a complex pattern of transformation products with formation of at least 13 minor components in maximum with individual peaks amounting to 7.2% in maximum (day 4). This large number of components detected as minor fractions added up to a maximum values of 28.8% after 7 days (Table 7.2.1.3-8).

Irradiation of foramsulfuron resulted in the formation of the urea-type compound AE F099095 (foramsulfuron urea), foramsulfuron sulfamic acid (BCS AW41401) and AE F092944 (foramsulfuron pyrimidinamine) at maximum values of 19.7% (day 5), 17.6% (day 5) and 26.5% (day 5), respectively. Additionally, AE F130619 (foramsulfuron amine) was found as a minor product at 0.1% AR in maximum (day 1).

The major and distinct transformation products observed requiring further assessment in environmental exposure assessments are summarised in Table 7.2.1.3-9.

The resulting photolytic pathway is summarised in Figure 7.2.1.3-1.

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Table 7.2.1.3-8: Indirect phototransformation of [pyrimidine-2-<sup>14</sup>C]foramsulfuron in sterile natural water, expressed as percentage of total applied radioactivity

Component	Irradiated	Sampling interval (days)						
		0.0	0.33	1	2	3	4	5
	Dark control	0.0	-	1	2	3	-	5
Foramsulfuron (Parent compound)	Irradiated	97.5 ± 1.1	84.3 ± 5.4	64.2 ± 2.0	51.5 ± 7.8	36.8 ± 10.2	17.9 ± 4.0	13.5 ± 9.7
	Dark control	97.5 ± 1.1	-	99.0 ± 0.4	90.8 ± 0.2	96.1 ± 0.2	-	92.8 ± 0.2
AE F130619 (Foramsulfuron amine)	Irradiated	0.0 ± 0.0	3.1 ± 1.7	6.1 ± 1.5	1.4 ± 0.5	5.2 ± 0.2	2.4 ± 0.3	2.3 ± 0.4
	Dark control	0.0 ± 0.0	-	0.0 ± 0.0	1.0 ± 0.2	1.0 ± 0.1	-	1.5 ± 0.5
AE F099095 (Foramsulfuron urea)	Irradiated	0.0 ± 0.0	1.1 ± 0.6	1.0 ± 0.5	10.5 ± 2.6	13.7 ± 2.0	16.0 ± 4.8	17.7 ± 1.5
	Dark control	0.0 ± 0.0	-	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	-	0.0 ± 0.0
Foramsulfuron sulfamic acid (BCS-AW41401)	Irradiated	0.0 ± 0.0	1.1 ± 1.1	9.7 ± 0.9	12.3 ± 2.0	15.5 ± 1.8	18.8 ± 3.3	17.6 ± 0.3
	Dark control	0.0 ± 0.0	-	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	-	0.0 ± 0.0
AE F092944 (Foramsulfuron pyrimidinamine)	Irradiated	2.5 ± 0.3	6.5 ± 1.8	12.6 ± 0.8	15.3 ± 0.7	17.4 ± 0.3	19.9 ± 0.9	26.5 ± 6.9
	Dark control	2.5 ± 0.3	-	3.0 ± 0.0	3.5 ± 0.0	3.7 ± 0.0	-	6.2 ± 0.3
Total unidentified radioactivity (each <8%)	Irradiated	0.0 ± 0.0	0.6 ± 0.8	1.5 ± 0.0	7.7 ± 0.2	12.4 ± 1.7	28.8 ± 15.0	21.0 ± 2.4
	Dark control	0.0 ± 0.0	-	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	-	0.0 ± 0.0
Total number of individual unknown transformation products	Irradiated	0	1	1	3	3	13	n.d.
	Dark control	0	-	-	-	0	-	0
Highest value for individual unknown transformation products	Irradiated	0.0	0.6	1.5	4.8*	8.9*	7.2*	17.9*
	Dark control	0.0	-	0.0	0.0	0.0	-	0.0
Total extractable	Irradiated	100.0 ± 1.4	100.4 ± 0.5	101.0 ± 0.3	101.9 ± 0.2	101.1 ± 1.3	100.8 ± 1.0	100.6 ± 0.3
	Dark control	100.0 ± 1.4	-	102.4 ± 0.5	95.1 ± 0.2	101.1 ± 0.1	-	100.5 ± 0.1
<sup>14</sup> C-Carbon dioxide	Irradiated	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	Dark control	n.d.	-	n.d.	n.d.	n.d.	-	n.d.
Volatile radioactivity	Irradiated	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	Dark control	n.d.	-	n.d.	n.d.	n.d.	-	n.d.
Total % recovery	Irradiated	100.0 ± 1.4	100.4 ± 0.5	101.0 ± 0.3	101.9 ± 0.2	101.1 ± 1.3	100.8 ± 1.0	100.6 ± 0.3
	Dark control	100.0 ± 1.4	-	102.4 ± 0.5	95.1 ± 0.2	101.1 ± 0.1	-	100.5 ± 0.1

Unless specified otherwise, mean values of duplicate sample analysis ± SD.; n.d. = not determined

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\* Value for polar mixture consisting of multiple components

Table 7.2.1.3-9: Products of indirect phototransformation of [pyrimidine-2-<sup>14</sup>C]foramsulfuron in sterile natural water

Label	Label position	Component	Maximum fraction (% AR)	Maximum occurrence after days *
2	2- pyrimidyl	AE F099095 (Foramsulfuron urea)	19.7	5
		Foramsulfuron sulfamic acid (BCS-AW41401)	17.6	5
		AE F092944 (Foramsulfuron pyrimidinamine, 2-Amino-4,6-dimethoxypyrimidine)	26.5	5

\* Total duration was 5 days (119 hours)

The experimental DT<sub>50</sub> values for foramsulfuron in irradiated and in dark control samples were calculated by applying a simple first order kinetic model.

The experimental half-life foramsulfuron was determined to 1.9 days for irradiated samples while degradation was slow in dark controls showing a DT<sub>50</sub> of 65.9 days. The experimental DT<sub>50</sub> has been calculated to 1.9 days (Table 7.2.1.3-10) with no correction for (insignificant) degradation processes in the dark. When transferring this result to outdoor conditions considering the (lower) light intensities of natural sunlight, half-lives were 13.2 days for Tokyo, Japan or, 9.6 days for Athens, Greece.

Table 7.2.1.3-10: Kinetics of indirect phototransformation of [pyrimidine-2-<sup>14</sup>C]foramsulfuron in sterile natural water

Single First Order Model, pyrimidine label				Calculated for natural light conditions at			
Test system	Experimental DT <sub>50</sub> (days)	Rate constant (days <sup>-1</sup> )	Chi <sup>2</sup> Err	Tokyo, Japan		Athens, Greece	
				DT <sub>50</sub> (days)	DT <sub>90</sub> (days)	DT <sub>50</sub> (days)	DT <sub>90</sub> (days)
Irradiated	1.9	0.3618	5.18	13.2	44.4	9.6	32.0
Dark control	65.9	0.0105	2.11	n.a.	n.a.	n.a.	n.a.

### III. Conclusion

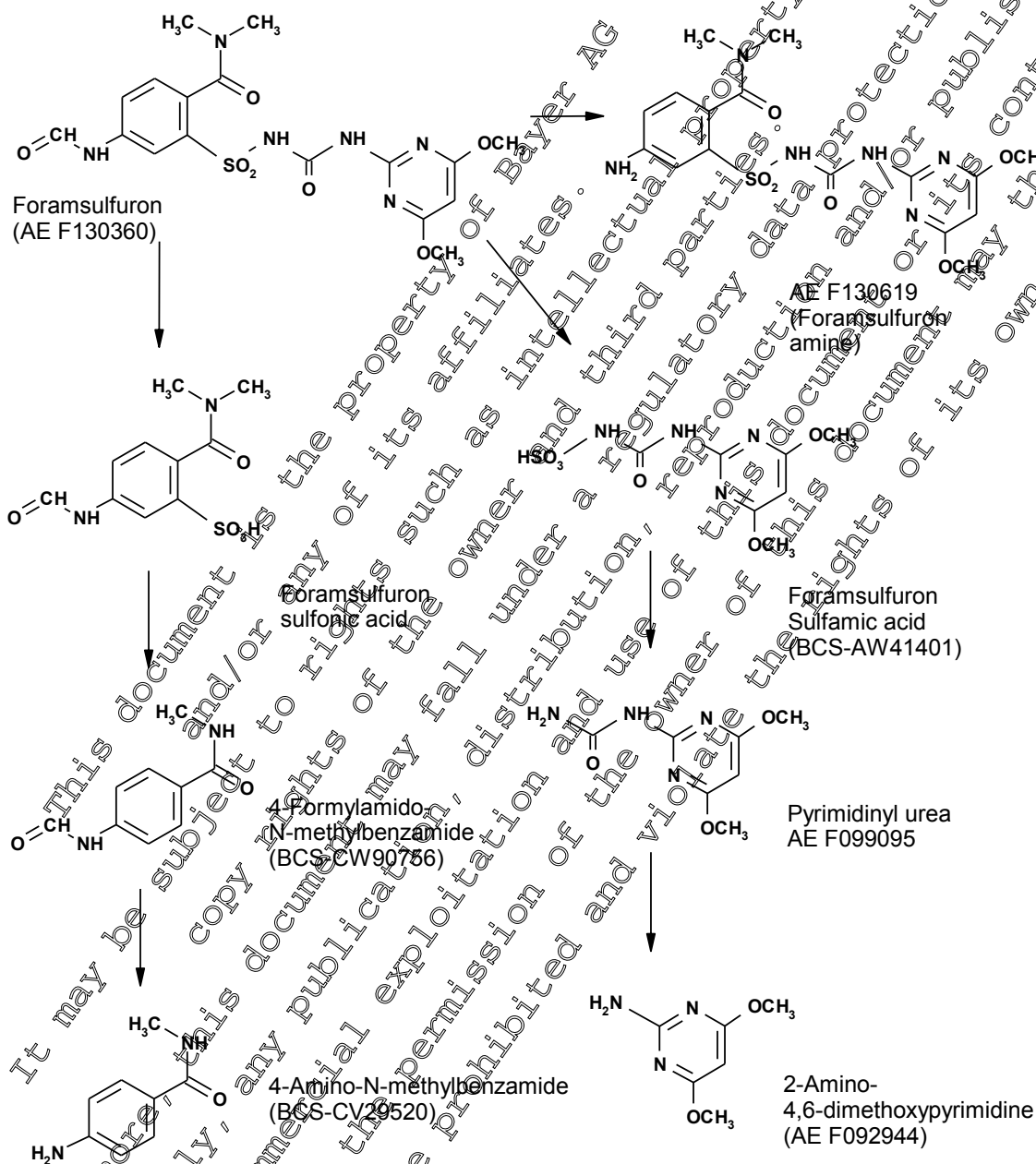
The indirect photolytic transformation of foramsulfuron in sterile natural water was moderate to result in a photolytic half-life of 9.6 environmental days when being referenced to natural light conditions of Athens, Greece.

Following irradiation of pyrimidine-2-<sup>14</sup>C-labeled foramsulfuron major photo-degradation products formed were AE F099095 (foramsulfuron urea) at a maximum of 19.7%, sulfamic acid (BCS-AW41401) at 17.6% of AR and AE F092944 (2-amino-4,6-dimethoxypyrimidine) at 26.5% in the course of the study.

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Indirect photolysis may therefore contribute to a limited extent to the overall elimination of foramsulfuron from the aquatic environment.

Figure 7.2.1.3-1: Indirect photolytic degradation after application of phenyl- or pyrimidine-labelled foramsulfuron to sterile natural water



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**CA 7.2.2 Route and rate of biological degradation in aquatic systems**

**CA 7.2.2.1 "Ready biodegradability"**

The ready biodegradability of foramsulfuron was not investigated experimentally.

The data requirement was addressed under Point 7.2.1.3.1 of the Dossier submitted and evaluated within the process for Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments. Consequently there is no detailed description in this update.

The evaluation revealed that foramsulfuron can be regarded as not readily biodegradable which is supported by the results of biological degradation tests performed on aerobic mineralization in surface water and sediment/water in addition.

**CA 7.2.2.2 Aerobic mineralisation in surface water**

The aerobic mineralisation of foramsulfuron in surface water was investigated in

- non-sterile natural water of pH 7.5 at 22°C and at two test concentrations following application of phenyl-UL-<sup>14</sup>C-labeled active substance (CA 7.2.2.2.1).

Being a new data requirement this point was not addressed in the original Dossier submitted and evaluated within the process for Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments.

<b>Report:</b>	[redacted]; 2013; M-453421-01
<b>Title:</b>	phenyl-UL- <sup>14</sup> C-Foramsulfuron: Aerobic Mineralization in surface water
<b>Report No:</b>	D62860
<b>Document No:</b>	M-453421-01-1
<b>Guidelines:</b>	OECD Test Guideline No. 309, not specified
<b>GLP/GEP:</b>	yes

**Executive Summary**

The mineralisation of phenyl-UL-<sup>14</sup>C-labeled foramsulfuron was investigated in non-sterile natural water at pH 7.5 at two test concentrations of 10.90 µg a.s./L (low dose) and 108.5 µg a.s./L (high dose). Samples were incubated at 21.7-20.6 °C in the dark for a maximum of 58 days. Microbial activity of the test water was demonstrated by incubation of <sup>14</sup>C-phenyl-labeled benzoic acid in reference controls. The overall mean of the total recovered radioactivity was above 98% for treated samples of both doses. Values of the test substance in the test water decreased insignificantly from 96.2% of AR for low dose (98.3% for high dose) at time zero to 93.8% (94.3% for high dose) at the end of the test.

Formation of other degradation products including volatile components and carbon dioxide was minimal accounting for less than 5% in maximum for a single component in the course of the study.

Values of the DT<sub>50</sub> and DT<sub>90</sub> for the mineralization of foramsulfuron could not be determined due to the insufficient decline observed under the conditions of the test.

## I. Material and Methods

### A. Materials

- 1. Test Material:** [Phenyl-UL-<sup>14</sup>C]Foramsulfuron  
 Specific radioactivity: 4.44 MBq/mg  
 Radiochemical purity: 96.4%  
 Chemical purity: not reported  
 Sample ID: KML 9377 / 253773/A

### 2. Test water

The natural water used for the test was freshly collected (0 to 15 cm depth) from a lake at 0 Aargau (AG), Switzerland. Water samples were characterized as summarised in Table 7.2.2.2-1.

Table 7.2.2.2-1: Physico-chemical characteristics of test water

Water	Froeschweiler Pond
pH	7.1
Colour	Light yellow-brown
Dissolved oxygen concentration at collection (mg/L)	7.1
Total hardness (°dH)	12.0
Biological oxygen demand (mg/L)	<0.5
Total organic carbon (TOC, mg/L)	3.1
Dissolved Organic Carbon (DOC, mg/L)	14.1
Total phosphorus (mg/L)	0.21
Dissolved orthophosphate (mg/L)	0.003
Total nitrogen (mg/L)	0.76
Nitrate NO <sub>3</sub> <sup>-</sup> (mg/L)	6.54
Nitrite NO <sub>2</sub> <sup>-</sup> (mg/L)	<0.8
Ammonium NH <sub>4</sub> <sup>+</sup> (mg/L)	2.94

Before start of incubation the test water was passed through a 0.2 mm sieve.

### B. Study design

**1. Experimental conditions:** Samples of 600 ml test water each were filled into all-glass incubation flasks and pre-equilibrated prior to treatment at approximate study conditions (darkness, 20 °C) for 6 days. The test was performed with phenyl-UL-<sup>14</sup>C-foramsulfuron at initial concentrations of 10.9 µg/L (low dose) and 108.5 µg/L (high dose). Following application the samples were attached to flow-through systems allowing moisturized air to pass through and with traps to collect <sup>14</sup>C-carbon dioxide and other volatiles (2 M aqueous potassium hydroxide and ethylene glycol). Samples were incubated at 21.7 ± 0.6 °C in the dark for 58 days in maximum.

In addition samples containing untreated water, solvent controls and biological controls were incubated under the same conditions and removed for analysis at selected time points. Solvent controls and biological controls contained the reference substance UL-<sup>14</sup>C-phenyl-benzoic acid.

**2. Sampling:** Duplicate samples each of both test concentrations were removed for analysis after 0, 7, 14, 21, 28 and 58 days of incubation.

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Samples for determination of microbial activity (biological controls) were investigated after 0, 3 and 18 days of incubation. Solvent controls were taken for analysis after 18 days of incubation. Finally, sterile controls were removed for analysis after 78 days.

The complete samples were immediately processed and HPLC analysis was usually performed the same day. Therefore no additional investigations of storage stability were necessary.

The pH, oxygen concentration and the redox potential was determined at each sampling interval.

**3. Analytical procedures:** The water of high dose samples was analysed directly while samples of the low dose were concentrated under reduced pressure (rotary evaporation, 35°C) prior to analysis. The <sup>14</sup>C-material balance was established for each sample following analysis of the water and determination of volatile radioactivity in the traps. For high dose samples and following quantitation of radioactivity in water by LSC, analysis was performed by reversed phase HPLC and <sup>14</sup>C-flow through detection techniques. Samples of the low dose were analysed by TLC followed by <sup>14</sup>C detection (phosphor imaging).

Based on the lowest integrable peak, the LOD was estimated to be about 0.6% of AR.

**4. Kinetic evaluation:** No kinetic evaluation was performed.

#### **II. Results and Discussion**

The temperature was maintained at 21.7 ± 0.6 °C during the test. Biological activity of the test water was confirmed by the degradation of reference substance <sup>14</sup>C-benzoic acid within 14 days of incubation. The pH, oxygen concentration and redox potential of the test water was shown to be within the same range for treated samples and for untreated controls.

The material balances and distribution of radioactivity are summarised for irradiated samples and dark controls in Table 7.2.2.2-2 (low dose) and Table 7.2.2.2-3 (high dose). The mean material balances were 99.8% ± 0.9% AR for low dose samples and 100.4% ± 1.7% for the high dose. The complete material balances indicate no significant losses of radioactivity from samples in the course of the test including processing till analysis. Formation of <sup>14</sup>C-carbon dioxide or other volatile components was negligible to account for less than 0.1% of AR for both concentrations tested.

Biotransformation of phenyl labeled foramsulfuron was negligible to result in values of 96.2% AR at time zero to 93.8% after 58 days for the low dose and 98.3% AR at time zero to 94.3% after 58 days for the high dose. Degradation was negligible in sterile controls as it is documented by a value of 95.9% for foramsulfuron after 78 days of incubation. Formation of minor fractions added up to maximum values of 6.1% after 58 days distributed into two components with none present at more than 4.6% AR in the course of the study (Table 7.2.2.2-3).

Consequently, no major and distinct transformation products were observed requiring further assessment in environmental exposure assessments.

Since degradation of foramsulfuron was insignificant under the conditions of the test, no experimental DT<sub>50</sub>-value for foramsulfuron was calculated.



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Table 7.2.2.2-2: Degradation of [phenyl-UL-<sup>14</sup>C]foramsulfuron in low dosed samples of aerobic natural water expressed as percentage of total applied radioactivity

Component		Sampling interval (days)					
		0	7	14	21	28	58
Foramsulfuron	Mean*	96.2	96.6	95.8	95.0	95.5	93.0
	SD	±0.7	±0.9	±0.1	±0.7	±0.7	±0.6
Unknown Peak 1	Mean*	4.5	3.3	3.8	4.2	3.0	4.0
	SD	±0.5	±0.1	±0.5	±0.3	±0.6	±1.4
Unknown Peak 2	Mean*	0.0	0.0	0.0	0.0	0.8	0.8
	SD	±0.0	±0.0	±0.0	±0.0	±0.0	±1.1
Total radioactivity in water	Mean*	100.7	99.9	99.6	98.2	98.5	98.5
	SD	±0.2	±0.7	±0.3	±0.7	±0.1	±0.5
Methanol rinse	Mean*	n.a.	0.4	0.8	0.8	0.6	0.6
	SD	n.a.	±0.2	±0.1	±0.1	±0.1	±0.1
<sup>14</sup> CO <sub>2</sub>	Mean*	n.a.	<0.1	0.2	0.1	0.1	0.1
	SD	n.a.	n.a.	±0.2	n.a.	n.a.	±0.1
Other volatiles	Mean*	n.a.	<0.1	<0.1	<0.1	<0.1	0.1
	SD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total radioactivity (%)	Mean*	100.7	100.3	100.6	98.9	99.1	99.2
	SD	±0.2	±0.6	±0.3	±0.6	±0.1	±0.6

Values given as percentages of initially applied radioactivity.  
SD = standard deviation; \* Mean values of two replicates.  
n.a. = not analysed or not applicable

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Table 7.2.2.2-3: Degradation of [phenyl-UL-<sup>14</sup>C]foramsulfuron in high dosed samples of aerobic natural water, expressed as percentage of total applied radioactivity

Component		Sampling interval (days)							sterile
		0	7	14	21	28	58		
Foramsulfuron	Mean*	98.3	97.0	97.6	94.5	95.3	94.0	92.9	
	SD	±1.0	±0.4	±0.4	±0.5	±0.1	±0.8	±1.3	
Unknown Peak 1	Mean*	3.5	3.4	3.1	2.0	2.5	4.5	4.0	
	SD	±1.3	±0.2	±0.1	±0.5	±0.5	±0.4	±0.5	
Unknown Peak 2	Mean*	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	1.5	
	SD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	±0.0	
Total radioactivity in water	Mean*	101.8	100.4	100.7	97.5	97.8	98.8	102.0	
	SD	±0.2	±0.2	±0.5	±0.0	±0.5	±0.5	±0.6	
Methanol rinse	Mean*	n.a.	0.5	0.7	0.7	0.6	0.5	0.5	
	SD	n.a.	±0.1	±0.0	±0.1	±0.0	±0.0	±0.0	
<sup>14</sup> CO <sub>2</sub>	Mean*	n.a.	<0.1	0.2	0.1	0.1	0.1	<0.1	
	SD	n.a.	n.a.	±0.2	n.a.	n.a.	n.a.	n.a.	
Other volatiles	Mean*	n.a.	<0.1	<0.1	<0.1	<0.1	0.1	<0.1	
	SD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	
Total radioactivity (%)	Mean*	100.7	100.3	100.6	98.9	99.1	99.2	102.4	
	SD	±0.2	±0.6	±0.0	±0.6	±0.1	±0.6	±0.6	

Values given as percentages of initially applied radioactivity.  
SD = standard deviation; \* Mean values of two replicates.  
n.a. = not analysed or not applicable; n.d. = not detected

**III. Conclusion**

The biotransformation including mineralisation of foramsulfuron in non-sterile natural water was insignificant under the ‘pelagic’ conditions of the test.

No major transformation products were thus observed requiring consideration in environmental risk assessments.

No experimental value could be calculated for the DT<sub>50</sub> of foramsulfuron in water under conditions of aerobic mineralisation testing.





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CA 7.2.2.3 Water/sediment study

<b>Report:</b>	[redacted];2000;M-238019-01
<b>Title:</b>	Degradation of [U- <sup>14</sup> C-phenyl] and [2- <sup>14</sup> C-pyrimidyl]-AE F130360 in two contrasting sediment-water systems under laboratory aerobic conditions at 20°C
<b>Report No:</b>	B002256
<b>Document No(s):</b>	Report includes Trial Nos.: CF97E521 M-238019-01-2
<b>Guidelines:</b>	EU (=EEC): 7.2.1.3.2; PMRA: T-1-255; USEPA (=EPA): 162-3; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[redacted];2000;M-238016-01
<b>Title:</b>	The degradation of [U- <sup>14</sup> C-phenyl] and [2- <sup>14</sup> C-pyrimidyl]-AE F130360 in an anaerobic sediment/water system under laboratory conditions at 20°C AE F130360
<b>Report No:</b>	B002252
<b>Document No(s):</b>	Report includes Trial Nos.: CF97E521 M-238016-01-2
<b>Guidelines:</b>	PMRA: T-1-255; USEPA (=EPA): 162-3; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[redacted];2000;M-238381-01
<b>Title:</b>	Degradation of [U- <sup>14</sup> C-phenyl] and [2- <sup>14</sup> C-pyrimidyl]-AE F130360 in an anaerobic sediment/water system under laboratory anaerobic conditions at 10°C AE F130360
<b>Report No:</b>	B002242
<b>Document No(s):</b>	Report includes Trial Nos.: CF97E521 M-238381-01-2
<b>Guidelines:</b>	PMRA: T-1-255; USEPA (=EPA): 162-3; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[redacted];2013;M-454536-01
<b>Title:</b>	Kinetic evaluation of aerobic aquatic metabolism of foramsulfuron and its metabolites in water/sediment systems according to FOCUS kinetics
<b>Report No:</b>	ChSa-15-0228
<b>Document No:</b>	M-454536-01-1
<b>Guidelines:</b>	not applicable; not applicable
<b>GLP/GEP:</b>	no

The degradation of foramsulfuron under conditions of water/sediment testing was investigated in:

- 2 contrasting sediments and their associated water at 20°C following application of phenyl-UL-<sup>14</sup>C- or pyrimidyl-2-<sup>14</sup>C-labeled active substance (KCA 7.2.2.3 /01).

The data requirement was addressed under Point 7.2.1.3.2 of the Dossier submitted and evaluated within the process for Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments. Consequently there is no detailed description of this study in this update.

The evaluation revealed that foramsulfuron completely dissipated in water/sediment systems by a combination of partitioning to the sediment from the water phase and also degradation in water and sediment.



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Degradation of foramsulfuron proceeded via three pathways in total with de-methylation at an oxygen atom resulting in AE 0338795 to be the major route. AE 0338795 was subsequently degraded completely in the test systems.

Foramsulfuron also degraded via hydrolysis at the formamide moiety to form AE F130649 while hydrolysis at the 'sulfonyl urea bridge' resulted in the formation of AE F103745 and AE F092944. Degradation of foramsulfuron is facilitated by lower pH and microbial activity.

Half-lives for dissipation from the complete systems (water and sediment) ranged from 34 days to 55 days. The DT<sub>50</sub> for dissipation from the water phase ranged from 13 days to 21 days. The degradation was accompanied by significant formation of non-extractable residues (NER) to undergo slow further degradation within the normal organic carbon material turnover. Release of residues from NER was therefore slow with bound material readily metabolized and mineralised once being desorbed from sediment particles.

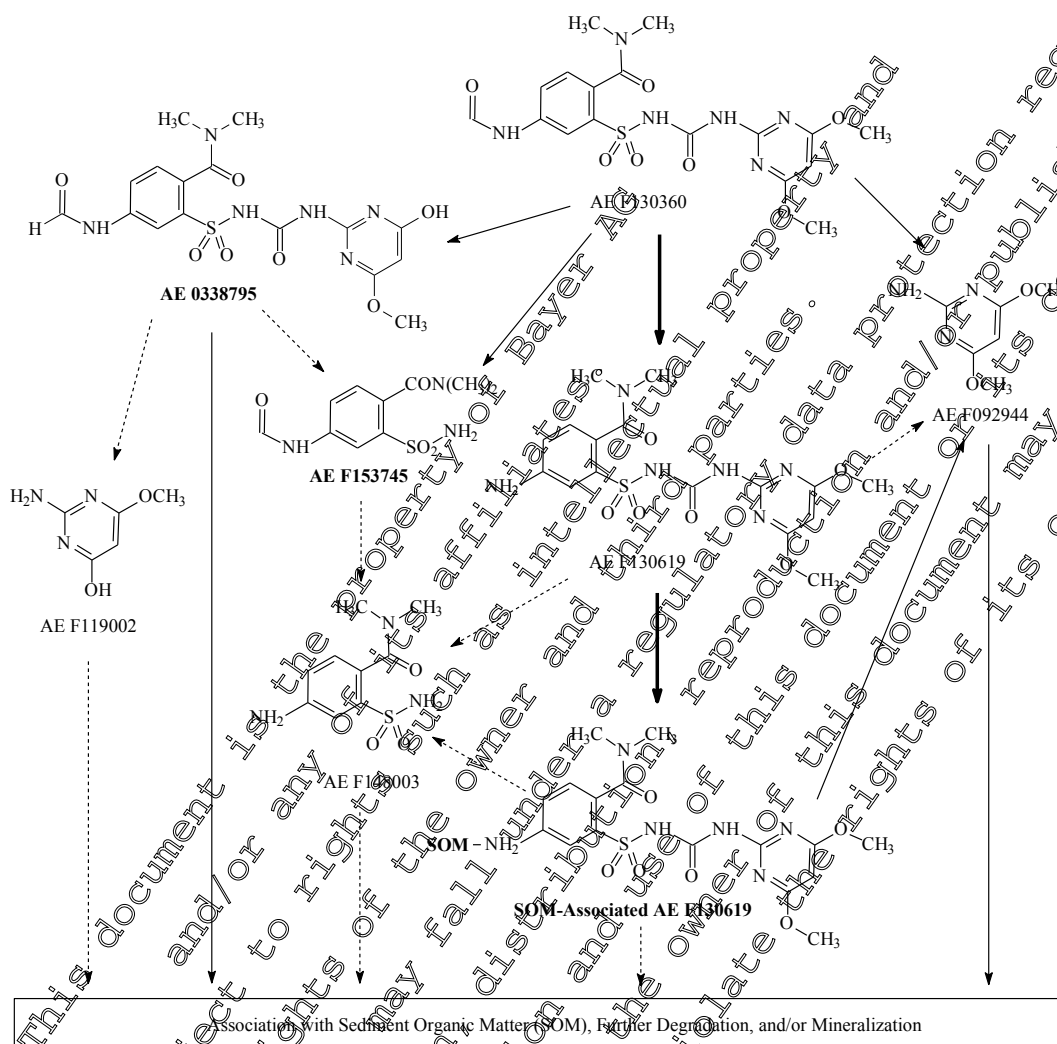
Due to their occurrence as major metabolites, at more than 10% AR in water/sediment testing, the O-de-methylated compound AE 0338795 and the sulfonamide compound AE P153745 were considered within the environmental risk assessments for surface water.

The results of degradation tests in water/sediment systems under conditions of the laboratory resulted in the metabolic pathway summarised in Figure 7.2.23-1.

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Figure 7.2.2.3-1: Proposed pathway of metabolism of foramsulfuron in water/sediment systems



Note: Compound names in boldface refer to components which are present in significant quantities.

Moreover, the degradation of foramsulfuron in anaerobic water/sediment systems was investigated in:

- 1 sediment and its associated water at 20°C following application of phenyl-UL-<sup>14</sup>C- or pyrimidyl-2-<sup>14</sup>C-labeled active substance (KCA 7.2.2.3 /02).
- 1 sediment and its associated water at 10°C following application of phenyl-UL-<sup>14</sup>C- or pyrimidyl-2-<sup>14</sup>C- labeled active substance (KCA 7.2.2.3 /03).

The data has been addressed under Point 7.2.1.3.2 of the Dossier submitted and evaluated within the process for Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments. Consequently there is no detailed description of this existing data in this update.

The data are not a requirement in the EU and thus supplemental information with no direct consideration in current environmental risk assessments.



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No separate kinetic analysis of the sediment/water degradation data had been performed within the process of Annex I Inclusion. Following new guidance introduced by FOCUS (2006) the degradation data from sediment/water testing have been kinetically re-evaluated as included under KCA 7.2.2.3 /04.

<b>Report:</b>		:2013;M-454536-01
<b>Title:</b>	Kinetic evaluation of aerobic aquatic metabolism of foramsulfuron and its metabolites in water / sediment systems according to FOCUS kinetics	
<b>Report No:</b>	EnSa-13-0228	
<b>Document No:</b>	M-454536-01-1	
<b>Guidelines:</b>	not applicable; not applicable	
<b>GLP/GEP:</b>	no	

**Executive Summary**

The kinetics of dissipation from water and sediment and the degradation of foramsulfuron in total systems were evaluated from data of tests performed in two water/sediment systems with two positions of radiolabel (KCA 7.2.2.3 /01).

The evaluation followed FOCUS kinetic guidance to derive best fits to measured data for evaluation against trigger endpoints and for use as modeling endpoints in aquatic exposure assessments. Separate analysis was performed for foramsulfuron and its metabolites AE F130619, AE 0338795, AE F153745 and AE F092944 at Level I for the compartments water, sediment and total systems.

For degradation of foramsulfuron in total systems, the dissipation from water and the dissipation from sediment SFO was found to be the appropriate kinetic model. An exception was observed for water of the Hoechst system resulting in FOMC (phenyl-label) and DFOP (pyrimidine-label) as best fits for evaluation against trigger endpoints, respectively.

Half-lives ( $DeT_{50}$ ) of foramsulfuron in total systems are estimated to range from 27.3 to 39.6 days for the two systems and two positions of radiolabel investigated to result in a geometric mean half-life of 32.9 days.

The corresponding half-lives for the dissipation of foramsulfuron from water ( $DisT_{50, water}$ ) range from 14.8 to 36.9 days resulting in a geometric mean value of 23.4 days.

The half-lives for the dissipation from sediment ( $DisO_{50, sediment}$ ) were calculated to range from 40.1 to 45.0 days resulting in a geometric mean value of 42.5 days.

The kinetic parameters at Level P-I were compiled for the active substance foramsulfuron and metabolites AE F130619, AE 0338795, AE F153745 and AE F092944 in Table 7.2.2.3-11.

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Table 7.2.2.3-1: Half-lives for the degradation of foramsulfuron in total systems and for the dissipation from water and sediment according to FOCUS Level I

Compound	System	DegT <sub>50, total system</sub> (days)	DisT <sub>50, water</sub> (days)	DisT <sub>50, sediment</sub> (days)
Foramsulfuron	Pikeville	27.3	14.8	45.0
	Hoechst Sand	30.6	36.9*	40.1
	<b>Mean (geometric)</b>	<b>32.9</b>	<b>23.4</b>	<b>42.5</b>
AE F130619	Pikeville	5.4	16.8	n.d.
	Hoechst Sand	45.8	63.3	103
	<b>Mean (geometric)</b>	<b>15.7</b>	<b>32.6</b>	<b>103</b>
AE 0338795	Pikeville	n.d.	n.d.	27.9
	Hoechst Sand	65.4	104.0	89.0
	<b>Mean (geometric)</b>	<b>65.4</b>	<b>104.0</b>	<b>49.8</b>
AE F153745	Pikeville	71	n.d.	n.d.
	Hoechst Sand	n.d.	31.2	-
	<b>Mean (geometric)</b>	<b>72</b>	<b>31.2</b>	-
AE F092944	Pikeville	110	-	147
	Hoechst Sand	-	-	-
	<b>Mean (geometric)</b>	<b>110</b>	-	<b>147</b>

Geometric mean values from two positions of radiolabel tested

\* Trigger evaluation: Best fit half-lives following FOMC kinetics are 34.4 days for the phenyl-label and 21.6 days for pyrimidine-label from DFOP kinetics

### K. Material and Methods

The kinetic evaluation was based on data of a water-sediment study (KCA 7.2.2.3/01) conducted with phenyl- and pyrimidine-labeled foramsulfuron in a sandy (Hoechst Sand) and a silty clay loam sediment (Pikeville) and their associated water at 20°C in the dark for a maximum of 365 days.

#### Data pre-processing

Generally replicates were taken into account separately. The data were checked for consistency and clear outliers. Data for non-extractable residues (NER) and CO<sub>2</sub> were not fitted within the evaluation (open system).

For the residues in the total sediment/water systems the following procedure was applied:

- For data processing of day zero samples, radioactivity assigned to metabolites, non-extractable residues (NER) and CO<sub>2</sub> was added to the parent compound and thus metabolite concentrations were set to 0 %. Parent compound was attributed to the water phase only thus resulting in a value of zero for the sediment phase since the test substance was applied to the water phase.
- Residues values below the limit of quantification (LOQ = 1 % AR) were set to 0.5 times the LOQ for the first non-detect at the end of the curve. The curve could be cut at this time point in case of no later detects. For metabolites, the last non-detect at the beginning of a curve was set to 0.5 times the LOQ for occurrences later than day 0. Samples reported as < LOQ and lying between two detects were also set to 0.5 times the LOQ.

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For metabolites there was also inclusion of sampling intervals beyond day 120 to allow for a reasonable evaluation of the kinetics.

Kinetic models

The kinetic evaluation of water-sediment data was performed according to FOCUS Level I to result in dissipation or degradation kinetics in single compartments, i.e. water, sediment and total systems. The dissipation from the sediment is calculated on the basis of a conservative approach to result in "apparent" dissipation times by starting at the time point of maximum occurrence followed by the decline, if possible.

No evaluations according to Level II were performed since not regarded as mandatory. For lower-tier calculations or the comparison with persistence registers a Level I evaluation of the dissipation may be often appropriate.

Contrary to the parent, for metabolites it may be often neither feasible nor meaningful to differentiate between SFO and the bi-phasic models, using Level I and a simultaneous fit of the complete metabolic pathway (i.e. considering formation and decline of metabolites). A bi-phasic approach would result in too many free parameters needed to describe such systems. Even for SFO the number of free parameters is often at the limit and the use of bi-phasic kinetics could easily multiply the number of free parameters.

For inferring kinetic degradation parameters in total systems, the proposed metabolic pathway as given in Figure 7.2.2.3-1 was converted into multi-compartment models illustrated in Figure 7.2.2.3-2 (phenyl-label) and Figure 7.2.2.3-3 (pyrimidine-label).

Each compound was represented by one compartment as the total of measured occurrences in water and sediment with no values associated with a sink compartment. Between compartments transformation reactions were assumed to proceed only one-way. The initial amount of the parent compound was free fitted and the initial amount for metabolites was fixed to a value of zero. All data were weighted equally thus corresponding to an absolute error model.

For the evaluation of dissipation one single compartment (water or sediment or total system) was considered without metabolite formation and degradation as described earlier. If needed, the time axis was shifted to the time  $t_{max}$  of maximum occurrences and residue data were chosen accordingly to result in the corresponding apparent dissipation values.

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Figure 7.2.2.3-2: Compartment model for kinetic evaluation of residues from phenyl-labeled foramsulfuron and metabolites in total water-sediment systems (Level I)

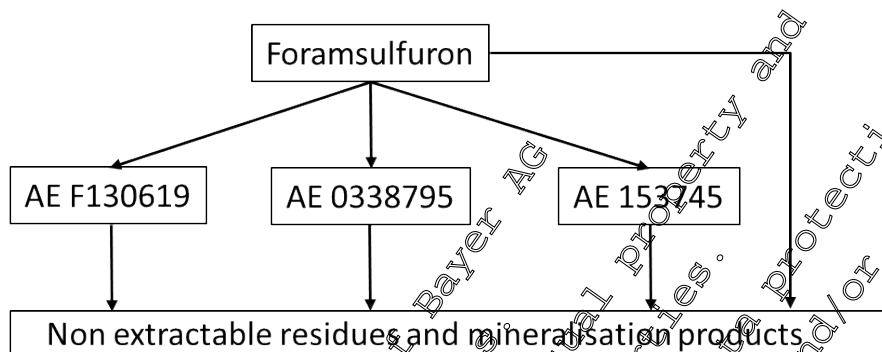
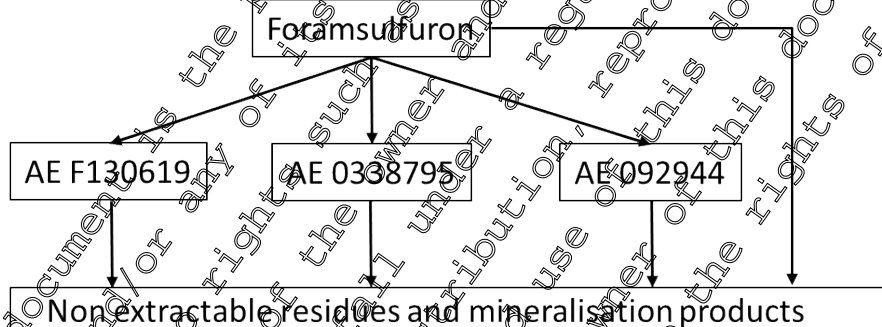


Figure 7.2.2.3-3: Compartment model for kinetic evaluation of residues from pyrimidine-labeled foramsulfuron and metabolites in total water-sediment systems (Level I)



At least four kinetic models consisting of single first-order (SFO), first-order multiple-compartment (FOMC, Gustafson-Holden), double first order in parallel (DFOP), and the hockey-stick (HS) model were available, in principle, according to the set of models proposed by FOCUS.

While best-fits should be taken to derive trigger or persistence endpoints SFO should be used to derive modeling input parameters if an acceptable fit can be obtained.

Before a use of bi-phasic kinetic models FOMC, DFOP and HS the following major cases were taken into account:

1. A check whether a degradation or dissipation to 10% of the initial amount  $M_0$  was reached within experimental period, then the estimation of the  $DT_{50}$  could be simplified according to the relation  $DT_{50} = DT_{90} / (\ln(10) / \ln(2))$ . By this method the equivalent SFO-curve meets the bi-phasic curve at the time  $DT_{90}$  bi-phasic and consequently the residue values at earlier times are over-predicted.
2. In case a value of 10% for  $M_0$  was not reached within the runtime of the study, FOMC should not be used to derive modelling endpoints.
3. In case a value of 10% for  $M_0$  was not reached within the runtime of the study, the  $DT_{50}$  could be derived for DFOP and HS models from the slower part of the bi-phasic curve using the relation  $DT_{50} = \ln(2) / k_2$ .

### Statistical evaluation

The identification of the most appropriate kinetic model for the description of experimental data according to FOCUS is mainly based on the three criteria of visual assessment of fits of calculated transformation curves to experimental data, the value of error of chi-square ( $\chi^2$  test and a single-sided significance t-test.

The choice of the appropriate kinetic model was primarily based on visual assessment of the fit and the scaled error  $\varepsilon$  was used which was derived from  $\chi^2$ -error via the following function:

$$\varepsilon = \frac{\sigma}{\bar{y}} = \frac{\sqrt{\sum_{i=1}^n (y_i - \hat{y}_i)^2 / \chi_{m,\alpha}^2}}{\bar{y}}$$

Within the current evaluation, single first-order (SFO) kinetics had been tested first since SFO is being used as the simplest kinetic model almost exclusively in environmental exposure models. In case the SFO fit should not be visually acceptable or in case of a significant exceedance of value for  $\chi^2$ -error of 15%, bi-phasic models were tested. Finally the model was chosen which was visually acceptable and provided a significantly better fit in terms of the scaled error  $\varepsilon$ .

The approach avoided the use of over-parameterised models simply and only being chosen on the basis of a marginally better fit. Finally it should be noted that a value of  $\chi^2$ -error below 15% should only be considered as guidance and not as an absolute cut-off criterion. This is true, in particular, for the modelling of metabolite data with errors for  $\chi^2$  being higher, but with fits still representing a reasonable description of their formation and degradation behaviour.

## II Results and Discussion

The kinetic evaluation of water-sediment data was performed according to FOCUS Level I to result in dissipation or degradation kinetics in single compartments, i.e. water, sediment and total systems. No evaluations according to Level II were performed.

### 1. Degradation in total systems for foramsulfuron and metabolites AE F130619, AE 0338795, AE F153745 and AE F092944 according to Level I

For the total of four data sets under investigation it turned out that application of an all-SFO kinetic model to the parent substance and metabolite data resulted in good fits. Apart from very low  $\chi^2$ -errors there was also no sign of systematic variations of the residuals. Consequently, no further testing of other kinetic models was considered necessary.

For the Pikeville system fitting of the SFO model to residue values of phenyl-labeled foramsulfuron resulted in unacceptable fits for metabolite AE F0338795 due to the scattering of observed data with very high values for the  $\chi^2$ -error. No values for the  $DT_{50}$  were thus derived for metabolite AE F0338795. For metabolite AE F153745, the calculated curve indicated some systematic deviation from observed values, to result in a rather conservative estimate for the degradation. Nevertheless, the fit was accepted and a  $DT_{50}$  was derived.

For residues following application of pyrimidine-labeled foramsulfuron to system Pikeville the large scattering, but systematic variation of the observed data for the two metabolites AE F130619 and AE F0338795 resulted in high values of  $\varepsilon$ . Consequently, the fits were not considered acceptable with no value for the  $DT_{50}$  derived.





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For the Hoechst system fitting of the SFO model to residue values of phenyl-labeled foramsulfuron the erratic, non-systematic time course of the residues of metabolite AE F153745 prevented acceptable fits to the data with no values for the DT<sub>50</sub> derived.

For residues of pyrimidine-labeled foramsulfuron in system Hoechst an increased value for ε was calculated for the SFO fit for metabolite AE 0338795. This was accepted since the time course of the residues was reasonably well described. For AE F092944, however, no reliable DT<sub>50</sub> could be derived resulting from a large Chi<sup>2</sup>-error and a high t-test probability.

Table 7.2.2.3-2: Degradation of foramsulfuron in total systems: scaled error ε, visual acceptability (VA) and significance of dissipation rates (t-prob) for single first-order (SFO) kinetic model applied (level I)

System		SFO model					
		Pikeville			Hoechst Sand		
Compound	Label	ε	VA	t-prob.	ε	VA	t-prob.
Foramsulfuron	1	6.6	+	<0.0001	4.0	+	<0.0001
	2	5.0	+	<0.0001	3.0	+	<0.0001
AE F130619	1	16.2	+	0.0002	7.7	+	0.0001
	2	45.7	-	0.14	6.4	+	<0.0001
AE 0338795	1	49.4	o	0.009	25.2	+	0.0003
	2	43.6	o	0.002	37.4	o	0.002
AE F153745	1	26.8	-	0.002	11.3	-	0.005
	2	-	-	-	-	-	-
AE F092944	1	-	-	-	-	-	-
	2	14.4	+	0.0004	6.9	-	0.24

Label 1 = phenyl, Label 2 = pyrimidine, t-prob = t-probability test

VA = Visual acceptability: + = good, o = medium, - = bad, ε = Scaled error

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Table 7.2.2.3-3: Half-lives for the degradation of foramsulfuron and metabolites in total systems (SFO, level I)

Compound	System	Label	DegT <sub>50</sub> (days)
Foramsulfuron	Pikeville	1	26.0
		2	28.7
	Mean (geometric)		27.3
	Hoechst Sand	1	37.9
		2	41.7
Mean (geometric)		39.6	
<b>Mean (geometric)</b>			<b>32.9</b>
AE F130619	Pikeville	1	5.4
		2	n.d.
	Mean (geometric)		3.4
	Hoechst Sand	1	44.2
		2	47.0
Mean (geometric)		45.8	
<b>Mean (geometric)</b>			<b>15.7</b>
AE 0338795	Pikeville	1	n.d.
		2	n.d.
	Mean (geometric)		n.d.
	Hoechst Sand	1	62.5
		2	68.5
Mean (geometric)		65.4	
<b>Mean (geometric)</b>			<b>65.4</b>
AE F153745	Pikeville	1	72.1
		2	72.1
	Mean (geometric)		72.1
	Hoechst Sand	1	n.d.
		2	n.d.
Mean (geometric)		n.d.	
<b>Mean (geometric)</b>			<b>72.1</b>
AE F092944	Pikeville	1	-
		2	109.6
	Mean (geometric)		109.6
	Hoechst Sand	1	-
		2	n.d.
Mean (geometric)		n.d.	
<b>Mean (geometric)</b>			<b>110</b>

Label 1 = phenyl, Label 2 = pyrimidine  
n.d. = not determined

## 2. Dissipation from water for parent compound and metabolites AE F130619, AE 0338795, AE F153745 and AE F092944 according to Level I

The dissipation of foramsulfuron and its metabolites from the water was evaluated starting from the observed maximum value till the end of the study. Where appropriate for the parent compound foramsulfuron, different kinetic models were fitted to the residue data for determination of best fits then being used to derive persistence endpoints. For metabolites, a few data points were available for most cases not allowing for the calculation of reliable fits with non-SFO models.



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For the Pikeville system, there was no sign of a systematic variation of residuals when fitting the parent data using a SFO-model which would suggest that another model would improve the fit. Therefore, only the SFO model was fitted to all decline data for the water of test system Pikeville for both positions of radiolabel tested.

For the Hoechst Sand system, fitting a SFO-model to residue values of phenyl-labeled foramsulfuron in the water resulted in an acceptable fit but with systematically varying residuals. Therefore, the FOMC kinetic model was additionally fitted to the residue data while improving the visual fit and the  $\epsilon$  value. Consequently, the DT<sub>50</sub> of 34.4 days derived from the FOMC model was considered as appropriate persistence endpoint, while for modelling purposes a DT<sub>50</sub> of 25.6 days was derived from the SFO approach. For metabolites AE F130619 and AE 0338795, the observed data showed some non-systematic variation to result in increased values for  $\epsilon$  and the t-test probability. The fits, however, provided a conservative description of the decline of residues and were therefore accepted.

For the Hoechst Sand system, fitting a SFO model to residue values of pyrimidine-labeled foramsulfuron in the water resulted in clearly systematically varying residuals and was not accepted. Therefore, the DFOP kinetic model was fitted to the residue data since more than 10% of AR had remained at the last sampling interval while improving the visual fit and the  $\epsilon$  value. Consequently, the DT<sub>50</sub> of 63 days derived from the DFOP model was considered as appropriate persistence endpoint while for modelling purposes a DT<sub>50</sub> of 25.6 days was derived from the SFO fit. For metabolite AE F092944, no decline fit could be derived since no clear maximum could be found in the observed data.

Table 7.2.2.3-4: Dissipation of foramsulfuron residues from water: scaled error  $\epsilon$ , visual acceptability (VA) and significance of dissipation rates (t-prob) for single first-order (SFO) kinetic model applied (level I)

System	Label	SFO model					
		Pikeville			Hoechst Sand		
Compound	Label	$\epsilon$	VA	t-prob.	$\epsilon$	VA	t-prob.
Foramsulfuron	1	12.8	+	0.0001	8.6*	o	<0.0001
	2	13.0	+	0.0001	8.9**	-	0.0004
AE F130619	1	8.3	+	0.0015	20.3	o	0.05
	2	10.9	+	0.0015	10.9	+	0.0211
AE 0338795	1	28.8	-	0.1051	19.1	-	0.07
	2	0.7	-	0.0068	15.0	o	0.0366
AE F153745	1	22.4	-	0.1940	0.6	+	0.005
	2	-	-	-	-	-	-
AE F092944	1	-	-	-	-	-	-
	2	37.2	-	0.0883	-	-	-

Label 1 = phenyl, Label 2 = pyrimidine; t-prob = t-probability test

VA = Visual acceptability: + = good, o = medium, - = bad;  $\epsilon$  = scaled error

\* For persistence evaluation, FOMC use resulted in a better fit ( $\epsilon$  = 6.4, t-prob = not applicable, visual acceptability = +)

\*\* For persistence and modeling evaluation, DFOP use resulted in a better fit ( $\epsilon$  = 3.6, t-prob for k1 = 0.01, t-prob for k2 = 0.09, visual acceptability = +)

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Table 7.2.2.3-5: Half-lives for the dissipation of foramsulfuron residues from water (SFO, level I)

Compound	System	Label	DisT <sub>50</sub> (days)
Foramsulfuron	Pikeville	1	14.7
		2	14.9
	Mean (geometric)		14.8
	Hoechst Sand	1	25.6*
			53.3**
Mean (geometric)		26.9	
<b>Mean (geometric)</b>			
AE F130619	Pikeville	1	15.6
		2	18.1
	Mean (geometric)		16.8
	Hoechst Sand	1	137.5
		2	29.0
Mean (geometric)		63.3	
<b>Mean (geometric)</b>			
AE 0338795	Pikeville	1	n.d.
		2	n.d.
	Mean (geometric)		n.d.
	Hoechst Sand	1	124.2
		2	87.2
Mean (geometric)		104.0	
<b>Mean (geometric)</b>			
AE F153745	Pikeville	1	n.d.
		2	n.d.
	Mean (geometric)		n.d.
	Hoechst Sand	1	31.2
		2	31.2
Mean (geometric)		31.2	
<b>Mean (geometric)</b>			
AE F092944	Pikeville	1	-
		2	-
	Mean (geometric)		-
	Hoechst Sand	1	-
		2	-
Mean (geometric)		-	
<b>Mean (geometric)</b>			

Label 1 = phenyl, Label 2 = pyrimidine

n.d. = not determined

\* For persistence evaluation, FOMC best fit resulted in DT<sub>50</sub> of 34.4 days\*\* DT<sub>50</sub>-value from SFO model was 26.9 days. For persistence evaluation, the DFOP best fit resulted in a DT<sub>50</sub> of 21.6 days while a value of 53.3 days was estimated for modeling. For modeling, the value was derived from the slow phase (k<sub>2</sub>) of the DFOP curve (DT<sub>50</sub> = ln2/k<sub>2</sub>).**3. Dissipation from sediment** for parent compound and metabolites AE F130619, AE 0338795, AE F153745 and AE F092944 according to Level I

The dissipation of foramsulfuron and its metabolites from the sediment was evaluated starting from the observed maximum value till the end of the study. However, the approach resulted in no more than five data points remaining for kinetic evaluation. Consequently, no bi-phasic kinetic models were tested beyond the SFO approach.



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For the Pikeville test system there was no sign of a systematic variation of residuals when fitting the parent data with a SFO-model which would suggest that another model would not improve the fit. Therefore, only the SFO model was fitted to all decline data for the sediment of system Pikeville for both positions of radiolabel.

For the metabolites AE F130619 and AE F153745, no visually acceptable fit could be achieved from phenyl-labelled foramsulfuron with no values derived for the DT<sub>50</sub>. No sufficient residue data were available for AE F130619 from application of pyrimidine-labeled foramsulfuron.

For the Hoechst test system none of the metabolites showed a clear decline following application of phenyl-labeled foramsulfuron resulting from very low residue levels observed during the study. Consequently, only the parent residue data were kinetically evaluated. No sufficient data were available for metabolite AE F092944 to describe the dissipation from Hoechst test systems after application of pyrimidine-labeled foramsulfuron. The datasets remaining for the other components were evaluated using the SFO model.

Table 7.2.2.3-6: Dissipation of foramsulfuron residues from sediment: scaled error  $\epsilon$ , visual acceptability (VA) and significance of dissipation rates (t-prob) for single first-order (SFO) kinetic model applied (level 1)

System	Label	SFO model					
		Pikeville			Hoechst Sand		
Compound	Label	$\epsilon$	VA	t-prob.	$\epsilon$	VA	t-prob.
Foramsulfuron	1	10.2	-	0.004	5.4	+	0.0013
	2	10.6	+	0.007	9.2	+	0.004
AE F130619	1	27.7	-	0.11	-	-	-
	2	-	-	-	0.5	+	0.0074
AE 0338795	1	2.9	+	<0.0001	-	-	-
	2	1.2	o	0.05	4.5	+	0.0086
AE F153745	1	14.3	-	0.07	-	-	-
	2	-	-	-	-	-	-
AE F092944	1	-	-	-	-	-	-
	2	-	+	0.01	-	-	-

Label 1 = phenyl, Label 2 = pyrimidine, t-prob = t-probability test  
VA = Visual acceptability: + good, o = medium, - bad;  $\epsilon$  = Scaled error



Table 7.2.2.3-7: Half-lives for the dissipation of foramsulfuron residues from sediment (SFO, level I)

Compound	System	Label	DisT <sub>50</sub> (days)
Foramsulfuron	Pikeville	1	42.9
		2	47.1
	Mean (geometric)		45.0
	Hoechst Sand	1	53.8
		2	29.9
Mean (geometric)		40.1	
<b>Mean (geometric)</b>			<b>42.5</b>
AE F130619	Pikeville	1	n.d.
		2	n.d.
	Mean (geometric)		n.d.
	Hoechst Sand	1	-
		2	103
Mean (geometric)		103	
<b>Mean (geometric)</b>			<b>103</b>
AE 0338795	Pikeville	1	15.7
		2	49.6
	Mean (geometric)		31.9
	Hoechst Sand	1	-
		2	89.0
Mean (geometric)		89.0	
<b>Mean (geometric)</b>			<b>49.8</b>
AE F153745	Pikeville	1	n.d.
	Mean (geometric)		-
	Hoechst Sand	1	-
		2	-
Mean (geometric)		-	
<b>Mean (geometric)</b>			<b>-</b>
AE F092944	Pikeville	1	-
		2	147
	Mean (geometric)		147
	Hoechst Sand	1	-
		2	-
Mean (geometric)		-	
<b>Mean (geometric)</b>			<b>147</b>

Label 1 = phenyl, Label 2 = pyrimidine  
n.d. = not determined

### III. Conclusion

The degradation of phenyl- and pyrimidine-labeled foramsulfuron under conditions of a water/sediment test was shown to proceed via the formation of metabolites AE F130619, AE 0338795, AE F153745 and AE F092944.

In general and for the components observed the kinetic evaluation resulted in an all-SFO fit of residue data for the degradation in total systems and for the dissipation from water and sediment.

The results can therefore be used as input parameters for modelling in environmental risk assessments and for evaluation against persistence triggers.

Deviations from this all-SFO approach were observed for the parent compound foramsulfuron only for the dissipation from water of system Hoechst. In this case, the use of the FOMC model of phenyl-label



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residue data showed a better fit to the data to result in a DisT<sub>50</sub> of 34.4 days from water for the trigger evaluation. Following application of pyrimidine-labeled foramsulfuron to the Hoechst system, the fit according to the DFOP kinetic model was shown to be most adequate to describe the experimental data. Its use resulted in a DisT<sub>50</sub> of 21.6 days from water for trigger evaluation of the parent compound. The results of kinetic evaluation in terms of DegT<sub>50</sub>- and DisT<sub>50</sub>-values derived for the various compartments investigated are summarised in Table 7.2.2.3-8.

In total systems and for use as modelling endpoint the kinetic evaluation resulted in a geometric mean value for the DegT<sub>50</sub> of 32.9 days for the parent compound. For metabolites these values are 15.7 days for AE F130619, 65.4 days for AE 0338795, 72.1 days for AE F153745 and 110 days for AE F092944. For evaluation against persistence triggers the worst case DegT<sub>50</sub> in total system is 39.6 days (Hoechst sand) for parent compound foramsulfuron. For metabolites these values are 45.8 days for AE F130619, 65.4 days for AE 0338795, 72.1 days for AE F153745 and 110 days for AE F092944.

For the dissipation from water and for use as modelling endpoint the corresponding geometric mean value for the DisT<sub>50</sub> is 23.4 days for the parent compound. For the metabolites these values are 32.6 days for AE F130619, 104.0 days for AE 0338795 and 31.2 days for AE F153745. No DisT<sub>50</sub> from water could be derived for AE F092944.

For evaluation against persistence triggers the worst case DisT<sub>50</sub> of the parent compound from water is 27.3 days (Hoechst system)<sup>7</sup>. For the metabolites these values are 63.3 days for AE F130619, 104.0 days for AE 0338795 and 31.2 days for AE F153745. No DisT<sub>50</sub> from water could be derived for AE F092944.

For the dissipation from sediment and for use as modelling endpoint the geometric mean value for the DisT<sub>50</sub> is 42.5 days for the parent compound. For the metabolites these values are 103 days for AE F130619, 49.8 days for AE 0338795 and 147 days for AE F092944. No DisT<sub>50</sub> from sediment could be derived for AE F153745.

For evaluation against persistence triggers the worst case DisT<sub>50</sub> of the parent compound from sediment is 45.0 days (Pikeville system). For the metabolites these values are 103 days for AE F130619, 89.0 days for AE 0338795 and 147 days for AE F092944. No worst case DisT<sub>50</sub> from sediment could be derived for AE F153745.

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<sup>7</sup> This geometric mean value is derived from 34.4 days (FOMC-model, phenyl-label) and 21.6 days (DFOP-model, pyrimidine-label).

Table 7.2.2.3-8: Mean values of half-lives for the dissipation of foramsulfuron from water and sediment and degradation in total systems according to FOCUS Level I

Compound	System	DegT <sub>50</sub> , total system (days)	DisT <sub>50</sub> , water (days)	DisT <sub>50</sub> , sediment (days)
Foramsulfuron	Pikeville	27.3	14.8	45.0
	Hoechst Sand	30.6	36.9*	40.1
	<b>Mean (geometric)</b>	<b>32.9</b>	<b>23.4</b>	<b>42.5</b>
AE F130619	Pikeville	5.4	16.8	n.d.
	Hoechst Sand	45.8	63.3	103
	<b>Mean (geometric)</b>	<b>15.7</b>	<b>32.6</b>	<b>103</b>
AE 0338795	Pikeville	n.d.	n.d.	27.9
	Hoechst Sand	65.4	104.0	89.0
	<b>Mean (geometric)</b>	<b>65.4</b>	<b>104.0</b>	<b>49.8</b>
AE F153745	Pikeville	72.1	n.d.	n.d.
	Hoechst Sand	n.d.	31.2	-
	<b>Mean (geometric)</b>	<b>72.1</b>	<b>31.2</b>	-
AE F092944	Pikeville	110	-	147
	Hoechst Sand	-	-	-
	<b>Mean (geometric)</b>	<b>110</b>	-	<b>147</b>

Label 1 = phenyl, Label 2 = pyrimidine

\* For persistence evaluation only, DisT<sub>50</sub>-value from water following FOMC best fit was of 34.4 days (phenyl-label). DFOP best fit resulted in DT<sub>50</sub> of 21.6 days for persistence (pyrimidine label).

#### CA 7.2.2.4 Irradiated water/sediment study

This new point is regarded as an optional data requirement in the EU. Foramsulfuron was shown to degrade well under standard conditions of water/sediment testing. In view of the overall limited photolytic degradation observed no additional information is regarded as required to result in a significantly better understanding of the behavior of foramsulfuron in an aquatic environment.

#### CA 7.2.2.3 Degradation in the saturated zone

This data requirement had been addressed under Point 7.2.1.4 of the Dossier submitted and evaluated within the process for Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments.

The evaluation revealed that the results of risk assessment in ground water demonstrated no significant risk for a contamination of sub-soils or the saturated zone by the parent compound and its metabolites, when applied according to good agricultural practice. Therefore, the separate investigations on the degradation in the saturated zone are not regarded as necessary.





**CA 7.3 Fate and behaviour in air**

**CA 7.3.1 Route and rate of degradation in air**

<b>Report:</b>	██████████ v: ██████████; 2000;M-194295-01
<b>Title:</b>	Estimation of the reaction with photochemically produced hydroxyl radicals in the atmosphere Code: AE F130360
<b>Report No:</b>	C006613
<b>Document No:</b>	M-194295-01-1
<b>Guidelines:</b>	Deviation not specified
<b>GLP/GEP:</b>	no

This data requirement had been addressed under Point 7.2.2 of the Dossier submitted and evaluated within the process for Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments.

The evaluation revealed that based on rapid degradation in the atmosphere (half-life of 0.07 days in maximum) as calculated by the software AOPWIN, foramsulfuron would not remain stable and thus available for long-range transport due to its susceptibility for reactions with photochemically produced hydroxyl radicals. The value for the vapour pressure of foramsulfuron is  $4.2 \times 10^{-11}$  Pa at 20°C as reported in Appendix 1 of SANCO/10374/2002-Final from Nov 2002.

**CA 7.3.2 Transport via air**

This new requirement had not been addressed in the Dossier submitted or evaluated within the process for Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments.

Due to its low half-life in the atmosphere (0.07 days) combined with a low vapour pressure ( $4.2 \times 10^{-11}$  Pa at 20°C) indicating non-volatility to result in a low value for the Henry constant ( $4.52 \times 10^{-1}$  Pa x m<sup>3</sup> x mole<sup>-1</sup> at 20°C) foramsulfuron is clearly not subject to transport via air.

In view of the value measured for vapour pressure being below the triggers of 10<sup>-5</sup> Pa for soil and 10<sup>-5</sup> Pa for plant, no study on transport of the active substance foramsulfuron via air is necessary.

**CA 7.3.3 Local and global effects**

This new requirement had not been addressed in the Dossier submitted or evaluated within the process for Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments.

Foramsulfuron is applied at low application rates in the field accompanied by fast degradation. Both aspects indicate the presence of only low actual amounts of active substance to be present under outdoor conditions short-term and long-term and thus to be available to set effects at local or global level with respect to its global warming potential (GWP), ozone depleting potential (OPD), photochemical ozone creation potential (POCP), accumulation in the troposphere, acidification potential (AP) or eutrophication potential (EP).

Moreover the potential for local effects of foramsulfuron is considered in risk assessments performed following its use under field conditions in particular by considering factors like spray drift. The

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combination of exposure assessments with potential effects measured in soil and surface water do thus cover the environmental compartments of interest. In contrast and since there is no aerial application envisaged, air is not a compartment regarded to be major compartment of potential foramsulfuron occurrence following its intended use in the environment.

Following its intended use, its uncritical degradation behavior in air and its low vapour pressure foramsulfuron cannot be transported long range to set effects in the environment at the global level.

**CA 7.4 Definition of the residue****CA 7.4.1 Definition of the residue for risk assessment**

The route and rate of degradation of phenyl- or pyrimidine-labeled foramsulfuron has been investigated after application to various test systems in the laboratory with their results delivering endpoints for use in soil, ground water and surface water risk assessments.

Following their occurrence above the trigger values set in the relevant tests, metabolites and transformation products are potential residues that have to be addressed.

Residue definition for soil:

Within the process of Annex I inclusion the parent compound foramsulfuron and metabolites AE F092944 and AE F130619 were considered for risk assessment due to their occurrence at >10% of AR in aerobic soil degradation tests.

Following new triggers set it is proposed to include AE F153745 in addition.

The residue definition for soil is therefore the parent compound foramsulfuron and metabolites AE F092944, AE F130619 and AE F153745.

Residue definition for ground water:

The risk assessment for ground water includes by default all components defined for the risk assessment in soil which is the active substance foramsulfuron and metabolites AE F092944, AE F130619 and AE F153745.

Residue definition for surface water:

The risk assessment for surface water includes by default the active substance foramsulfuron and those components defined for risk assessment in soil and ground water, i.e. metabolites AE F092944, AE F130619 and AE F153745.

During the process of evaluation for Annex I inclusion the metabolite AE 0338795 was additionally included in the surface water risk assessment due to its occurrence at >10% of AR in water/sediment systems. AE 0338795 was observed in water/sediment tests only thus not originating from aerobic soil degradation testing.

Following current data requirements, no metabolites were found to occur at levels between 5 to 10% of AR in water/sediment tests.

Current data requirements request also to consider metabolites potentially observed at 'significant level' in other aquatic route studies. These studies include, in particular, sterile abiotic hydrolysis and photolysis (>10% AR) and mineralization in surface water (starting at 5% AR at two successive sampling intervals).



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No additional metabolites were observed in sterile buffer hydrolysis or tests on mineralization in surface water.

Additional photolysis tests performed in sterile aqueous buffer and natural water resulted in the observation of the four compounds 4-Formamido-N-methylbenzamide (FMP, BCS-CW90756), 4-Amino-N-methylbenzamide (AMB, BCS-CV29520), AE F099095 (foramsulfuron urea) and foramsulfuron sulfamic acid (BCS-AW41401) at >10% AR.

It is therefore proposed to consider these compounds in addition within the risk assessment in surface water.

**CA 7.4.2 Definition of the residue for monitoring**

Following risk assessments in soil, ground water and surface water according to the GAP defined, the environmental safety of all components under assessment could be demonstrated according to the requirements set.

It is therefore justified to define the parent compound foramsulfuron only as the relevant residue for monitoring in soil, ground water and surface water.

**CA 7.5 Monitoring data**

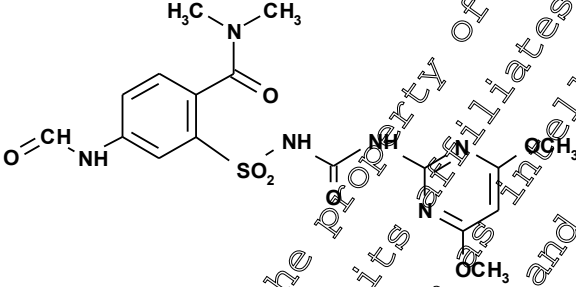
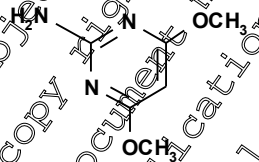
Foramsulfuron was not subject of formal monitoring studies in soil or water at EU or national level. Moreover, there are no published monitoring data available indicating findings of foramsulfuron in environmental areas after intended agricultural use. With the safety demonstrated for the active substance as well as for metabolites there is no necessity for monitoring of foramsulfuron residues in the various compartments of the environment.

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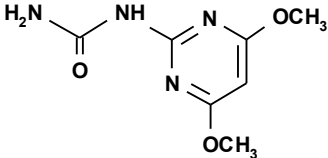
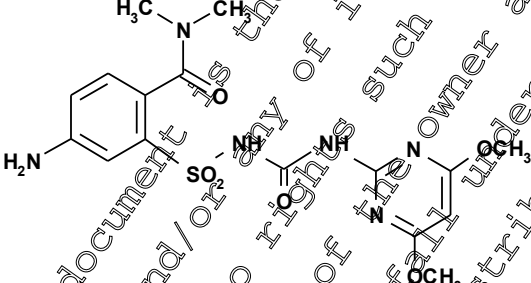
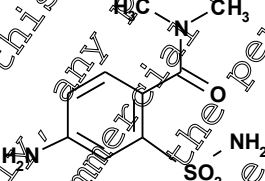
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List of metabolites observed in environmental fate testing

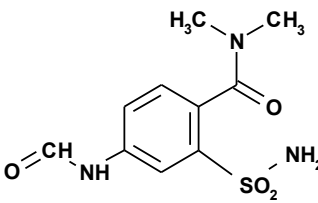
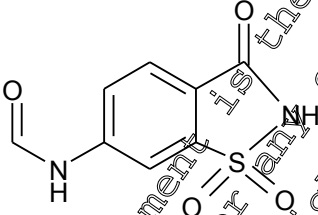
In the original study reports on biotic or abiotic transformation of foramsulfuron the metabolites are denominated by different synonyms. In order to present a common system of nomenclature for the evaluation in the dossier a list of metabolites observed in environmental fate testing is included.

	<b>Report name</b> <b>Structure</b> <b>IUPAC name</b> <b>CAS name</b> <b>[CAS registry number]</b>	<b>Molecular formula</b> <b>Molar mass</b> <b>Other names / codes</b>	<b>Occurrence</b>
<p>a.s.</p>	<p><b>Foramsulfuron (parent substance)</b></p>  <p>N,N-dimethyl-2-[[[4-(4,6-dimethoxy-2-pyrimidinyl)amino]ureidosulfonyl]-4-formylaminobenzamide (IUPAC) 2-[[[[4,6-dimethoxy-2-pyrimidinyl]amino]carbonyl]amino]sulfonyl]-4-formylaminobenzamide (CAS) CAS no. 173169-574</p>	<p>C<sub>20</sub>H<sub>20</sub>N<sub>6</sub>O<sub>7</sub>S 452.45 g/mol</p> <p><b>Foramsulfuron</b> (Common name) AE F 30360 BCS-AA47626</p>	<p>Parent substance used as test material in all reports</p>
<p>M01</p>	 <p>2-amino-4,6-dimethoxypyrimidine (IUPAC) 4,6-Dimethoxy-2-pyrimidinamine (CAS) CAS no: 36315-01-2</p>	<p>C<sub>6</sub>H<sub>8</sub>N<sub>3</sub>O<sub>2</sub> 155.16 g/mol</p> <p>AE F092944 BCS-AA25052 Foramsulfuron-pyrimidinamine ADMP K-1782 Metabolite E</p>	<p>Soil, aerobic Soil, anaerobic Hydrolysis, buffer Photolysis, buffer Photolysis, nat. water Water/Sediment</p>

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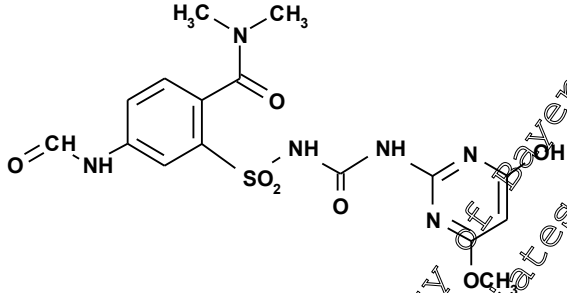
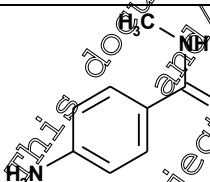
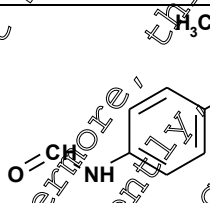
	Report name Structure IUPAC name CAS name [CAS registry number]	Molecular formula molar mass Other names / codes	Occurrence
M02	<p><b>AE F099095</b></p>  <p>4,6-dimethoxypyrimidin-2-ylurea (IUPAC) (4,6-dimethoxy-2-pyrimidinyl)urea (CAS) CAS no: 151331-81-6</p>	<p><math>C_7H_{10}N_4O_3</math> 198.18 g/mol</p> <p>AE F099095 BCS-AB40283 Foramsulfuron-urea 05537 DMPU Métabolyte B</p>	<p>Soil, aerobic Soil, anaerobic Soil photolysis Photolysis, buffer Photolysis, nat. water</p>
M03	<p><b>AE F130619</b></p>  <p>4-amino-2-[3-(4,6-dimethoxypyrimidin-2-yl)ureidosulfonyl]-N,N-dimethylbenzamide (IUPAC) 4-amino-2-[[[4,6-dimethoxy-2-pyrimidinyl]amino]carbonyl]amino]sulfonyl]-N,N-dimethylbenzamide (CAS) CAS no: 190520-75-2</p>	<p><math>C_{16}H_{20}N_6O_6S</math> 424.48 g/mol</p> <p>AE F130619 BCS-AU59648 Foramsulfuron-amine</p>	<p>Soil, aerobic Soil, anaerobic Hydrolysis, buffer Photolysis, nat. water Water/Sediment</p>
M04	<p><b>AE F148003</b></p>  <p>4-amino-N,N-dimethyl-2-sulfamoylbenzamide (IUPAC) 4-amino-2-(aminosulfonyl)-N,N-dimethylbenzamide (CAS) CAS no: 190521-44-9</p>	<p><math>C_9H_{13}N_3O_3S</math> 243.31 g/mol</p> <p>AE F148003 BCS-AU73987</p>	<p>Soil, aerobic Soil, anaerobic Hydrolysis, buffer Water/Sediment</p>

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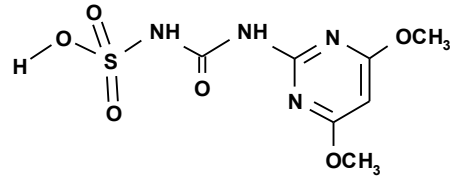
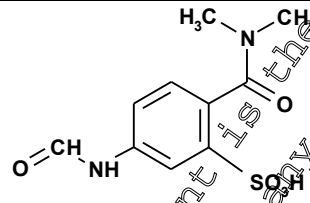
	<b>Report name</b> <b>Structure</b> <b>IUPAC name</b> <b>CAS name</b> <b>[CAS registry number]</b>	<b>Molecular formula</b> <b>molar mass</b> <b>Other names / codes</b>	<b>Occurrence</b>
<b>M05</b>	<p><b>AE F153745</b></p>  <p>4-formylamino-N,N-dimethyl-2-sulfamoylbenzamide (IUPAC) 2-(aminosulfonyl)-4-(formylamino)-N,N-dimethyl-benzamide (CAS) CAS no: 173159-94-9</p>	<p>C<sub>10</sub> H<sub>13</sub> N<sub>3</sub> O<sub>4</sub> 271.32 g/mol</p> <p>AE F153745 BCS-AU8001</p>	<p>Soil, aerobic Soil, anaerobic Hydrolysis, buffer Water/Sediment</p>
<b>M06</b>	<p><b>AE 0014940</b></p>  <p>N-(1,1-dioxido-2-oxo-2,3-dihydro-1,2-benzothiazol-5-yl)formamide (IUPAC) 6-formamido-1,2-benzisothiazol-3(2H)-one 1,1-dioxide (IUPAC) CAS no: NA</p>	<p>C<sub>7</sub> H<sub>6</sub> N<sub>2</sub> O<sub>4</sub> S 226.27 g/mol</p> <p>AE 0014940 BCSAW41697</p>	<p>Hydrolysis, buffer Water/Sediment</p>

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	Report name Structure IUPAC name CAS name [CAS registry number]	Molecular formula molar mass Other names / codes	Occurrence
M07	AE 0338795 	C <sub>16</sub> H <sub>18</sub> N <sub>6</sub> O <sub>7</sub> 438.42 g/mol AE 0338795 BCS-AW78710 4-(formylamino)-2-[[[4-hydroxy-6-methoxy-2-pyrimidinyl]amino]sulfonyl]-N,N-dimethylbenzamide	Water/Sediment
M08	4-Amino-N-methylbenzamide 	C <sub>8</sub> H <sub>10</sub> N <sub>2</sub> O 150.18 g/mol AMB BCS-CV29520	Photolysis, buffer Photolysis, nat. water
M09	4-Formamido-N-methylbenzamide 	C <sub>9</sub> H <sub>10</sub> N <sub>2</sub> O <sub>2</sub> 178.19 g/mol FMB BCS-CW90756	Photolysis, buffer Photolysis, nat. water

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	Report name Structure IUPAC name CAS name [CAS registry number]	Molecular formula molar mass Other names / codes	Occurrence
M10	<b>Foramsulfuron sulfamic acid</b>		
	 <p>[4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamic acid (IUPAC) Sulfamic acid, N-[[[4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]- (CAS) CAS no: 591747-53-4</p>	<p>C<sub>7</sub>H<sub>10</sub>N<sub>4</sub>O<sub>6</sub>S 278.24 g/mol</p> <p>BCS-AW41401</p>	<p>Photolysis, buffer Photolysis, nat. water</p>
M11	<b>Sulfonic acid</b>		
	 <p>2-(dimethylcarbamoyl)-5-formamido benzenesulfonic acid (IUPAC) CAS no: NA</p>	<p>C<sub>12</sub>H<sub>12</sub>N<sub>2</sub>O<sub>5</sub>S 272.28 g/mol</p> <p>BCS: n.a. Foramsulfuron sulfonic acid</p>	<p>Photolysis, nat. water</p>

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