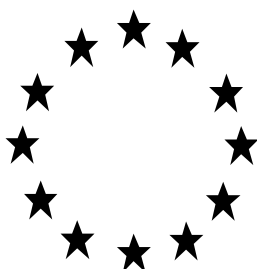


Draft Renewal Assessment Report
under Regulation (EC) 1107/2009



FORAMSULFURON

Active substance data

Volume 3

Annex B.8.

Fate and behaviour in the environment

Rapporteur Member State: Finland
Co- Rapporteur Member State: Slovakia

March 2015

List(s) of endpoints**List of endpoint****Volume 1**

Level 1: Statement of subject matter and purpose for which the monograph was prepared

Level 2: Reasoned statement of the overall conclusions drawn by the Rapporteur Member State

Level 3: Proposed decision with respect to the application

Appendix 1: Guidance documents used in this assessment

Appendix 2: Reference list

Appendix 3: Standard terms and abbreviations

Appendix 4: Specific terms and abbreviations

Volume 2

Annex A: List of the tests and studies submitted and of information available

Volume 3 – for Active substance and Product(s), respectively

Annex B: RMS summary, evaluation and assessment of the data and information

Annex B.1: Identity

Annex B.2: Phys/chem.

Annex B.3: Data application and further information.

Annex B.4: Proposal for classification and labelling

Annex B.5: Analytical method

Annex B.6: Toxicology and metabolism

Annex B.7: Residues in crop

Annex B.8: Fate and behaviour

Annex B.9: Ecotoxicology

Volume 4

Annex C: Confidential information and summary and assessment of information relating to the collective submission of dossiers

Version History

When	What
2015/March	First draft RAR

Table of contents

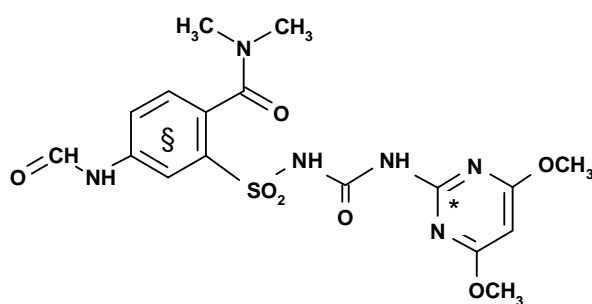
B.8	Environmental fate and behaviour	5
B.8.	Environmental fate and behaviour.....	6
B.8.1	Route and rate of degradation in soil.....	6
B.8.1.1	Aerobic degradation	6
B.8.1.1.1	Aerobic degradation of the active substance.....	6
B.8.1.1.2	Aerobic degradation of the metabolites	37
B.8.1.2	Anaerobic degradation.....	74
B.8.1.3	Photodegradation on soil	75
B.8.1.4	Field dissipation data.....	81
B.8.1.4.1	Soil dissipation studies	81
B.8.1.4.2	Soil accumulation studies	82
B.8.1.5	Summary of studies on route and rate of degradation in soil	82
B.8.2	Adsorption, desorption and mobility in soil.....	82
B.8.2.1	Adsorption/desorption studies.....	82
B.8.2.1.1.	Adsorption/desorption of the active substance.....	82
B.8.2.1.2.	Adsorption/desorption of the metabolites	83
B.8.2.2	Leaching studies.....	86
B.8.2.3	Field leaching/lysimeter studies	86
B.8.2.4.	Summary and assessment of adsorption, desorption and mobility in soil.....	93
B.8.3	Predicted environmental concentrations in soil (PEC _s).....	93
B.8.4	Fate and behaviour in water	93
B.8.4.1	Abiotic degradation in water.....	93
B.8.4.1.1	Hydrolysis.....	93
B.8.4.1.2.1	Direct photochemical transformation in water	95
B.8.4.1.2.2	Indirect phototransformation in water	107
B.8.4.2	Biological degradation in water	119
B.8.4.2.1	Ready biodegradability.....	119
B.8.4.2.2	Aerobic mineralisation in surface water	120
B.8.4.2.3	Degradation in water sediment system	124
B.8.4.2.4	Irradiated water/sediment study	154
B.8.4.3	Degradation in the saturated zone	155
B.8.4.4	Summary of studies on fate and behaviour in water	155
B.8.5	Impact on water treatment procedures.....	155
B.8.6	Predicted environmental concentrations in surface water and in ground water (PEC _{sw} , PEC _{gw})... 155	155
B.8.6.1	Predicted environmental concentrations in groundwater	155
B.8.6.2	Predicted environmental concentrations in surface water	155
B.8.7	Fate and behaviour in air	156
B.8.7.1	Studies on volatilisation.....	157
B.8.7.2	Summary of fate and behavior in air	157
B.8.8	Predicted environmental concentrations in air (PEC _a).....	157
B.8.9	Definition of the residue	157
B.8.10	Monitoring data.....	157
B.8.11	References relied on	158
Appendix 1:	List of metabolites observed in environmental fate testing.....	171

B.8 Environmental fate and behaviour

Most data on the fate and behaviour of foramsulfuron (AE F130360) in soil, water and air were evaluated during Annex I inclusion in the year 2001. This document therefore focuses on those environmental fate studies which were not evaluated in DAR and addendum 2001 by Germany.

For a better overview, existing data and their evaluation resulting from the process of Annex I inclusion are summarised and amended by new data generated in order to fulfil current requirements. The numbering and the headlines correspond to latest EU requirements.

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



(§) Label 1: [phenyl-UL- ^{14}C]

(*) Label 2: [pyrimidyl-2- ^{14}C]

Metabolites and transformation products

An overview of the metabolites and transformation products identified is presented in Appendix 1.

B.8. Environmental fate and behaviour

B.8.1 Route and rate of degradation in soil

B.8.1.1 Aerobic degradation

B.8.1.1.1 Aerobic degradation of the active substance

Reference:	KCA 7.1.1.1 /01; Judge, D. N.; Abbott, P. B.; Allen, R.;2000;M-185910-01 Degradation of (U-14C-phenyl) and (2-14C-pyrimidyl)-AE F130360 in three European soils under laboratory aerobic conditions at 20 °C Code: AE F130360
Report No.:	C003294
Guideline:	PMRA: T-1-255; SETAC: 1.1; USEPA (=EPA): Section N, 162-1;Deviation not specified
GLP:	Yes
Previous evaluation:	In DAR (2001)
	Acceptable
Reference:	KCA 7.1.1.1 /02;Judge, D. N.;1999;M-186637-01 Degradation of (U-14C-phenyl) and (2-14C-pyrimidyl)-AE F130360 in two U.S. soils under laboratory aerobic conditions at 25 °C Code: AE F130360
Report No.:	C003704
Guideline:	EU (=EEC): 95/36 7.1.1.1; PMRA: T-1-255; SETAC: 1995; USEPA (=EPA): N 162-1
GLP:	Yes
Previous evaluation:	In DAR (2001)
	Acceptable
Reference:	KCA 7.1.2.1.1 /03; Judge, D. N.; Abbott, P. B.; Ramanarayan, T. S.; 2000; M-238314-01 Degradation of [U-14C-phenyl] and [2-14-pyrimidyl] AE F130360 in a European soil under laboratory aerobic conditions at 10 °C: AE F130360
Report No.:	B002565
Guideline:	USEPA (=EPA): 162-1;
GLP:	Yes
Previous evaluation:	In DAR (2001)
	Acceptable

These studies were evaluated within the process of Annex I inclusion and were considered acceptable by the RMS Germany. These studies were not re-evaluated, since the studies were performed according to the USEPA: 162-1 which is in line with OECD test guideline No. 307: Aerobic and Anaerobic Transformation in Soil. Therefore only the results for the degradation of the active substance and the formation of the metabolites are presented. These results are presented for the better understanding of kinetic evaluation of the degradation of the active substance and the metabolites. The RMS comments on the kinetic evaluation of the degradation are given in tables for each soil and the overall conclusion after the last study.

The route of degradation in aerobic soil has been investigated under laboratory conditions in three studies following application of phenyl-UL-¹⁴C- and pyrimidyl-2-¹⁴C- labelled 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 /01);
- 2 soils at 25°C and moisture at 75% of field capacity at 0.33 bar (KCA 7.1.1.1 /02)
- 1 soil at 10°C and 40 % MWHC and application of phenyl-UL-14C- and pyrimidyl-2-14C-labeled active substance (KCA 7.1.2.1.1 /03)

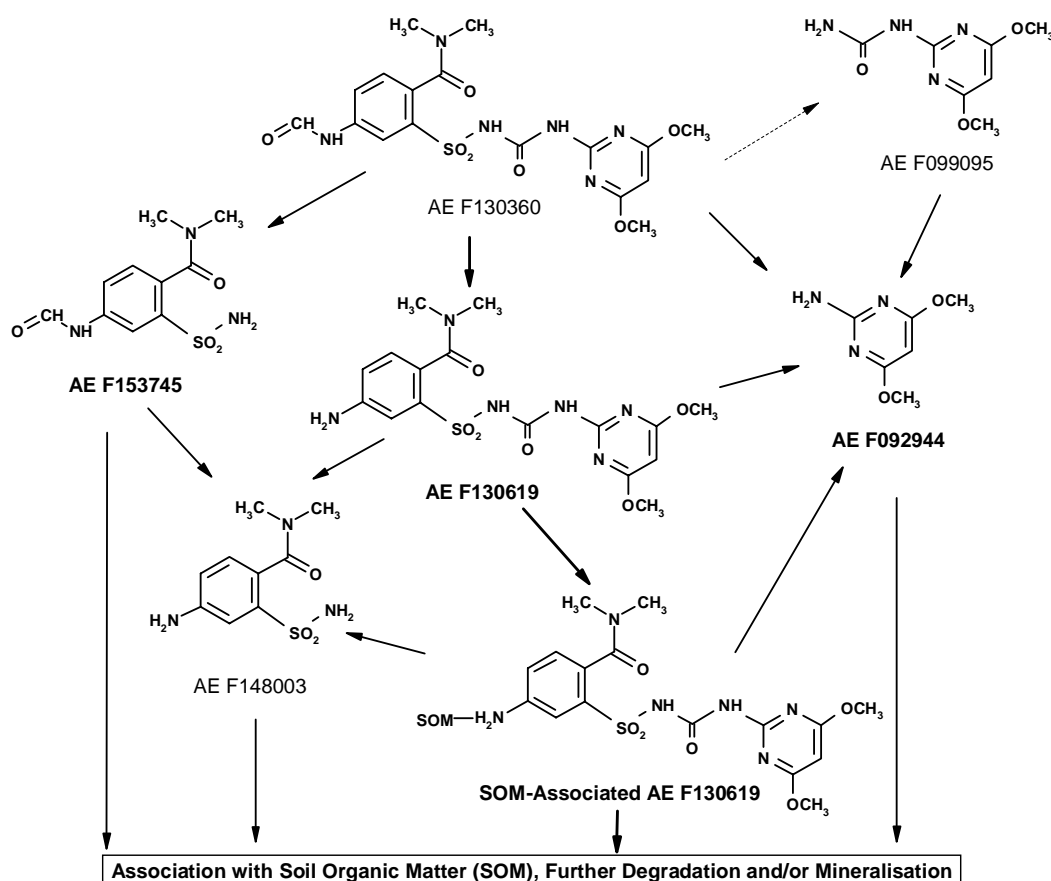
The evaluation revealed that the degradation of foramsulfuron predominantly proceeded via loss of the formyl group as a biotically induced hydrolysis step to result into the formation of the major (>10%

AR) 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 summarized in Figure B.8.1.1.1-1. The degradation data resulting from the above listed three studies with the active substance were kinetically evaluated following FOCUS guidance with the software KinGUI, version 2.

Figure B.8.1.1.1-1. Proposed pathway of metabolism of foramsulfuron (AE F130360) in aerobic soil



Reference:	KCA 7.1.2.1.1 /05; Schmitt, Mikolasch, 2013; M-453563-02-1 Kinetic evaluation of laboratory aerobic soil degradation of foramsulfuron and its metabolites according to Focus
Report No.:	EnSa-12-0246
Guideline:	Not applicable
GLP:	No
Previous evaluation:	Submitted for the purpose of renewal
	Acceptable

The kinetic evaluation of the degradation behaviour of foramsulfuron and its metabolites in the three laboratory studies listed above was conducted following the guidance given by the FOCUS report on kinetic evaluation (FOCUS, 2006). The principles of kinetic evaluation are first described below and the results of the three aerobic studies reported thereafter.

Data Pre-processing

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 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).

Kinetic modelling approaches

For fits of compounds under evaluation, SFO kinetics was tested first due to its simplicity and its nearly exclusive use in environmental exposure models. If the fit was not good the FOMC and DFOP were tested. 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.

Temperature and Moisture Normalisation

The DT₅₀-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.

Modelling approach

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 B.8.1.1.1-2 for the phenyl label and in Figure B.8.1.1.1-3 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 B.8.1.1.1-2. Compartmental model for degradation of phenyl labelled foramsulfuron in aerobic soil.

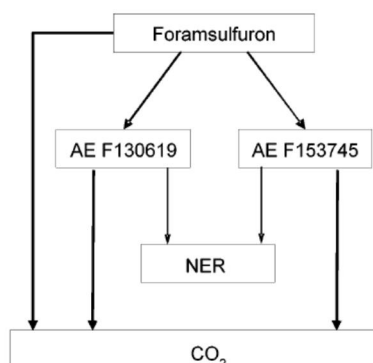
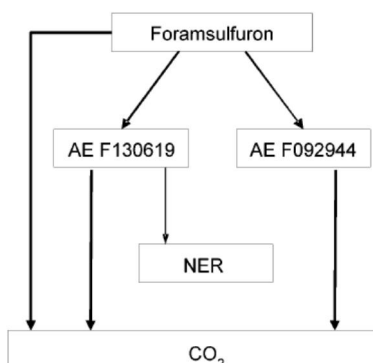


Figure B.8.1.1.1-3. Compartmental model for degradation of pyrimidyl labelled foramsulfuron in aerobic soil.



Reference:	KCA 7.1.1.1 /01; Judge, D. N.; Abbott, P. B.; Allen, R.;2000;M-185910-01 Degradation of (U-14C-phenyl) and (2-14C-pyrimidyl)-AE F130360 in three European soils under laboratory aerobic conditions at 20 °C Code: AE F130360
Report No.:	C003294
Guideline:	PMRA: T-1-255; SETAC: 1.1; USEPA (=EPA): Section N, 162-1;Deviation not specified
GLP:	Yes
Previous evaluation:	In DAR (2001)
	Acceptable

In this study the route of degradation in aerobic soil has been investigated under laboratory conditions following application of phenyl-UL-14C- and pyrimidyl-2-14C- labelled active substance to three soils under standard conditions of 20°C and moisture at 40 % MWHC. The time course of phenyl and pyrimidyl labelled foramsulfuron (AE F130360) and the formation and decline of its metabolites in different soils are presented before the kinetic evaluation. The figures for visual fits are presented after each kinetic evaluation.

1. Soil Shuttleworth; phenyl label

Table B.8.1.1.1-1 Time course of phenyl labelled foramsulfuron (AE F130360) and the formation and decline of its metabolites in Shuttleworth sandy loam under non-sterile aerobic conditions at 20 °C (% of applied radioactivity)

Time [days]	Phenyl radiolabeled components (PH)					
	AE F130360	AE F130619	AE F153745	Others	PH-NER	PH- ¹⁴ CO ₂
0	95.6	< LOD	6.7	5.6	na	Na
1	77.9	< LOD	5.5	14.0	6.2	0.0
3	76.0	3.8	7.8	3.9	13.5	0.0
8	49.4	5.5	< LOD	1.2	41.4	0.1
10	44.5	3.7	5.7	2.0	43.3	0.1
14	31.3	4.0	< LOD	2.3	55.4	0.1
28	16.3	1.8	1.5	1.9	72.3	0.2
56	8.5	< LOD	3.1	4.7	71.0	0.2
80	7.4	< LOD	3.0	4.7	73.8	0.4
134	3.5	0.1	1.7	4.4	87.6	0.6

< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity na: Not analysed

The statistical evaluation of the fit to the phenyl labelled foramsulfuron data yielded acceptable results with SFO kinetics, however, this fit was not accepted due to systematic variation of the residuals (Table B.8.1.1.1-2). Thus alternatively the model was fitted using the FOMC kinetic for the parent. In fact a significant improvement was achieved resulting in an acceptable fit to the parent data (Figure B.8.1.1.1-4). For the metabolite AE F153745, however, no reliable DT₅₀ could be derived because of the unusual time course of the observed data and a respectively bad visual fit with a very large Chi²-error of 58%.

The DT₅₀ values for use in environmental fate simulations derived from the fit were 15.6 days for foramsulfuron and 6.5 days for AE F130619.

Table B.8.1.1.1-2. Summary of the degradation kinetic evaluation of phenyl labelled foramsulfuron in Shuttleworth soil

	kinetic model	M_0	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	CI	
									lower	upper
Foramsulfuron	SFO	99.52		k = 0.0865	8.0	26.6	12.0	<0.0008	0.0662	0.107
	FOMC	100.9		$\alpha = 1.2569$ $\beta = 9.8972$	7.3	51.9	8.5	$\alpha: 0.0006$ $\beta: 0.0143$	0.5563 1.4014	1.958 18.393
AE F130619	SFO		0.14	k = 0.1067	6.5	21.6	25.8	<0.0007	0.0468	0.167
AE F153745	SFO				n.d.	n.d.	57.5			

Study conclusion (Schmitt & Mikolasch 2012):

Parent SFO: fit visually not acceptable, statistically acceptable ($\chi^2 = 12\%$);
(comment RMS: residual plot shows systematic deviations and therefore not acceptable)

Parent FOMC: fit visually and statistically acceptable
10% initial concentration was met within experimental period

Best fit model / trigger endpoint for parent: FOMC / 7.3 d
Modelling endpoint for parent: Pseudo-SFO DT50 = FOMC DT90/3.32 = 15.6 d

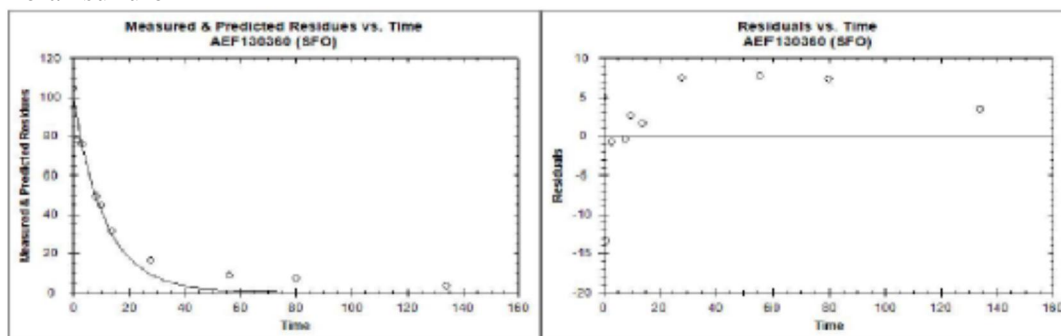
AE F130619 SFO: fit visually acceptable but not statistically acceptable
(comment RMS: χ^2 can be >15% for metabolites if visually acceptable, therefore considered acceptable)

Best fit model / trigger endpoint for AE F130619 : SFO = 6.5 d
Modelling endpoint for AE F130619: SFO 6.5 d

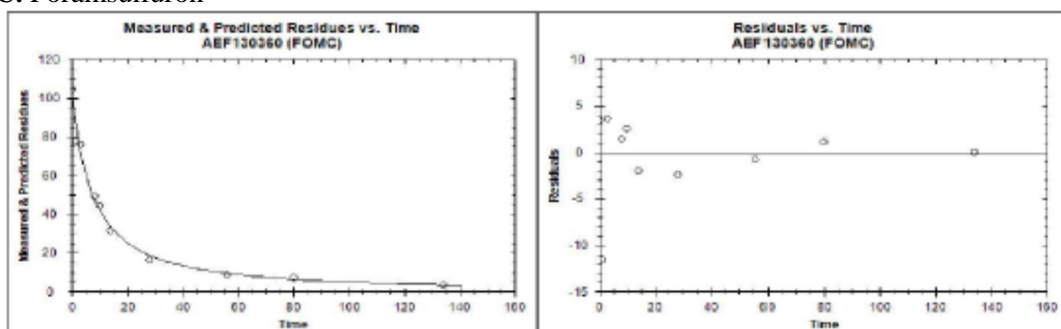
For the metabolite AE F153745, however, no reliable DT50 could be derived because of the unusual time course of the observed data and a respectively bad visual fit with a very large Chi²-error of 58%.

Figure B.8.1.1.1-4. Result of model fit to residue data for foramsulfuron and its metabolites in soil Shuttleworth (phenyl label, 20°C).

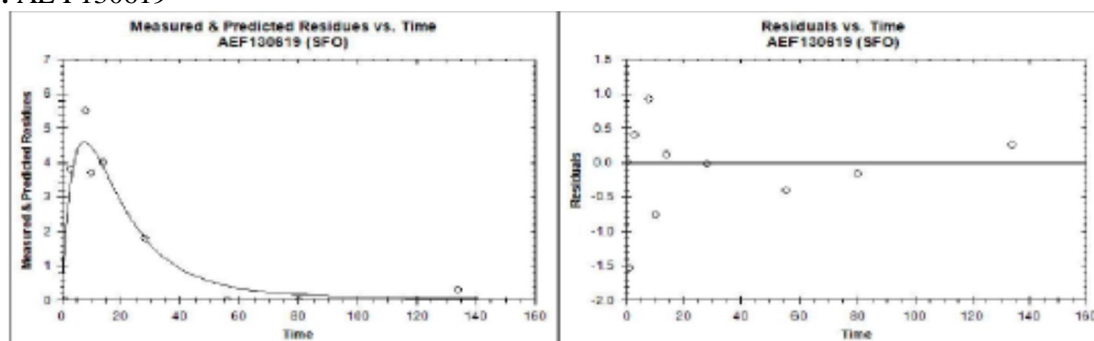
SFO: Foramsulfuron



FOMC: Foramsulfuron



SFO: AE F130619



1. Soil Shuttleworth; pyrimidyl label

Table B.8.1.1.1-3. Time course of pyrimidyl labelled foramsulfuron (AE F130360) and the formation and decline of its metabolites in Shuttleworth sandy loam under non-sterile aerobic conditions at 20 °C (% of applied radioactivity)

Time [days]	Pyrimidyl radiolabeled components (PY)					
	AE F130360	AE F130619	AE F092944	Others	PY-NER	PY- ¹⁴ CO ₂
0	98.6	< LOD	4.6	3.8	na	na
1	75.3	< LOD	9.2	14.2	5.2	0.0
3	71.7	2.4	12.9	4.1	10.9	0.0
8	62.1	4.7	2.5	2.7	34.3	0.6
10	51.7	2.6	7.5	3.6	37.0	1.1
14	39.6	1.7	3.1	5.1	45.8	1.2
28	19.0	< LOD	12.4	2.0	62.9	2.8
56	9.1	0.4	16.9	1.5	61.1	3.5
80	7.2	< LOD	13.5	1.8	54.7	4.5
134	3.0	< LOD	13.8	1.8	75.7	5.9

< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity

na: Not analysed

Fitting the model to the residue data using SFO kinetics for all compartments, led to the results shown in Figure B.8.1.1.1-5. Due to the very large Chi²-error and an unacceptable visual fit (systematic variation of the residuals) for the parent compartment this fit was not accepted. Thus alternatively the model was fitted using the FOMC kinetic for the parent (Table B.8.1.1.1-4). In fact a significant improvement was achieved resulting in an acceptable fit to the parent data. For the metabolite AE F130619, however, no reliable DT₅₀ could be derived due to a bad visual fit with a very large Chi²-error of 80%. For AE F092944 the fit was also not good and resulted in a large Chi²-error of 40% and a p-value beyond 0.1. These issues are, however, mainly caused by a large scatter in the first data points, while the model fits the later observed data well. Therefore for AE F092944 nevertheless a DT₅₀ was derived from the fit.

The results are compiled in Table B.8.1.1.1-4. For foramsulfuron a pseudo-SFO DT₅₀ of 19.6 days and for AE F092944 a DT₅₀ of 141.7 days were derived for use in environmental fate simulations.

Table B.8.1.1.1-4. Summary of the degradation kinetic evaluation of pyridimyl labelled foramsulfuron in Shuttleworth soil

	kinetic model	M_0	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	CI	
									lower	upper
Foramsulfuron	SFO	105.1		k = 0.0714	9.7	32.2	10.1	n.a.	n.a.	n.a.
	FOMC	97.8		$\alpha = 1.7164$ $\beta = 23.0987$	11.5	65.3	11.0	$\alpha: 0.0119$ $\beta: 0.0353$	0.2974 -1.1336	3.135 47.331
AE F130619	SFO			k =	n.d.	n.d.	80.2			
AE F092944	SFO		0.22		141.7	470.8	39.8	k: 0.1178		

Study conclusion (Schmitt & Mikolasch 2012):

Parent SFO: fit visually not acceptable, statistically acceptable (χ^2 10%);
(comment RMS: residual plot shows systematic deviations and therefore not acceptable)

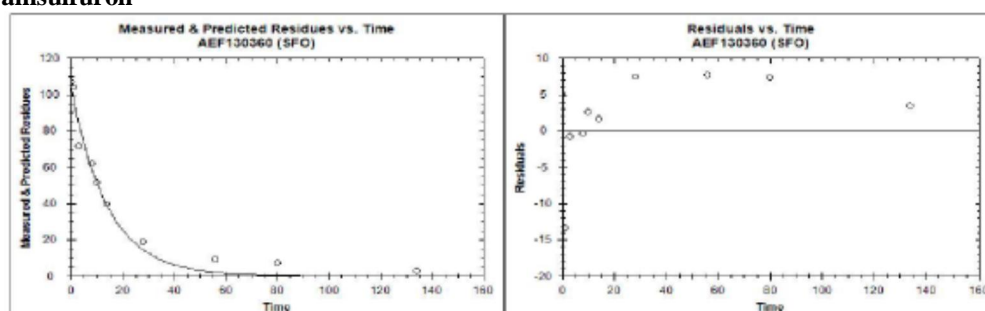
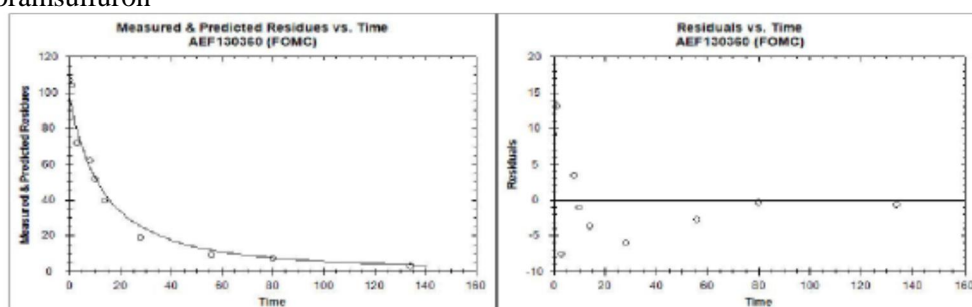
Parent FOMC: fit visually and statistically acceptable
(comment RMS: agreed; 10% initial concentration was met within experimental period)

Best fit model / trigger endpoint for parent: FOMC / 11.5 d
Modelling endpoint for parent: Pseudo-SFO DT50 = FOMC DT90/3.32 = 19.6 d

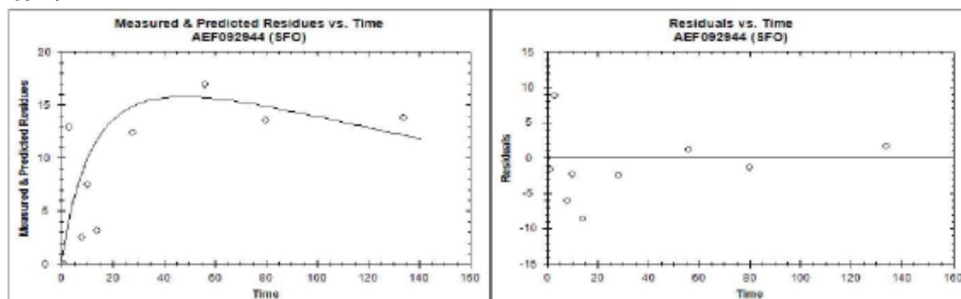
AE F092944 SFO: fit visually not acceptable and statistically not acceptable (χ^2 40%);
(comment RMS: χ^2 can be >15% for metabolites if visually acceptable. The unacceptable fit was mainly caused by a large scatter in the first data points, while the model fits the later observed data well. Therefore the DT50 derived can be considered acceptable)

Best fit model / trigger endpoint for AE F092944 : SFO = 141.7 d
Modelling endpoint for AE F130619: SFO 141.7 d

For the metabolite AE F130619, however, no reliable DT50 could be derived because of the unusual time course of the observed data and a respectively bad visual fit with a very large Chi²-error of 80%.

Figure B.8.1.1.1-5. Result of model fit to residue data for foramsulfuron and its metabolites in soil Shuttleworth (pyrimidyl label, 20°C).**SFO: Foramsulfuron****FOMC: Foramsulfuron**

SFO: AE F092944



2. Soil Orainville; phenyl label

Table B.8.1.1.1-5. Time course of phenyl labelled foramsulfuron (AE F130360) and the formation and decline of its metabolites in Orainville clay loam under non-sterile aerobic conditions at 20 °C (% of applied radioactivity)

Time [days]	Phenyl radiolabeled components (PH)					
	AE F130360	AE F130619	AE F153745	Others	PH-NER	PH- ¹⁴ CO ₂
0	96.9	1.8	1.7	5.0	na	Na
1	58.1	27.3	< LOD	2.4	18.6	0.0
3	33.8	13.6	< LOD	5.3	49.0	0.1
7	13.8	1.4	< LOD	10.8	69.4	0.2
14	6.7	2.3	< LOD	4.4	79.0	0.2
21	6.5	2.5	< LOD	5.1	80.1	0.3
28	5.2	2.1	< LOD	4.3	82.0	0.3
56	2.2	1.3	0.2	3.7	85.0	0.5

< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity

na: Not analysed

For this soil no sufficient observed data for the metabolite AE F153745 were available and the respective compartment was removed from the model. Fitting the model to the residue data using SFO kinetics for the parent compartment, led to the results shown in Figure B.8.1.1.1-6. Due to the large Chi²-error and an unacceptable visual fit (systematic variation of the residuals) for the parent compartment this fit was not accepted. Thus alternatively the model was fitted using the FOMC kinetic for the parent (Figure B.8.1.1.1-6). In fact a significant improvement was achieved resulting in an acceptable fit to the parent data and also for the metabolite AE F130619.

The results are compiled in Table B.8.1.1.1-6. The DT₅₀ values for use in environmental fate simulations derived from the fit were 3.5 days for foramsulfuron and 0.7 days for AE F130619.

Table B.8.1.1.1-6. Summary of the degradation kinetic evaluation of phenyl labelled foramsulfuron in Orainville soil

	kinetic model	M_0	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	CI	
									lower	upper
Foramsulfuron	SFO	107.36		k = 0.5268	1.3	4.4	19.7	not obtained		
	FOMC	105.4		$\alpha = 0.9824$ $\beta = 1.2194$	1.2	11.5	4.4	α : n.a. β : n.a.	0.00 0.00	infinite infinite
AE F130619	SFO		1.0	k = 1.0109	0.7	2.3	16.3	n.a.	n.a.	n.a.

Study conclusion (Schmitt & Mikolasch 2012):

Parent SFO: fit visually not acceptable, statistically acceptable ($\chi^2 = 19.7\%$);
(comment RMS: residual plot shows systematic deviations and therefore not acceptable)

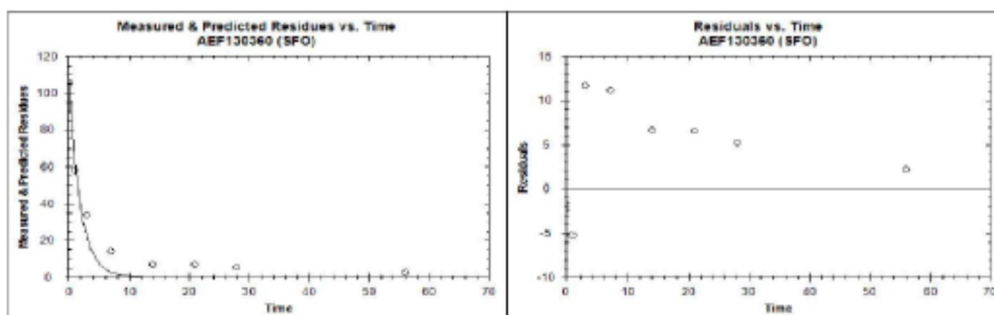
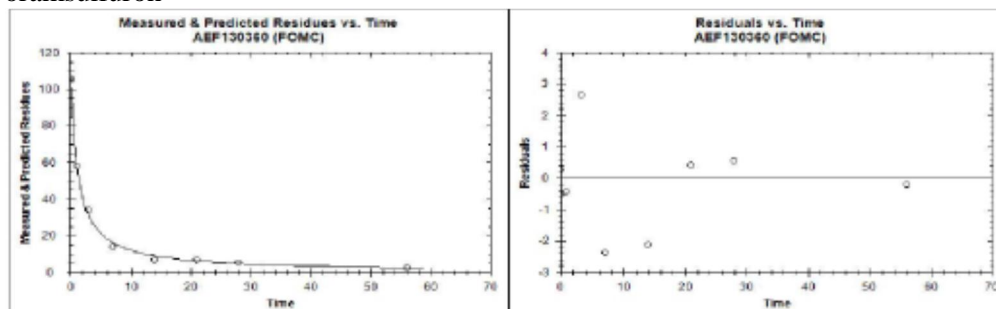
Parent FOMC: fit visually and statistically acceptable
(comment RMS: agreed; 10% initial concentration was met within experimental period)

Best fit model / trigger endpoint for parent: FOMC / 1.2 d
Modelling endpoint for parent: Pseudo-SFO DT50 = FOMC DT90/3.32 = 3.5 d

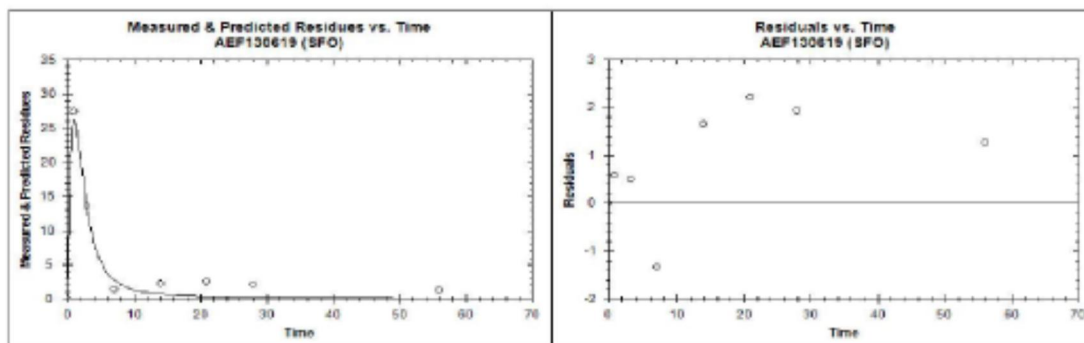
AE F130619 SFO: fit visually acceptable, but not statistically acceptable ($\chi^2 = 16.3\%$);
(comment RMS: χ^2 can be >15% for metabolites if visually acceptable, therefore considered acceptable)

Best fit model / trigger endpoint for AE F130619 : SFO / 0.7 d
Modelling endpoint for AE F130619: SFO / 0.7 d

For this soil no sufficient observed data for the metabolite AE F153745 were available and the respective compartment was removed from the model.

Figure B.8.1.1.1-6. Result of model fit to residue data for foramsulfuron and its metabolites in soil Oraiville (phenyl label, 20°C).**SFO: Foramsulfuron****FOMC: Foramsulfuron**

SFO: AE F130619



2. Soil Orainville; pyrimidyl label

Table B.8.1.1.1-7: Time course of pyrimidyl labelled foramsulfuron (AE F130360) and the formation and decline of its metabolites in Orainville clay loam under non-sterile aerobic conditions at 20 °C (% of applied radioactivity)

Time [days]	Pyrimidyl radiolabeled components (PY)					
	AE F130360	AE F130619	AE F092944	Others	PY-NER	PY- ¹⁴ CO ₂
0	94.1	1.6	3.4	2.7	na	na
1	50.7	30.8	1.9	0.6	18.7	0.1
3	24.8	15.1	< LOD	9.0	49.2	0.3
7	14.5	< LOD	2.7	8.1	68.3	0.6
14	6.4	2.5	1.1	2.2	78.0	1.0
21	6.0	3.4	1.9	1.7	76.7	1.1
28	4.5	2.1	2.1	2.0	77.9	1.5
56	2.6	1.3	1.8	1.5	81.6	2.4
107	3.8	0.5	1.1	2.2	93.1	2.5
143	na	na	na	na	90.7	4.1
196	na	na	na	na	92.2	5.0
199	na	na	na	na	85.5	5.4

< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity na: Not analysed

Fitting the model to the residue data using SFO kinetics for the parent compartment led to the results shown in Figure B.8.1.1.1-7. Due to the very large Chi²-error and an unacceptable visual fit (systematic variation of the residuals) for the parent compartment this fit was not accepted. Thus alternatively the model was fitted using the FOMC kinetic for the parent (Figure B.8.1.1.1-7). In fact a significant improvement was achieved resulting in an acceptable fit to the parent data. For the metabolite AE F092944, however, no reliable DT₅₀ could be derived because of the very large Chi²-errors of 77%.

The results are compiled in Table B.8.1.1.1-8. For foramsulfuron a pseudo-SFO DT₅₀ of 3.1 days and for AE F130619 a DT₅₀ of 0.9 days were derived for use in environmental fate simulations.

Table B.8.1.1.1-8. Summary of the degradation kinetic evaluation of pyrimidyl labelled foramsulfuron in Orainville soil

	kinetic model	M_0	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	CI	
									lower	upper
Foramsulfuron	SFO	101.4		$k = 0.6804$	1.0	3.4	23.4	<0.0001	0.5562	0.805
	FOMC	101.6		$\alpha = 0.8737$ $\beta = 0.7983$	1.0	10.3	3.9	$\alpha: <0.001$ $\beta: <0.001$	0.7693 0.6122	0.978 0.984
AE F130619	SFO		0.84	$k = 0.8534$	0.9		24.0	<0.0001	0.6919	1.015
AE F092944	SFO		0.02	$k = 0.0042$			76.6	0.238		

Study conclusion (Schmitt & Mikolasch 2012):

Parent SFO: fit visually not acceptable, statistically not acceptable ($\chi^2 = 23.4$ %);
(comment RMS: residual plot shows systematic deviations and therefore not acceptable)

Parent FOMC: fit visually and statistically acceptable
(comment RMS: agreed; 10% initial concentration was met within experimental period)

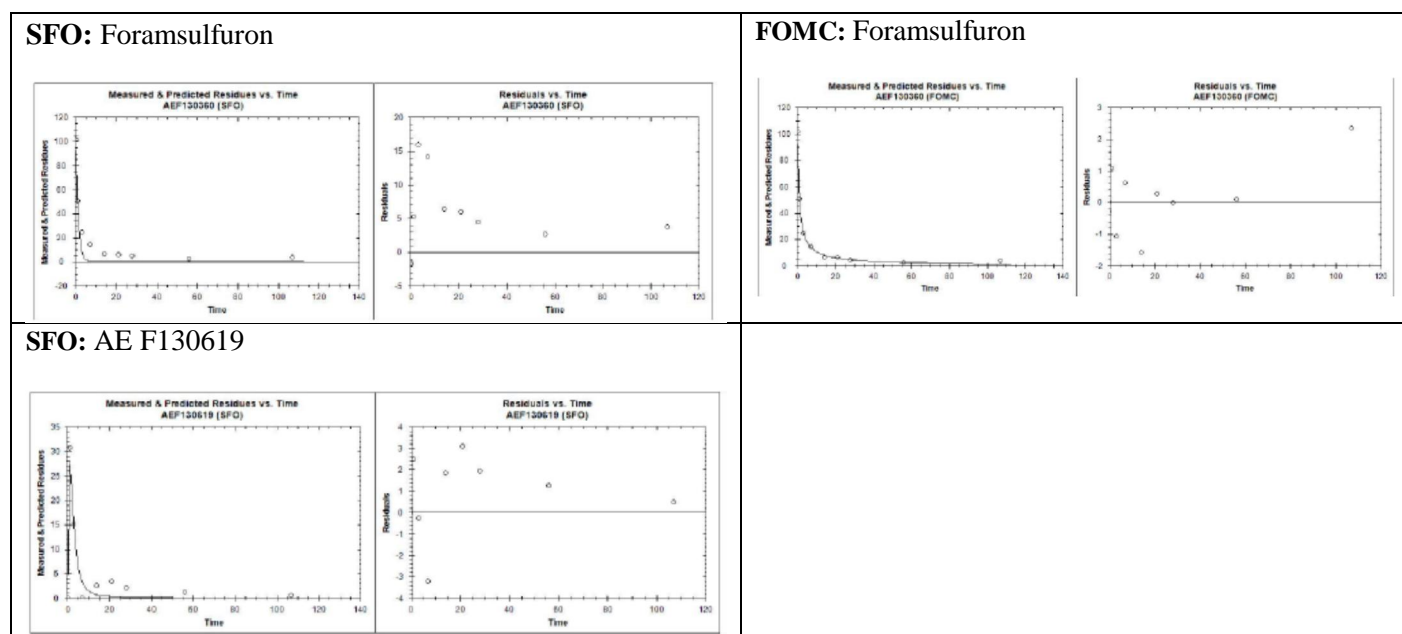
Best fit model / trigger endpoint for parent: FOMC / 1.0 d
Modelling endpoint for parent: Pseudo-SFO DT50 = FOMC DT90/3.32 = 3.1 d

AE F130619 SFO: fit visually acceptable, but not statistically acceptable ($\chi^2 = 24$ %);
(comment RMS: χ^2 can be >15% for metabolites if visually acceptable, therefore considered acceptable)

Best fit model / trigger endpoint for AE F130619 : SFO / 0.9 d
Modelling endpoint for AE F130619: SFO / 0.9 d

For the metabolite AE F092944 no reliable DT50 could be derived because of the very large Chi²-errors of 77%.

Figure B.8.1.1.1-7. Result of model fit to residue data for foramsulfuron and its metabolites in soil Oraiville (pyrimidyl label, 20°C).



3. Soil Chantepie; phenyl label

Table B.8.1.1.1-9. Time course of phenyl labelled foramsulfuron (AE F130360) and the formation and decline of its metabolites in Chantepie clay loam under non-sterile aerobic conditions at 20 °C (% of applied radioactivity)

Time [days]	Phenyl radiolabeled components (PH)					
	AE F130360	AE F130619	AE F153745	Others	PH-NER	PH- ¹⁴ CO ₂
0	99.5	0.8	4.8	3.7	na	na
1	84.6	4.2	4.1	3.0	14.6	0.0
3	54.8	3.3	< LOD	7.5	43.6	0.1
7	30.7	2.1	1.6	3.6	65.5	0.2
14	na	na	na	na	74.5	0.2
21	17.5	< LOD	2.3	3.7	82.7	0.3
28	15.5	< LOD	1.9	3.8	85.5	0.3
56	9.3	< LOD	1.8	2.7	91.5	0.7
107	4.3	< LOD	2.3	3.2	93.3	1.2

< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity

na: Not analysed

Fitting the model to the residue data using SFO kinetics for the parent compartment led to the results shown in Figure B.8.1.1.1-8. Due to the large Chi²-error and an unacceptable visual fit (systematic variation of the residuals) for the parent compartment this fit was not accepted. Thus alternatively the model was fitted using the FOMC kinetic for the parent (Figure B.8.1.1.1-8). In fact a significant improvement was achieved resulting in an acceptable fit to the parent data and for the metabolite AE F130619. For AE F153745, however, the visual fit, particularly to the first observed data point, is not acceptable. Respectively the optimisation resulted in very large Chi²-error of 57%. Therefore no DT₅₀ was derived for this metabolite.

The results are compiled in Table B.8.1.1.1-10. The DT₅₀ values for use in environmental fate simulations derived from the fit were 10.6 days for foramsulfuron and 0.2 days for AE F130619.

Table B.8.1.1.1-10. Summary of the degradation kinetic evaluation of phenyl labelled foramsulfuron in Chantepie soil

	kinetic model	M_0	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	CI	
									lower	upper
Foramsulfuron	SFO	101.7		k = 0.1420	4.9	16.2	18.0	<0.0001		
	FOMC	106.9		$\alpha = 0.9068$ $\beta = 3.092$	3.5	35.4	5.3	α : <0.001 β : <0.001	0.6859 1.759	1.128 4.3
AE F130619	SFO		0.85	k = 3.45	0.2	0.7	30.7	n.a.	n.a.	n.a.
AE F153745	SFO			k =	n.d.	n.d.	57.3			

Study conclusion (Schmitt & Mikolasch 2012):

Parent SFO: fit visually not acceptable, statistically acceptable ($\chi^2 = 12\%$);
(comment RMS: residual plot shows systematic deviations and therefore not acceptable)

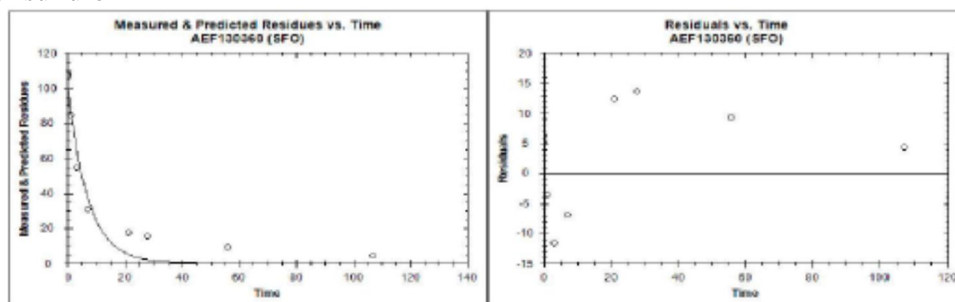
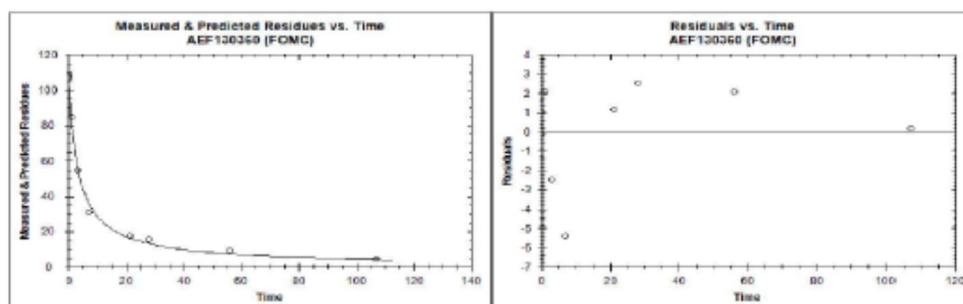
Parent FOMC: fit visually and statistically acceptable
(comment RMS: agreed; 10% initial concentration was met within experimental period)

Best fit model / trigger endpoint for parent: FOMC / 3.5 d
Modelling endpoint for parent: Pseudo-SFO DT50 = FOMC DT90/3.32 = 10.6 d

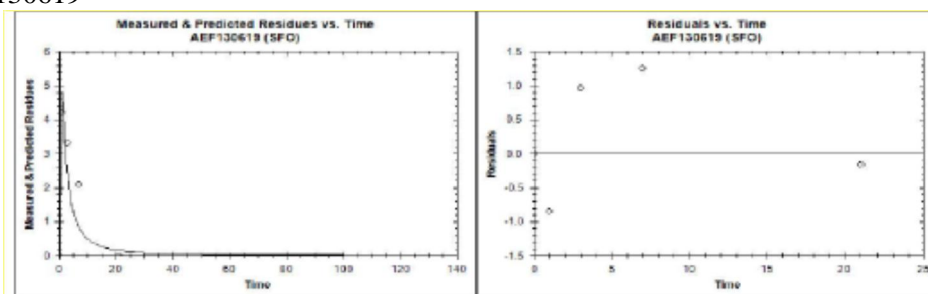
AE F130619 SFO: fit visually acceptable, but not statistically acceptable ($\chi^2 = 38\%$);
(comment RMS: χ^2 can be >15% for metabolites if visually acceptable, therefore considered acceptable)

Best fit model / trigger endpoint for AE F130619 : SFO = 0.2 d
Modelling endpoint for AE F130619: SFO 0.2 d

For AE F153745, due to very large Chi²-error of 57% no DT50 was derived for this metabolite.

Figure B.8.1.1.1-8. Result of model fit to residue data for foramsulfuron and its metabolites in soil Chantepie (phenyl label, 20°C).**SFO: Foramsulfuron****FOMC: Foramsulfuron**

SFO: AE F130619



3. Soil Chantepie; pyrimidyl label

Table B.8.1.1.1-11. Time course of pyrimidyl labelled foramsulfuron (AE F130360) and the formation and decline of its metabolites in Chantepie clay loam under non-sterile aerobic conditions at 20 °C (% of applied radioactivity)

Time [days]	Pyrimidyl radiolabeled components (PY)					
	AE F130360	AE F130619	AE F092944	Others	PY-NER	PY- ¹⁴ CO ₂
0	93.2	0.4	6.2	2.7	na	na
1	82.6	2.7	4.0	2.3	10.8	0.0
3	51.0	5.5	2.6	2.2	44.1	0.5
7	31.8	0.9	1.9	4.7	63.7	1.3
14	na	na	na	na	72.4	2.5
21	19.1	0.6	6.2	1.6	69.8	3.6
28	12.8	< LOD	7.9	1.9	71.5	4.8
56	9.0	0.2	6.9	1.1	72.8	7.8
107	32	< LOD	4.6	3.1	73.1	16.3

< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity

na: Not analysed

Fitting the model to the residue data using SFO kinetics for the parent compartment led to the results shown in Figure B.8.1.1.1-9. Due to the large Chi²-error and an unacceptable visual fit (systematic variation of the residuals) for the parent compartment this fit was not accepted. Thus alternatively the model was fitted using the FOMC kinetic for the parent (Figure B.8.1.1.1-9). In fact a significant improvement was achieved resulting in an acceptable fit to the parent data. For the metabolite AE F130619 no reliable DT₅₀ could be derived because of the extremely large Chi²-error. In case of AE F092944 the statistical quality of the fit was also worse than what is generally accepted. However, since visually the time-course of the observed data was acceptable a DT₅₀ was derived from this fit, which is assumed to be at least a worst case estimate. The results from both evaluations are compiled in Table B.8.1.1.1-12.

For foramsulfuron a pseudo-SFO DT₅₀ of 10.5 days and for AE F092944 a DT₅₀ of 254.4 days was derived for use in environmental fate simulations.

Table B.8.1.1.1-12. Summary of the degradation kinetic evaluation of pyrimidyl labelled foramsulfuron in Chantepie soil

	kinetic model	M_0	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	CI	
									lower	upper
Foramsulfuron	SFO	100.4		k = 0.1883	3.7	12.2	17.8	<0.0001		
	FOMC	101.4		$\alpha = 0.9323$ $\beta = 3.2158$	3.5	34.8	5.8	α : <0.001 β : <0.001	0.6685 1.6232	1.196 4.808
AE F130619	SFO			k =	n.d.	n.d.	82.4			
AE F092944	SFO		0.07	k = 0.0027	254.4	845.1	27.1	0.23	-0.0045	0.010

Study conclusion (Schmitt & Mikolasch 2012):

Parent SFO: fit visually not acceptable, statistically not acceptable ($\chi^2 = 17.8\%$);
(comment RMS: residual plot shows systematic deviations and therefore not acceptable)

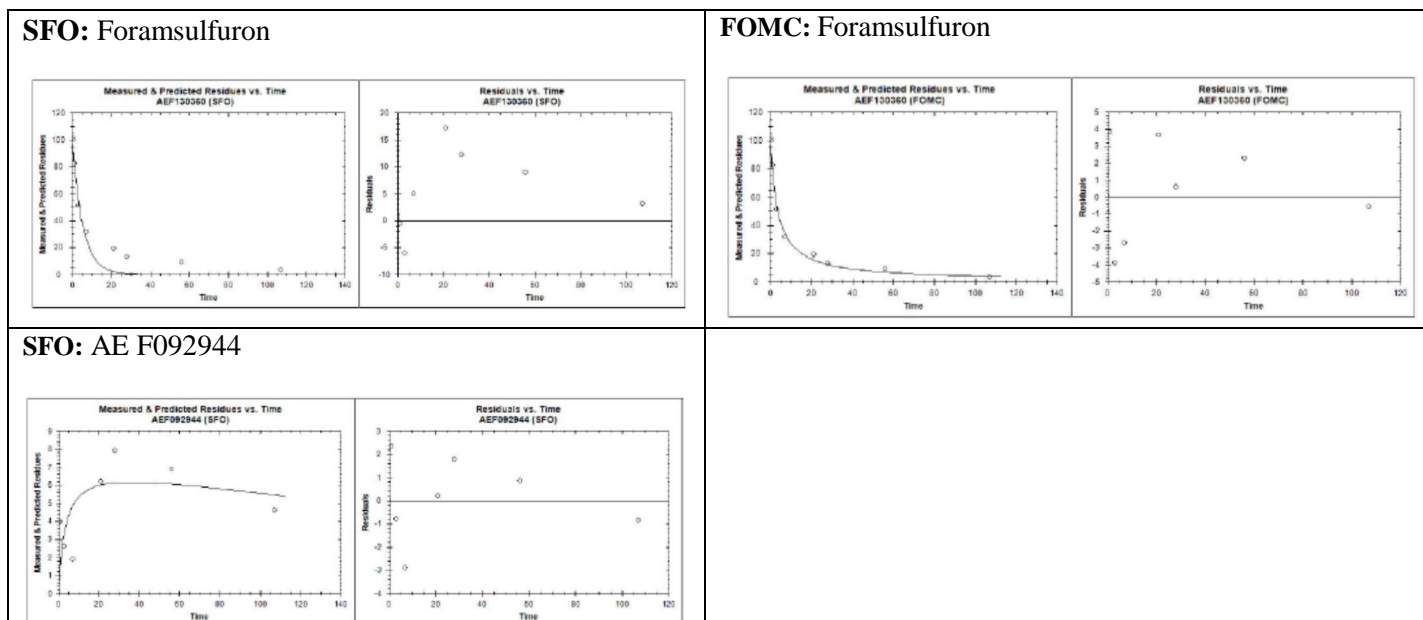
Parent FOMC: fit visually and statistically acceptable
(comment RMS: 10% initial concentration was met within experimental period)

Best fit model / trigger endpoint for parent: FOMC / 3.5 d
Modelling endpoint for parent: Pseudo-SFO DT50 = FOMC DT90/3.32 = 10.5 d

AE F092944 SFO: fit visually acceptable, but not statistically acceptable ($\chi^2 = 27\%$);
(comment RMS: χ^2 can be >15% for metabolites if visually acceptable, therefore considered acceptable)

Best fit model / trigger endpoint for AE F130619 : SFO = 254.4 d
Modelling endpoint for AE F130619: SFO 254.4 d

For the metabolite AE F130619 no reliable DT50 could be derived because of the extremely large Chi²-error.

Figure B.8.1.1.1-9. Result of model fit to residue data for foramsulfuron and its metabolites in soil Chantepie (pyrimidyl label, 20°C).

Reference:	KCA 7.1.1.1 /02; Judge, D. N.; 1999; M-186637-01 Degradation of (U-14C-phenyl) and (2-14C-pyrimidyl)-AE F130360 in two U.S. soils under laboratory aerobic conditions at 25 °C Code: AE F130360
Report No.:	C003704
Guideline:	EU (=EEC): 95/36 7.1.1.1; PMRA: T-1-255; SETAC: 1995; USEPA (=EPA): N 162-1
GLP:	Yes
Previous evaluation:	In DAR (2001)
	Acceptable

The route of degradation in aerobic soil has been investigated under laboratory conditions following application of phenyl-UL-¹⁴C- and pyrimidyl-2-¹⁴C- labelled active substance to two soils under standard conditions of 25°C and moisture at 75% of field capacity at 0.33 bar. The time course of phenyl and pyrimidyl labelled foramsulfuron (AE F130360) and the formation and decline of its metabolites in different soils are presented before the kinetic evaluation of the parent and the metabolites. The figures for visual fits are presented after each kinetic evaluation.

1. Soil Iowa; phenyl label

Table B.8.1.1.1-13. Time course of phenyl labelled foramsulfuron (AE F130360) and the formation and decline of its metabolites in Iowa silty clay loam under non-sterile aerobic conditions at 25 °C (% of applied radioactivity)

Time [days]	Phenyl radiolabeled components (PH)					
	AE F130360	AE F130619	AE F153745	Others	PH-NER	PH- ¹⁴ CO ₂
0	96.9	< LOD	2.3	0.5	2.2	na
3	68.0	10.4	< LOD	2.7	20.7	0.0
8	44.2	2.6	< LOD	12.5	43.3	0.0
14	36.0	1.8	< LOD	3.5	60.0	0.0
21	35.2	0.2	< LOD	0.0	67.4	0.0
30	25.5	4.4	< LOD	1.4	71.0	0.1
63	16.2	4.2	< LOD	1.7	78.6	0.2
90	14.2	3.3	< LOD	1.1	84.6	0.3
126	8.6	1.2	< LOD	3.8	85.2	0.4

< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity na: Not analysed

For this soil no sufficient observed data for the metabolite AE F153745 were available and the respective compartment was removed from the model. Fitting the model to the residue data using SFO kinetics for the parent, led to the result shown in Figure B.8.1.1.1-10. Due to the very high Chi²-error and an unacceptable visual fit (systematic variation of the residuals) for the parent compartment this fit was not accepted. Thus alternatively the model was fitted using the FOMC kinetic for the parent (Figure B.8.1.1.1-10). In fact a significant improvement was achieved resulting in an acceptable fit to the parent data.

For the metabolite AE F130619, however, no reliable DT₅₀ could be derived because of the unusual time course of the observed data and a respectively bad visual fit with a very large Chi²-error of 55%. The results from both evaluations are compiled in Table B.8.1.1.1-14. For foramsulfuron a pseudo-SFO DT₅₀ of 43.3 days was derived from the DT₉₀ for use in environmental fate simulations.

Table B.8.1.1-14. Summary of the degradation kinetic evaluation of phenyl labelled foramsulfuron in Iowa soil

	kinetic model	M_0	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	CI	
									lower	upper
Foramsulfuron	SFO	103.3		k = 0.0971	7.1	23.7	27.3	<0.0001		
	FOMC	101.3		$\alpha = 0.6076$ $\beta = 3.3265$	7.1	143.9	5.1	n.a.	0.00 0.00	infinite infinite
AE F130619	SFO		0.95	k = 0.6987	n.d.	n.d.	54.6			

Study conclusion (Schmitt & Mikolasch 2012):

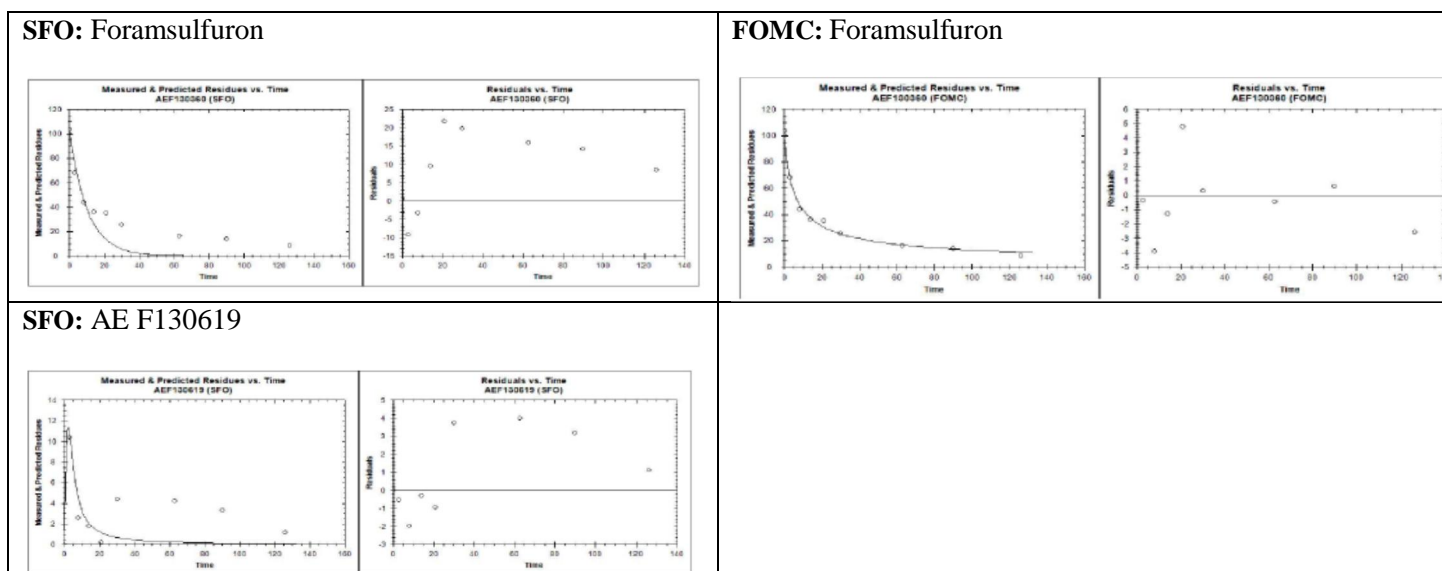
Parent SFO: fit visually not acceptable, statistically not acceptable ($\chi^2 = 25\%$);
(comment RMS: residual plot shows systematic deviations and therefore not acceptable)

Parent FOMC: fit visually and statistically acceptable
(comment RMS: agreed; 10% initial concentration was met within experimental period)

Best fit model / trigger endpoint for parent: FOMC / 7.1 d
Modelling endpoint for parent: Pseudo-SFO DT₅₀ = FOMC DT₉₀/3.32 = 43.3 d

For the metabolite AE F130619 no reliable DT₅₀ could be derived because of the unusual time course of the observed data and a respectively bad visual fit with a very large χ^2 -error of 55%.

For this soil no sufficient data for the metabolite AE F153745 were available and the respective compartment was removed from the model.

Figure B.8.1.1-10. Result of model fit to residue data for foramsulfuron and its metabolites in soil Iowa (phenyl label, 25°C).

1. Soil Iowa; pyrimidyl label

Table B.8.1.1.1-15. Time course of pyrimidyl labelled foramsulfuron (AE F130360) and the formation and decline of its metabolites in Iowa silty clay loam under non-sterile aerobic conditions at 25 °C (% of applied radioactivity)

Time [days]	Pyrimidyl radiolabeled components (PY)					
	AE F130360	AE F130619	AE F092944	Others	PY-NER	PY- ¹⁴ CO ₂
0	96.9	1.6	0.9	0.0	2.1	na
3	74.4	9.9	0.0	3.4	16.4	0.0
8	62.7	0.0	0.0	2.6	38.7	0.0
14	49.7	0.1	0.0	1.9	51.3	0.0
21	34.0	1.7	1.3	3.5	56.2	0.0
30	33.3	1.4	1.9	2.4	61.4	1.3
63	17.7	3.1	4.9	0.0	68.8	3.6
90	15.6	3.0	1.8	0.7	75.0	6.2
126	9.4	0.8	1.8	3.3	74.5	8.7

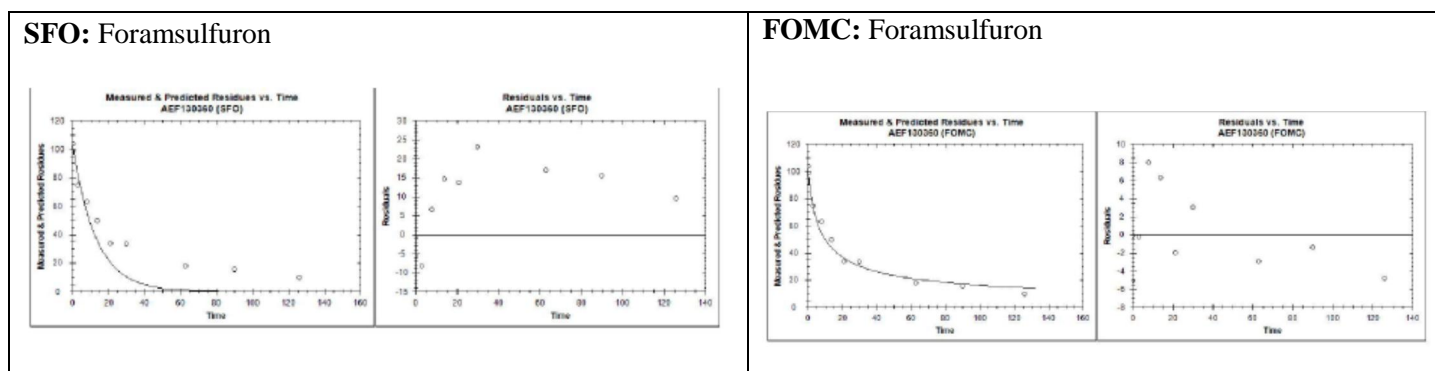
< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity na: Not analysed

Fitting the model to the residue data using SFO kinetics for the parent compartment led to the results shown in Figure B.8.1.1.1-11. Due to the large Chi²-error and an unacceptable visual fit (systematic variation of the residuals) for the parent compartment this fit was not accepted. Thus alternatively the model was fitted using the FOMC kinetic for the parent (Figure B.8.1.1.1-11). In fact a significant improvement was achieved resulting in an acceptable fit to the parent data. For the metabolites AE F130619 and AE F092944, however, no reliable DT₅₀ could be derived because of the unusual time course of the observed data and a respectively bad visual fit with very large Chi²-errors (68% and 60% respectively). The results are compiled in Table B.8.1.1.1-16. For foramsulfuron a DT₅₀ of 67.0 days was derived for use in environmental fate simulations.

Table B.8.1.1.1-16. Summary of the degradation kinetic evaluation of pyrimidyl labelled foramsulfuron in Iowa soil

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ ² [%]	prob > t	CI	
									lower	upper
Foramsulfuron	SFO	104.3		k = 0.0777	8.9	29.6	24.6			
	FOMC	103.7		α = 0.5626 β = 3.7783	9.2	226.2	8.0	n.a.	0.00 0.00	infinite infinite
AE F130619	SFO		0.98		n.d.	n.d.	67.7			
AE F092944	SFO				n.d.	n.d.	60.2			
Study conclusion (Schmitt & Mikolasch 2012):										
Parent SFO: fit visually not acceptable, statistically not acceptable (χ ² = 25 %); (comment RMS: residual plot shows systematic deviations and therefore not acceptable)										
Parent FOMC: fit visually and statistically acceptable (comment RMS: agreed; 10% initial concentration was met within experimental period)										
Best fit model / trigger endpoint for parent: FOMC / 9.2 d Modelling endpoint for parent: Pseudo-SFO DT50 = FOMC DT90/3.32 = 67.0 d										
For the metabolites AE F130619 and AE F092944 no reliable DT50 could be derived because of the unusual time course of the observed data and a respectively bad visual fit with very large Chi ² -errors (68% and 60% respectively).										

Figure B.8.1.1.1-11. Result of model fit to residue data for foramsulfuron and its metabolites in soil Iowa (pyrimidyl label, 25°C).



2. Soil North Carolina; phenyl label

Table B.8.1.1.1-17. Time course of phenyl labelled foramsulfuron (AE F130360) and the formation and decline of its metabolites in North Carolina sand under non-sterile aerobic conditions at 25 °C (% of applied radioactivity)

Time [days]	Phenyl radiolabeled components (PH)					
	AE F130360	AE F130619	AE F153745	Others	PH-NER	PH- ¹⁴ CO ₂
0	96.6	< LOD	4.2	0.5	0.2	na
3	62.7	10.0	4.9	2.7	22.2	0.0
8	47.5	7.7	3.0	12.5	41.4	0.0
14	40.6	5.3	2.2	3.5	50.1	0.0
21	30.3	4.6	< LOD	0.0	64.2	0.0
30	23.7	3.8	1.4	1.4	71.1	0.1
63	12.3	2.5	2.9	1.7	82.4	0.3
90	8.2	2.2	3.3	1.1	83.3	0.4
126	5.2	0.8	1.1	3.8	82.8	0.7

< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity na: Not analysed

Fitting the model to the residue data using SFO kinetics for the parent compartment, led to the results shown in Figure B.8.1.1.1-12. Due to the large Chi²-error and an unacceptable visual fit (systematic variation of the residuals) for the parent compartment this fit was not accepted. Thus alternatively the model was fitted using the FOMC kinetic for the parent (Figure B.8.1.1.1-12). In fact a significant improvement was achieved resulting in an acceptable fit to the parent data. For the metabolites AE F130619 and AE F153745, however, no reliable DT₅₀ could be derived because of the unusual time course of the observed data and a respectively bad visual fit with very large Chi²-errors (40% and 57% respectively).

The results from both evaluations are compiled in Table B.8.1.1.1-18. For foramsulfuron a DT₅₀ of 30.9 days was derived for use in environmental fate simulations.

Table B.8.1.1.1-18. Summary of the degradation kinetic evaluation of foramsulfuron in phenyl labelled North Carolina soil

	kinetic model	M_0	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	CI	
									lower	upper
Foramsulfuron	SFO	99.7		k = 0.0079	8.6	29.1	21.8	<0.0001	0.0047	0.111
Foramsulfuron	FOMC	100.7		$\alpha = 0.7143$ $\beta = 4.2577$	7.0	102.7	7.3	n.a. n.a.	0.00 0.00	infinite infinite
AE F130619	SFO		0.82	k = 0.5428	n.d.	n.d.	39.6			
AE F153745	SFO		0.18	k = 0.2050	n.d.	n.d.	56.6			

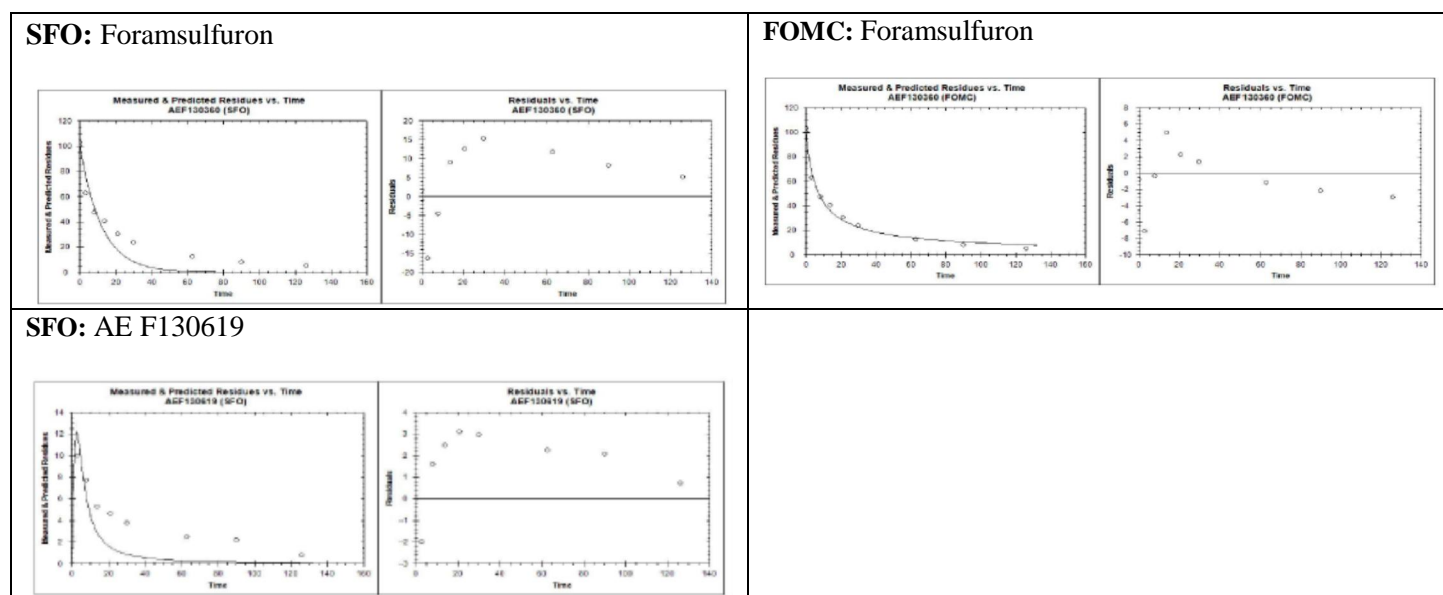
Study conclusion (Schmitt & Mikolasch 2012):

Foramsulfuron SFO: fit visually not acceptable, statistically not acceptable ($\chi^2 > 15\%$);
(comment RMS: residual plot shows systematic deviations)

Foramsulfuron FOMC: fit visually and statistically acceptable
(comment RMS: agreed; 10% initial concentration was met within experimental period)

Best fit model / trigger endpoint for foramsulfuron: FOMC / 7.0 d
Modelling endpoint: for foramsulfuron: Pseudo-SFO DT50 = FOMC DT90/3.32 / 30.9 d

For the metabolites AE F130619 and AE F153745, however, no reliable DT50 could be derived because of the unusual time course of the observed data and a respectively bad visual fit with very large Chi²-errors (40% and 57% respectively).

Figure B.8.1.1.1-12. Result of model fit to residue data for foramsulfuron and its metabolites in soil North Carolina (phenyl label, 25°C).

2. Soil North Carolina; pyrimidyl label

Table B.8.1.1.1-19. Time course of pyrimidyl labelled foramsulfuron (AE F130360) and the formation and decline of its metabolites in North Carolina sand under non-sterile aerobic conditions at 25 °C (% of applied radioactivity)

Time [days]	Pyrimidyl radiolabeled components (PY)					
	AE F130360	AE F130619	AE F092944	Others	PY-NER	PY- ¹⁴ CO ₂
0	99.6	< LOD	3.0	0.0	0.1	na
3	71.5	8.8	2.6	3.4	22.4	0.0
8	46.2	6.4	5.0	2.6	41.8	0.0
14	37.3	4.0	7.6	1.9	50.7	0.0
21	31.7	2.2	9.5	3.5	54.4	0.0
30	24.0	4.8	13.4	2.4	55.1	4.0
63	11.3	25	17.8	0.0	55.5	8.3
90	11.1	1.4	14.9	0.7	55.7	11.4
126	4.7	0.7	15.1	3.3	54.4	18.8

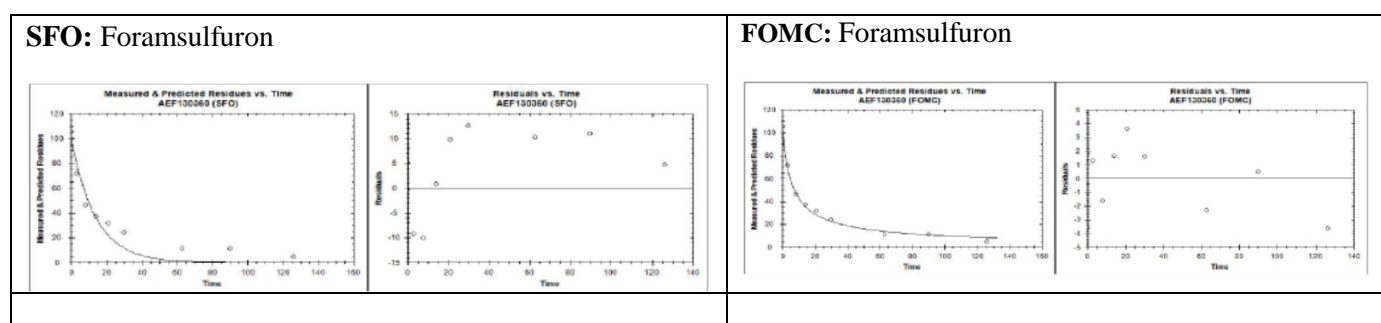
< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity na: Not analysed

Fitting the model to the residue data using SFO kinetics for the parent compartment led to the results shown in Figure B.8.1.1.1-13. Due to the large Chi²-error and an unacceptable visual fit (systematic variation of the residuals) for the parent compartment this fit was not accepted. Thus alternatively the model was fitted using the FOMC kinetic for the parent (Figure B.8.1.1.1-13.). In fact a significant improvement was achieved resulting in an acceptable fit to the parent data. For the metabolites AE F130619 and AE F092944, however, no reliable DT₅₀ could be derived. In both cases a systematic variation of the residuals was found indicating that the model was not able to describe the time-course of the residue data appropriately. This holds also for the NER compartment.

The results from both evaluations are compiled in Table B.8.1.1.1-20. For foramsulfuron a DT₅₀ of 28.0 days was derived for use in environmental fate simulations.

Table B.8.1.1.1-20. Summary of the degradation kinetic evaluation of foramsulfuron in pyrimidyl labelled North Carolina soil

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	CI	
									lower	upper
Foramsulfuron	SFO	100.3		k = 0.0723	9.6	31.8	18.5	<0.0001	0.0047	0.111
Foramsulfuron	FOMC	103.5		$\alpha = 0.7405$ $\beta = 4.3436$	6.7	93.0	4.8	n.a. n.a.	0.00 0.00	infinite infinite
AE F130619	SFO		0.85	k = 0.8463	n.d.	n.d.	47.1			
AE F092944	SFO		0.0	k = 0.0	n.d.	n.d.	18.3			
Study conclusion (Schmitt & Mikolasch 2012):										
<p>Foramsulfuron SFO: fit visually not acceptable, statistically not acceptable ($\chi^2 > 15\%$); (comment RMS: residual plot shows systematic deviations)</p> <p>Foramsulfuron FOMC: fit visually and statistically acceptable (comment RMS: agreed; 10% initial concentration was met within experimental period)</p> <p>Best fit model / trigger endpoint for foramsulfuron: FOMC / 6.7 d Modelling endpoint: for foramsulfuron: Pseudo-SFO DT50 = FOMC DT90/3.32 / 28.0 d</p> <p>For the metabolites AE F130619 and AE F092944, however, no reliable DT50 could be derived. In both cases a systematic variation of the residuals was found indicating that the model was not able to describe the time-course of the residue data appropriately.</p>										

Figure B.8.1.1.1-13. Result of model fit to residue data for foramsulfuron and its metabolites in soil North Carolina (pyrimidyl label, 25°C).

Reference:	KCA 7.1.2.1.1 /03; Judge, D. N.; Abbott, P. B.; Ramanarayan, T. S.; 2000; M-238314-01 Degradation of [U-14C-phenyl] and [2-14-pyrimidyl] AE F130360 in a European soil under laboratory aerobic conditions at 10 ° C: AE F130360
Report No.:	B002565
Guideline:	USEPA (=EPA): 162-1;
GLP:	Yes
Previous evaluation:	In DAR (2001)
	Acceptable

The route of degradation in aerobic soil has been investigated under laboratory conditions following application of phenyl-UL-14C- and pyrimidyl-2-14C- labelled active substance to one soil under standard conditions of 10°C and moisture at 40 % MWHC. The time course of phenyl and pyrimidyl labelled foramsulfuron (AE F130360) and the formation and decline of its metabolites in different soils are presented before the kinetic evaluation of the parent and the metabolites. The figures for visual fits are presented after each kinetic evaluation.

1. Soil Shuttleworth; phenyl label

Table B.8.1.1.1-21: Time course of phenyl labelled foramsulfuron (AE F130360) and the formation and decline of its metabolites in Shuttleworth sandy loam under non-sterile aerobic conditions at 10 °C (% of applied radioactivity)

Time [days]	Phenyl radiolabeled components (PH)					
	AE F130360	AE F130619	AE F153745	Others	PH-NER	PH- ¹⁴ CO ₂
0	97.8	< LOD	9.2	2.2	na	na
1	78.7	1.5	11.9	5.5	2.5	0.0
3	80.3	< LOD	12.9	4.8	3.7	0.0
8	68.5	3.0	3.0	7.3	27.2	0.1
10	75.6	1.4	10.0	2.0	2.1	0.0
15	48.5	4.6	2.7	4.4	38.2	0.1
27	33.3	3.3	1.6	2.7	56.4	0.2
55	28.2	0.8	1.8	1.5	62.5	0.2
83	18.8	< LOD	2.4	6.3	67.5	0.2
133	78.7	0.3	4.2	4.7	83.9	0.3

< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity

Fitting the model with SFO kinetics used for the parent compartment to the residue data for soil Shuttleworth (phenyl label, 10°C) led to the results shown in Figure B.8.1.1.1-14. The statistical evaluation of the fit to the parent data leads to acceptable fits, the visual inspection shows some weaknesses of the fit, as e.g. a systematic variation of the residuals. Thus alternatively the fit using the DFOP kinetic for the parent was tested (Figure B.8.1.1.1-14). In fact a significant improvement of the fit to the parent data was achieved. For the metabolites AE F130619 and AE F153745, however, no reliable DT₅₀ could be derived. In both cases the time-course of the residue data could not be described and the fit resulted in extremely high Chi²-errors >80%.

The results from both evaluations are compiled in Table B.8.1.1.1-21. The DT₅₀ value for use in environmental fate simulations derived from the fit was 56.7 days for foramsulfuron.

Table B.8.1.1.1-22. Summary of the degradation kinetic evaluation of phenyl labelled foramsulfuron in Shuttleworth soil at 10 °C

	kinetic model	M_0	ff	parameter	DT_{50} [days]	DT_{90} [days]	χ^2 [%]	prob > t	CI	
									lower	upper
Foramsulfuron	SFO	101.3		$k = 0.0422$	16.4	54.6	17.3	<0.0001	0.03058	0.054
	DFOP	100.6		$k_1 = 0.0946$ $k_2 = 0.0122$ $g = 0.4773$	18.5	135.3	13.1	$k_1: 0.0003$ $k_2: 0.0014$ $g: <0.001$	0.045796 0.004775 0.2794 49	0.143 0.020 0.675
AE F130619	SFO				n.d.	n.d.	90.2			
AE F153745	SFO				n.d.	n.d.	80.6			

*) Pseudo-SFO DT_{50} calculated from kinetic rate of slow DFOP compartment ($= \ln(2)/k_2$); n.d.: not determinable

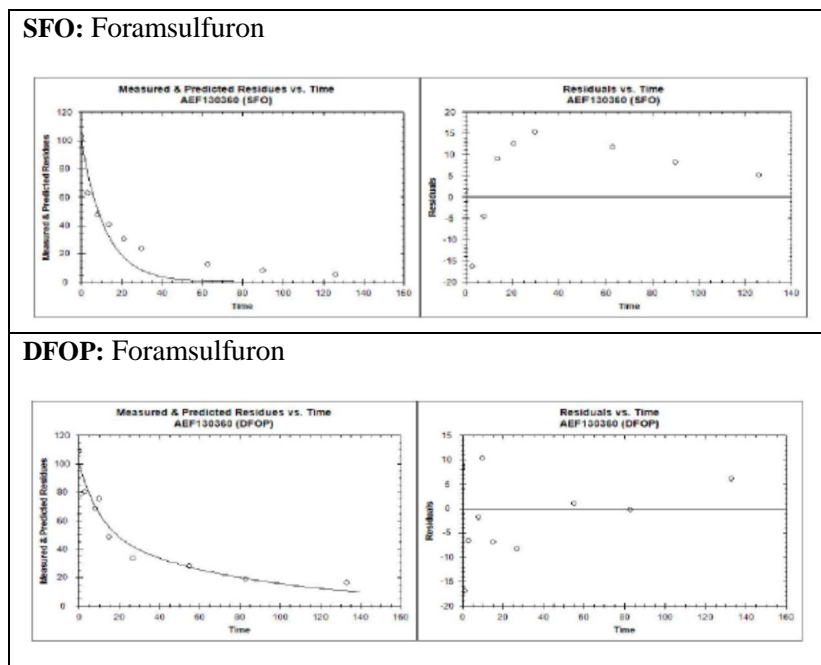
Study conclusion (Schmitt & Mikolasch 2012):

Parent SFO: fit visually not acceptable, statistically acceptable ($\chi^2 = 17.3\%$);
(comment RMS: residual plot shows systematic deviations and therefore not acceptable)

Parent DFOP: fit visually and statistically acceptable
(comment RMS: agreed; 10% concentration was not met within experimental period)

Best fit model / trigger endpoint for parent: DFOP / 18.5 d
Modelling endpoint for parent: Pseudo-SFO $DT_{50} = DFOP \ln(2)/k_2 = 56.7$ d

For the metabolites AE F130619 and AE F153745, however, no reliable DT_{50} could be derived. In both cases the time-course of the residue data could not be described and the fit resulted in extremely high χ^2 -errors >80%.

Figure B.8.1.1.1-14. Result of model fit to residue data for foramsulfuron and its metabolites in soil Shuttleworth (phenyl label, 10°C).

1. Soil Shuttleworth; pyrimidyl label

Table B.8.1.1.1-23: Time course of pyrimidyl labelled foramsulfuron (AE F130360) and the formation and decline of its metabolites in Shuttleworth sandy loam under non-sterile aerobic conditions at 10 °C (% of applied radioactivity)

Time [days]	Pyrimidyl radiolabeled components (PY)					
	AE F130360	AE F130619	AE F092944	Others	PY-NER	PY- ¹⁴ CO ₂
0	92.5	< LOD	10.6	3.6	na	na
1	79.9	0.9	12.3	5.8	2.6	0.0
3	86.9	0.8	9.1	1.9	3.2	0.0
8	78.1	< LOD	4.2	3.0	21.3	0.1
10	75.6	1.6	10.0	2.8	2.6	0.0
15	50.5	5.1	3.7	4.2	34.0	0.3
27	34.8	3.1	4.9	0.9	54.5	0.7
55	27.4	0.6	8.6	1.0	55.3	1.1
83	24.0	< LOD	10.3	2.6	66.7	1.2
133	16.1	< LOD	15.5	2.5	72.2	1.5

< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity

Fitting the model with SFO kinetics used for the parent compartment to the residue data for soil Shuttleworth (pyrimidyl label, 10°C) led to the results shown in Figure B.8.1.1.1-15. Due a systematic variation of the residuals the respective fit was not accepted and instead a model using the DFOP kinetic for the parent was tested (Figure B.8.1.1.1-15). In fact a significant improvement of the fit to the parent data was achieved. For the metabolites AE F130619 and AE F092944, however, no reliable DT₅₀ could be derived. In both cases the time course of the observed data could not be described by the model resulting in respectively large Chi²-errors of 103% and 46%, respectively. The results from both evaluations are compiled in Table B.8.1.1.1-24.

Table B.8.1.1.1-24. Summary of the degradation kinetic evaluation of pyrimidyl labelled foramsulfuron in Shuttleworth soil at 10 °C

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ ² [%]	prob > t	CI	
									lower	upper
Foramsulfuron	SFO	95.0		k = 0.0344	20.1	66.9	14.9	<0.0001	0.0266	0.042
	DFOP	99.4		k1 = 0.0698 k2 = 0.0080 g = 0.5716	20.5	181.9	11.0	k1: 0.0001 k2: 0.006 g: <0.001	0.0420 0.0212 0.2815	0.097 0.014 0.762
AE F130619	SFO				n.d.	n.d.	103.4	0.005		
AE F092944	SFO		0.22		n.d.	n.d.	46.0	0.5		

*) Pseudo-SFO DT₅₀ calculated from kinetic rate of slow DFOP compartment (= ln(2)/k₂); n.d.: not determinable

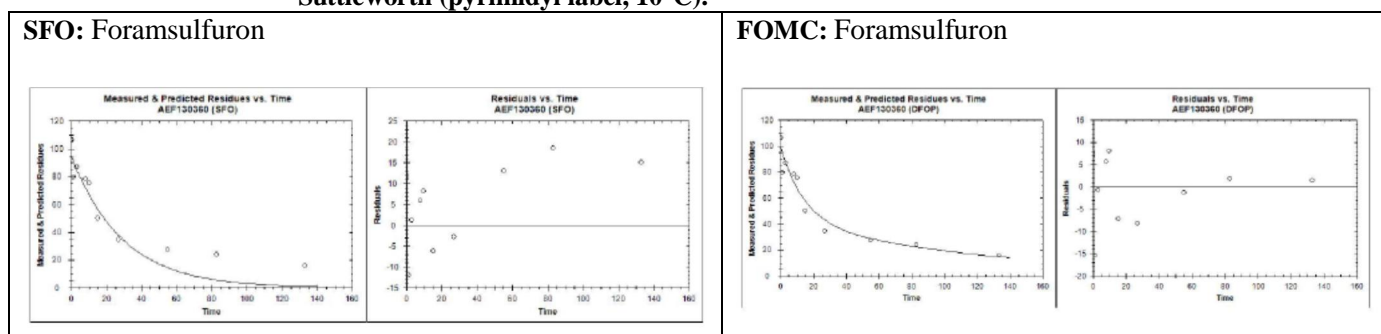
Study conclusion (Schmitt & Mikolasch 2012):

Parent SFO: fit visually not acceptable, statistically acceptable (χ² = 14.9%);
(comment RMS: residual plot shows systematic deviations and therefore not acceptable)
Parent DFOP: fit visually and statistically acceptable
10% concentration was not met within experimental period

Best fit model / trigger endpoint for parent: DFOP / 20.5 d
Modelling endpoint for parent: Pseudo-SFO DT₅₀ = DFOP ln(2)/k₂ = 86.6 d

For the metabolites AE F130619 and AE F092944, however, no reliable DT₅₀ could be derived. In both cases the time course of the observed data could not be described by the model resulting in respectively large Chi²-errors of 103% and 46%, respectively.

Figure B.8.1.1.1-15. Result of model fit to residue data for foramsulfuron and its metabolites in soil Shuttleworth (pyrimidyl label, 10°C).



Summary of results from all three aerobic degradation studies

Summary of calculation of non-normalised DT₅₀-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 DT₅₀-values were back-calculated from the corresponding value of the DT₉₀ derived either by the FOMC or the DFOP fit. The results are summarised in Table B.8.1.1.1-25. For purposes of evaluation against persistence triggers, the non-normalised values for DT₅₀- and the DT₉₀ derived are summarised in Table B.8.1.1.1-27.

Table B.8.1.1.1-25: Compilation of DT₅₀-values for foramsulfuron and its metabolites derived from the different data sets.

Study	Soil	Label	Best fit DT50 (days)	Modelling DT50 (days)	Kinetic model
Judge 2000a	Shuttleworth	Phenyl	7.3	15.6	FOMC ¹
	Shuttleworth	Pyrimidyl	11.5	19.6	FOMC ¹
	Orainville	Phenyl	1.2	3.5	FOMC ¹
	Orainville	Pyrimidyl	1.0	3.1	FOMC ¹
	Chantepie	Phenyl	3.5	10.6	FOMC ¹
	Chantepie	Pyrimidyl	3.5	10.5	FOMC ¹
Judge 1999	Iowa	Phenyl	7.1	43.3	FOMC ¹
	Iowa	Pyrimidyl	9.2	67.0	FOMC ¹
	North Carolina	Phenyl	7.0	30.9	FOMC ¹
	North Carolina	Pyrimidyl	6.7	28.0	FOMC ¹
Judge 2000b	Shuttleworth 10 °C	Phenyl	18.5	56.7	DFOP ²
	Shuttleworth 10 °C	Pyrimidyl	20.5	86.6	DFOP ²

¹ Modelling endpoint for parent: Pseudo-SFO DT50 = FOMC DT90/3.32

² Modelling endpoint for parent: Pseudo-SFO DT50 = DFOP ln(2)/k2

Normalisation of DT₅₀-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. This normalisation was conducted using the standard approach described in (FOCUS, 2000). The temperature normalisation was based on the Arrhenius equation for kinetic rates:

$$k = k^0 \cdot e^{-E_a/RT}$$

where E_a is the activation energy, R is the Rydberg constant and T the temperature. An activation energy of 65400 J/mol ($Q_{10} = 2.58$) was considered for the normalisation.

This leads to a normalisation factor for the DT₅₀ values of: $\frac{DT_{50}(T)}{DT_{50}(T_{ref})} = \frac{e^{-E_a/RT_{ref}}}{e^{-E_a/RT}}$.

The normalisation was carried out considering an activation energy of 65400 kJ/mol (EFSA, 2008).

For the moisture normalisation the Walker equation was used (Walker, 1974). The moisture-normalised DT_{50norm} is then determined as follows:

$$DT_{50, norm} = DT_{50} \cdot \left(\frac{\theta}{\theta_{ref}} \right)^{0.7}$$

where θ is the soil moisture content during incubation and θ_{ref} the reference moisture content, i.e. the field capacity. Since the field capacity of the test soils was not determined in all cases the value was chosen that is tabulated for the respective soil texture in the FOCUS report on ground water (FOCUS, 2000). If the moisture during incubation exceeds the reference moisture, no normalisation is conducted (the moisture normalisation factor has an upper limit of 1).

The parameters used in the laboratory tests and the respective correction factors calculated are summarised in Table B.8.1.1.1-26. The values of half-lives resulting from normalisation are summarised in Table B.8.1.1.1-27.

Table B.8.1.1.1-26: 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	0.33 bar				Moisture	Temp.
			[% m/m]	[% m/m]				[-]	[-]
Judge, 1999	North Carolina	Loamy sand	-	9	6.75	14	25	0.60	1.61
	Iowa	Clay loam	-	25	18.75	28	25	0.76	1.61
Judge, 2000a	Shuttleworth	Sandy loam	27	-	10.8	19	20	0.67	1.00
	Orainville	Clay loam	32	-	12.8	28	20	0.58	1.00
	Chantepie	Clay loam	32	-	12.8	28	20	0.58	1.00
Judge, 2000b	Shuttleworth	Sandy loam	40.4	10.9	16.1	-	10	1.32	0.39

* Calculated values according to FOCUS, 2000

** 75% of 0.33 bar or at 40% (55%) of MWHC

*** Values given in study report

The evaluation according to FOCUS 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 DT₅₀ were derived by back-calculation from the corresponding DT₉₀-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).

Table B.8.1.1.1-27: DT₅₀ and DT₉₀-values for parent compound foramsulfuron in aerobic soils under laboratory conditions for modelling evaluation and for trigger evaluation

Soil (Origin)	Label position	Non-normalised DT ₅₀ (days)	Non-normalised DT ₉₀ (days)	Non-normalised Pseudo-DT ₅₀ (days)	Normalised Pseudo-DT ₅₀ (days)	Model
		Best fit	Best fit	Modelling	Modelling	
Iowa, 25°C (Judge, 1999)	phenyl	7.1	143.8	43.3	53.0	FOMC
Iowa, 25°C (Judge, 1999)	pyrimidyl	9.2	222.4	67.0	82.0	FOMC
Mean (geometric)		8.1	178.8		65.9	
North Carolina, 25°C (Judge, 1999)	phenyl	7.0	102.6	30.9	29.8	FOMC
North Carolina, 25°C (Judge, 1999)	pyrimidyl	6.7	93.0	28.0	27.0	FOMC
Mean (geometric)		6.8	97.7		28.4	
Shuttleworth, 20°C (Judge, 2000a)	phenyl	7.3	51.8	15.6	10.5	FOMC
Shuttleworth, 20°C (Judge, 2000a)	pyrimidyl	11.5	65.1	19.6	13.1	FOMC
Shuttleworth, 10°C (Judge, 2000b)	phenyl			56.7	29.2	DFOP
Shuttleworth, 10°C (Judge, 2000b)	pyrimidyl			86.6	44.6	DFOP
Mean (geometric)		9.2	58.1		20.6	
Orainville, 20°C (Judge, 2000a)	phenyl	1.2	11.6	3.5	2.0	FOMC
Orainville, 20°C (Judge, 2000a)	pyrimidyl	1.0	10.3	3.1	1.8	FOMC
Mean (geometric)		1.1	10.9		1.9	
Chantepie, 20°C (Judge, 2000a)	phenyl	3.5	35.2	10.6	6.1	FOMC
Chantepie, 20°C (Judge, 2000a)	pyrimidyl	3.5	34.9	10.5	6.1	FOMC
Mean (geometric)		3.5	35.0		6.1	
Mean (geometric) for modelling		-	-		13.5	
Worst case for trigger evaluation (best fit)		9.2	178.8			
Shuttleworth, 10°C (Judge, 2000b)	phenyl	18.5	188.2	29.2		DFOP
Shuttleworth, 10°C (Judge, 2000b)	pyrimidyl	20.5	287.5	44.6		DFOP
Worst case mean for trigger evaluation		19.5	232.6			

For comparison with EU triggers the kinetic evaluation of degradation in aerobic soil at 20 to 25°C was performed according to FOCUS guidance to result in half-lives ranging from 1.1 to 9.2 days for foramsulfuron. The corresponding values for the DT₉₀ were 10.9 to 178.8 days. The worst case non-normalised half-life of 9.2 days and a DT₉₀ of 178.8 days were used against the persistence triggers.

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 B.8.1.1.1-28. For AE F130619 a 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 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.

Table B.8.1.1.1-28: 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 to AE F130619	Foramsulfuron to AE F092944
Orainville, 20°C (Judge, 2000a)	phenyl	1.0	-
Orainville, 20°C (Judge, 2000a)	pyrimidyl	0.84	-
Mean Orainville		0.92	-
Chantepie, 20°C (Judge, 2000a)	phenyl	0.85	-
Shuttleworth, 20°C (Judge, 2000a)	phenyl	0.14	-
Chantepie, 20°C (Judge, 2000a)	pyrimidyl	-	0.07
Shuttleworth, 10°C (Judge, 2000b)	pyrimidyl	-	0.22
Mean (arithmetic)		0.64 *	0.15

* Arithmetic mean calculated from average values for single soils

RMS comments and conclusion

All three studies were evaluated during the Annex I listing by RMS Germany and were considered acceptable. All the studies followed the OECD test guideline 307: Aerobic transformation in soil from 2002 and are therefore considered as valid. However, very long incubation periods of up to one year were used for most of the studied soils. This is much longer than the recommended duration of maximum 120 days for laboratory studies (OECD TG 307). Therefore, the Applicant suggested that for the kinetic evaluation of the degradation only the data measured up to day 120 days would be considered. RMS agrees with this approach, since over 90 % of the active substance was degraded within this time, except in one soil at 10 °C where data measured up to day 133 days were considered.

RMS agrees also with the proposed compartment models used for the kinetic evaluation. For the determination of the degradation rate, the data sets were analysed in accordance with the FOCUS Deg Kinetics Report (2006). For optimal goodness of fit, the initial value was allowed to be estimated by the model and all data points were weighted equally. The residue at time zero for metabolites formed from

the applied substance was on the other hand kept fixed at a value of zero. Hence, the calculated DT_{50} and DT_{90} are regarded as suitable and reliable for use in environmental exposure assessments. The geometric mean of normalised half-life of 13.5 days can be used as modelling endpoint and the worst case mean values of non-normalised half-lives can be used for evaluation against persistence triggers.

Acceptable formation fractions were obtained for AE F130619 and for AE F092944. 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. RMS agrees with the suggestion of the Applicant that the worst case values for formation fractions should be used in the environmental fate simulations. These formation fractions are 0.92 for the metabolite AE F130619 and 0.22 for the metabolites AE F153745 and AE F092944.

B.8.1.1.2 Aerobic degradation of the metabolites

1) The kinetic evaluations of the metabolites in the studies performed with the active substance are presented in the Section B.8.1.1.1 above.

2) In the evaluations for Annex I inclusion information on rate of degradation of metabolite AE F130619 in aerobic soil was derived from the following laboratory test:

- 4 soils under standard conditions of 20°C and moisture at 40 % MWHC following application of phenyl-UL-¹⁴C- and pyrimidyl-2-¹⁴C- labeled metabolite AE F130619 (KCA 7.1.2.1.2 /04). Data sets from laboratory tests were kinetically re-evaluated (KCA 7.1.2.1.2 /08).

3) For the renewal process, 2 new studies were submitted, one for the metabolite AE F153745 and one for the metabolite AE F092944.

All the metabolite studies were kinetically re-evaluated by Schmitt & Mikolasch 2013 (the reference below).

Reference:	KCA 7.1.2.1.2 /08; Schmitt, W.; Mikolasch, B.; 2013; M-453563-02; Amended: 2013-07-19 Kinetic evaluation of laboratory aerobic soil degradation of foramsulfuron and its metabolites according to Focus
Report No.:	EnSa-12-0246
Document No.:	M-453563-02-1
Guideline:	Not applicable
GLP:	Yes
Previous evaluation:	Submitted for the purpose of renewal
	Acceptable

2) Degradation of the metabolite AE F130619

Reference:	KCA 7.1.2.1.2 /04; Judge D.N., Abbott P.B., Allen R. (2000c) Judge D.N., (2000a, Amendment) Degradation of [U-14C-phenyl] and [2-14C-pyrimidyl]- AE F130619 in Four Soils under Laboratory Aerobic Conditions at 20 °C
Report No.:	
Guideline:	USEPA Section N, 162-1; Canada PMRA T-1-255
GLP:	Yes
Previous evaluation:	In DAR (2001)
	Acceptable

The route of degradation in aerobic soil has been investigated under laboratory conditions following application of phenyl-UL-14C- and pyrimidyl-2-14C- labelled AE F130619 in four soils under standard conditions of 20°C and moisture at 40 % MWHC. This study was evaluated during the Annex I inclusion in DAR and was considered acceptable. The study was not re-evaluated, since the study was performed according to the US EPA: 162-1 which is in line with OECD test guideline No. 307: Aerobic and Anaerobic Transformation in Soil.

Therefore only the results for the degradation of the metabolite AE F130619 are presented. The results are presented for the better understanding of kinetic evaluation of the degradation of the metabolite. The RMS comments on the kinetic evaluation of the degradation of the metabolite are given in tables for each soil and the overall conclusion at the end of the study.

Results

In the study with direct application of AE F130619 to soil apart from the applied substance also potential degradation products (AE F148003, AE F092944 and AE F099095) were analysed. However, in most cases analysis of extractable residues was stopped after 14 days and due to the very short period no reliable information on the kinetics was derivable. In addition the residues observed for the metabolites were generally very low. An exception was given by the trial with soil Chantepie using pyrimidyl labelled substance. In this case considerable residues of AE F092944 were found and samples were analysed up to 120 days. This dataset was tried to be evaluated for deriving endpoints for the metabolite, but it was not possible to achieve an acceptable fit of the kinetic model. Therefore it was decided generally to evaluate only the degradation of the applied substance and to derive a reliable DT₅₀ for AE F130619. The results for the degradation of the metabolite AE F130619 are presented in the tables below.

1. Soil Illinois; phenyl label

Table B.8.1.1.2-1. Time course of phenyl labelled AE F130619 and the formation and decline of its metabolites in Illinois sandy loam under non-sterile aerobic conditions at 20 °C (% of applied radioactivity)

Time [days]	Phenyl radiolabeled components (PH)				
	AE F130619	AE F153745	Others	PH-NER	PH- ¹⁴ CO ₂
0	79.6	< LOD	7.1	14.4	na
0.33	60.7	< LOD	8.5	31.0	0.0
1	40.9	< LOD	7.9	47.5	0.0
3	27.1	< LOD	8.2	60.5	0.1
7	18.9	< LOD	8.9	37.3	0.1
14	11.2	< LOD	7.1	77.0	0.1
22	na	na	na	84.4	0.2
28	na	na	na	51.7	0.2
63	na	na	na	92.7	0.3
120	na	na	na	91.1	0.4

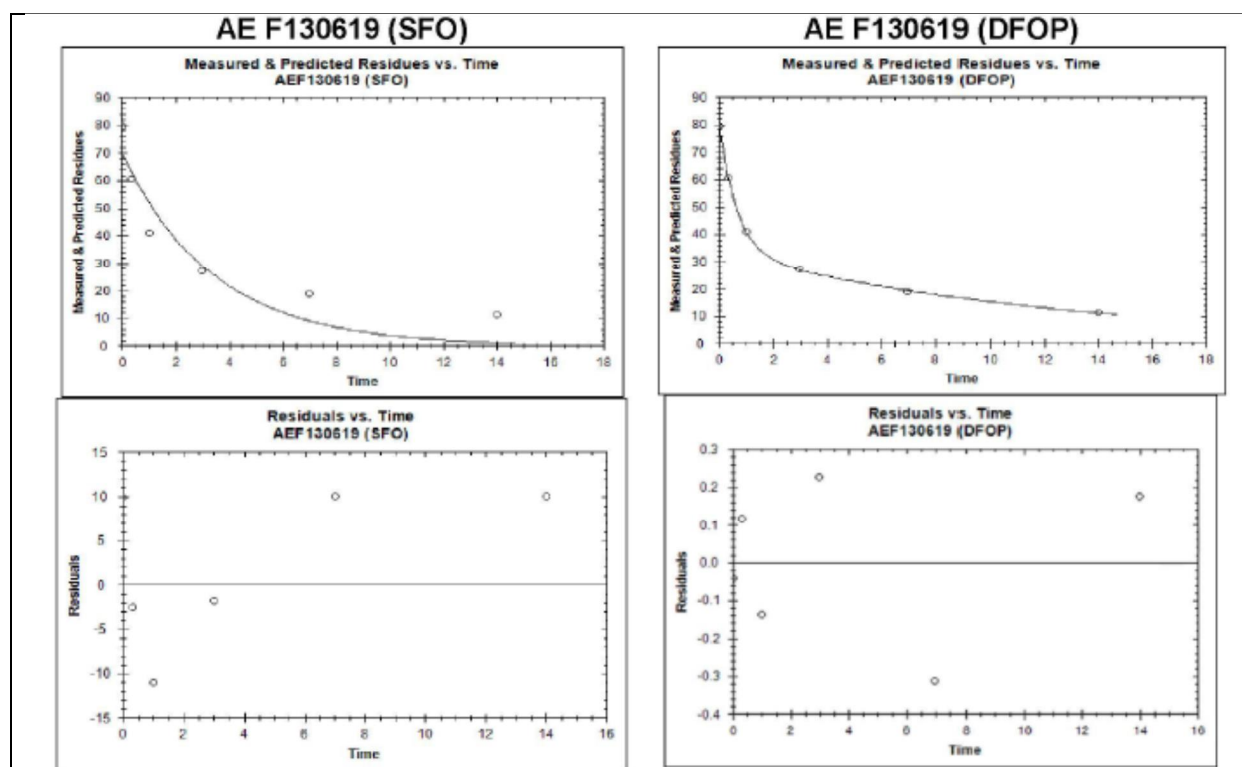
< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity na: Not analysed

Fitting the SFO model to the residue data did not lead to an acceptable fit to the observed data (Figure B.8.1.1.2-1). Therefore, following the FOCUS guidance for cases where less than 90% degradation was reached during the study period, a DFOP model was fitted to the data resulting in a significantly better visual fit (Figure B.8.1.1.2-1). Also the Chi²-error decreased strongly and was far below 15% (Table B.8.1.1.2-2). For the use in environmental fate simulations a pseudo SFO-DT₅₀ of 8.7 days was calculated from the kinetic rate of the slowly degrading DFOP compartment.

Table B.8.1.1.2-2. Summary of the kinetic evaluation of the degradation of phenyl labelled AE F130619 in Illinois soil

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ ² [%]	prob > t	parameter CI	
									lower	upper
AE F130619	SFO	69.7		k = 0.2937	2.4	7.8	17.0	0.0544	0.0138	0.574
	DFOP	79.6		k1 = 1.5184 k2 = 0.0794 g = 0.5796	1.1	18.1	0.5	k1: 0.0004 k2: 0.0007 g: 0.00009	1.4324 0.0737 0.5636	1.604 0.085 0.596
*) Pseudo-SFO DT50 calculated from kinetic rate of slow DFOP compartment (= ln(2)/k2) Study conclusion (Schmitt & Mikolasch 2012): AE F130619 SFO: fit visually not acceptable, statistically not acceptable (χ ² = 17%); (comment RMS: residual plot shows systematic deviations and therefore not acceptable) AE F130619 DFOP: fit visually and statistically acceptable (comment RMS: agreed; 10% concentration was not met within experimental period) Best fit model / trigger endpoint for AE F130619: DFOP / 1.1 d Modelling endpoint for AE F130619: Pseudo-SFO DT50 = DFOP ln(2)/k2 = 8.7 d										

Figure B.8.1.1.2-1. Result of model fit to residue data for AE F130619 in soil Illinois (phenyl label).



1. Soil Illinois; pyrimidyl label

Table B.8.1.1.2-3. Time course of pyrimidyl labelled AE F130619 and the formation and decline of its metabolites in Illinois sandy loam under non-sterile aerobic conditions at 20 °C (% of applied radioactivity)

Time [days]	Pyrimidyl radiolabeled components (PY)				
	AE F130619	AE F092944	Others	PY-NER	PY- ¹⁴ CO ₂
0	69.2	6.7	12.2	13.9	na
0.33	63.4	1.5	6.5	30.6	0.0
1	46.8	1.0	5.5	48.9	0.1
3	25.5	1.1	7.5	65.1	0.1
7	21.3	1.0	6.7	38.6	0.2
14	15.0	< LOD	10.5	72.4	0.3
22	na	na	na	87.4	0.6
28	na	na	na	54.5	0.6
63	na	na	na	92.0	1.5
120	na	na	na	91.2	2.8

< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity na: Not analysed

Fitting a SFO model to the residue data did not lead to a visually acceptable fit to the observed data (Figure B.8.1.1.2-2) because of systematically varying residues. Therefore, alternatively a DFOP model was fitted to the data resulting in a significantly better visual fit (Figure B.8.1.1.2-2). Also the Chi²-error decreased strongly and well below 15% (Table B.8.1.1.2-4). For the use in environmental fate simulations a pseudo SFO-DT₅₀ of 24.7 days was calculated from the kinetic rate of the slowly degrading DFOP compartment

Table B.8.1.1.2-4. Summary of the kinetic evaluation of the degradation of pyrimidyl labelled AE F130619 in Illinois soil

	kinetic model	M_0	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
AE F130619	SFO	64.5		k = 0.2047	3.4	11.2	14.4	0.0334	0.0442	0.365
	DFOP	70.9		k1 = 0.6799 k2 = 0.0281 g = 0.6732	1.9	42.2	4.1	k1: 0.0294 k2: 0.2154 g: 0.0099	0.3419 -0.0281 0.4847	1.018 0.084 0.862

*) Pseudo-SFO DT50 calculated from kinetic rate of slow DFOP compartment ($= \ln(2)/k_2$)

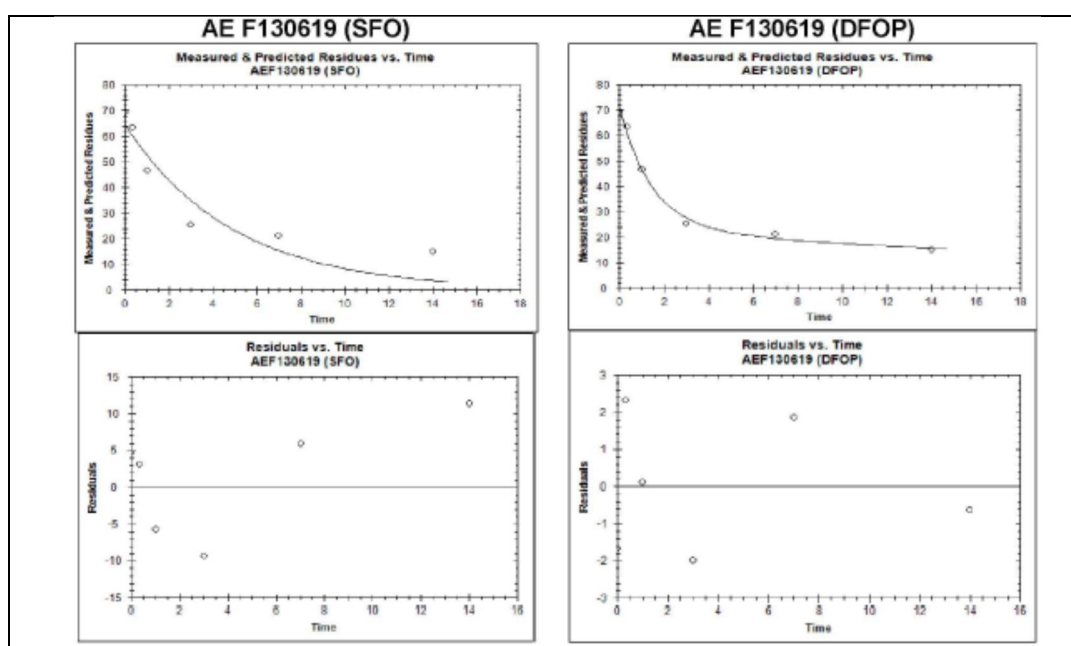
Study conclusion (Schmitt & Mikolasch 2012):

AE F130619 SFO: fit visually not acceptable, statistically acceptable ($\chi^2 = 14\%$);
(comment RMS: residual plot shows systematic deviations and therefore not acceptable)

AE F130619 DFOP: fit visually and statistically acceptable
(comment RMS: agreed; 10% concentration was not met within experimental period)

Best fit model / trigger endpoint for AE F130619: DFOP / 1.9 d
Modelling endpoint for AE F130619: Pseudo-SFO DT50 = DFOP $\ln(2)/k_2 = 24.7$ d

Figure B.8.1.1.2-2. Result of model fit to residue data for AE F130619 in soil Illinois (pyrimidyl label).



2. Soil Shuttleworth, phenyl label

Table B.8.1.1.2-5. Time course of phenyl labelled AE F130619 and the formation and decline of its metabolites in Shuttleworth sand under non-sterile aerobic conditions at 20 °C (% of applied radioactivity)

Time [days]	Phenyl radiolabeled components (PH)				
	AE F130619	AE F148003	Others	PH-NER	PH- ¹⁴ CO ₂
0	76.3	2.4	18.0	4.1	na
0.33	Poor Chromatography - Sample not reported			22.9	0.0
1	34.9	1.4	12.4	42.4	0.0
3	16.0	1.3	13.4	64.9	0.1
7	7.7	< LOD	20.6	20.8	0.1
14	3.3	< LOD	14.3	79.0	0.0
22	na	na	na	82.4	0.1
28	na	na	na	19.9	0.2
63	na	na	na	91.6	0.2
120	na	na	na	88.9	0.3

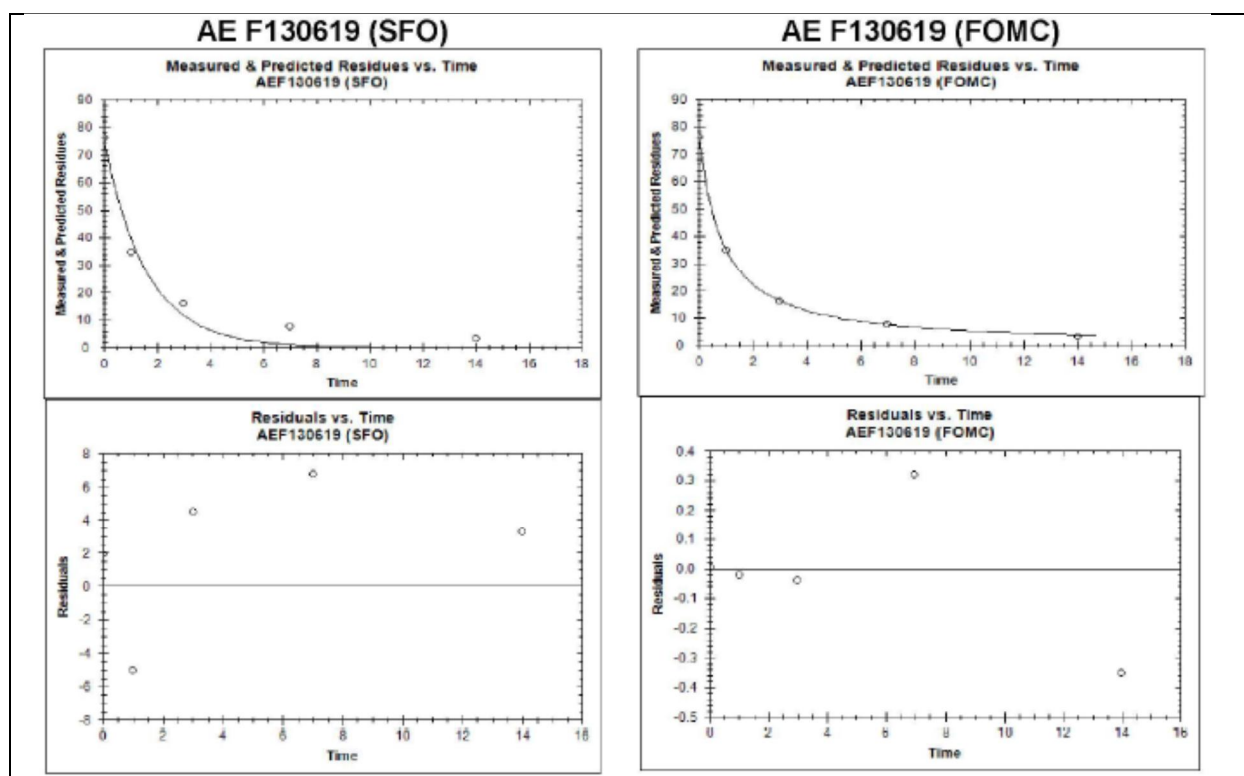
< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity na: Not analysed

Fitting the SFO model to the residue data did not lead to a visually acceptable fit to the observed data (Figure B.8.1.1.2-3) because of systematically varying residues. Therefore, alternatively a FOMC model was fitted to the data resulting in a significantly better visual fit (Figure B.8.1.1.2-3). Also the Chi²-error decreased strongly and was far below 15% (Table B.8.1.1.2-6). For the use in environmental fate simulations a pseudo SFO-DT₅₀ of 2.0 days was calculated from the derived DT₉₀.

Table B.8.1.1.2-6. Summary of the kinetic evaluation of the degradation of phenyl labelled AE F130619 in Shuttleworth soil

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ ² [%]	prob > t	parameter CI	
									lower	upper
AE F130619	SFO	74.4		k = 0.6221	1.1	3.7	13.3	0.0095	0.3590	0.885
AE F130619	FOMC	76.3		α = 1.1174 β = 0.9877	0.8	6.8	0.7	α: 0.0006 β: 0.0019	1.0403 0.8697	1.195 1.106
<p>Study conclusion (Schmitt & Mikolasch 2012):</p> <p>AE F130619 SFO: fit visually not acceptable, statistically acceptable (χ² 13.3%); (comment RMS: residual plot shows systematic deviations)</p> <p>AE F130619 FOMC: fit visually and statistically acceptable (comment RMS: 10% initial concentration was met within experimental period)</p> <p>Best fit model / trigger endpoint for AE F130619: FOMC / 0.8 d</p> <p>Modelling endpoint for AE F130619: Pseudo-SFO DT50 = FOMC DT90/3.32 / 2.0 d</p>										

Figure B.8.1.1.2-3. Result of model fit to residue data for AE F130619 in soil Shuttleworth (phenyl label).



2. Soil Shuttleworth, pyrimidyl label

Table B.8.1.1.2-7. Time course of pyrimidyl labelled AE F130619 and the formation and decline of its metabolites in Shuttleworth sand under non-sterile aerobic conditions at 20 °C (% of applied radioactivity)

Time [days]	Pyrimidyl radiolabeled components (PY)				
	AE F130619	AE F092944	Others	PY-NER	PY- ¹⁴ CO ₂
0	90.4	< LOD	4.3	6.0	na
0.33	55.2	11.8	11.8	20.1	0.0
1	36.3	14.2	10.4	39.0	0.0
3	15.3	14.0	10.8	59.4	0.1
7	6.8	5.0	20.0	17.5	0.3
14	4.9	12.4	8.2	70.9	0.8
22	1.3	30.1	8.9	58.8	1.3
28	3.0	31.9	7.3	15.0	1.5
63	1.1	34.7	8.9	56.5	1.8
120	< LOD	35.2	11.7	50.3	2.8

< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity na: Not analysed

Fitting the SFO model to the residue data did not lead to an acceptable fit to the observed data (Figure B.8.1.1.2-4). Both, the statistical and the visual quality do not meet the criteria required by FOCUS (2006) (Table B.8.1.1.2-8). Therefore, alternatively a FOMC model was fitted to the data resulting in a significantly better visual fit (Figure B.8.1.1.2-4). Also the Chi²-error decreased strongly and was far

below 15% (Table B.8.1.1.2-8). For the use in environmental fate simulations a pseudo SFO-DT₅₀ of 5 days was calculated from the derived DT₉₀.

Table B.8.1.1.2-8. Summary of the kinetic evaluation of the degradation of pyrimidyl labelled AE F130619 in Shuttleworth soil

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
AE F130619	SFO	84.5		k = 0.8457	0.8	2.7	19.3	k: 0.0004	0.5243	1.167
AE F130619	FOMC	89.9		α = 0.9053 β = 0.5092	0.6	6.0	5.0	α : <0.0001 β : 0.003	0.7468 0.3378	1.064 0.681

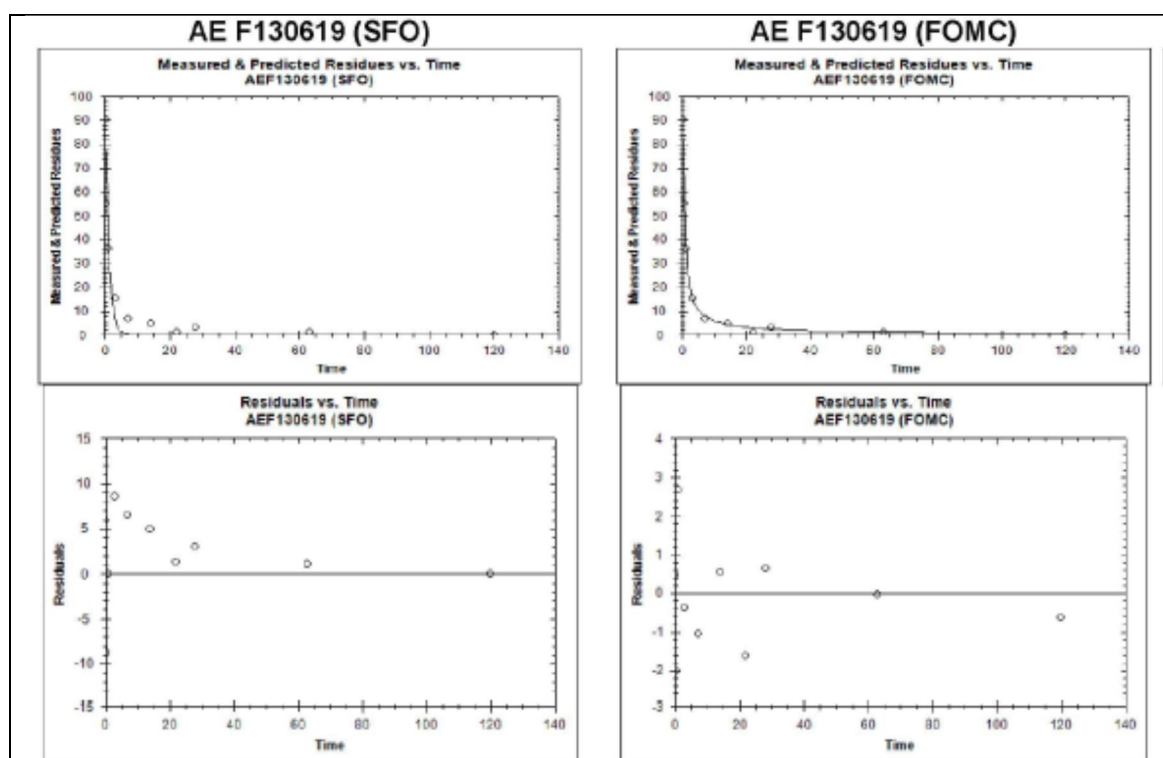
Study conclusion (Schmitt & Mikolasch 2012):

AE F130619 SFO: fit visually and statistically not acceptable (χ^2 19.3%);
(comment RMS: residual plot shows systematic deviations)

AE F130619 FOMC: fit visually and statistically acceptable
(comment RMS: agreed; 10% initial concentration was met within experimental period)

Best fit model / trigger endpoint for AE F130619: FOMC / 0.6 d
Modelling endpoint for AE F130619: Pseudo-SFO DT₅₀ = FOMC DT₉₀/3.32 / 1.8 d

Figure B.8.1.1.2-4. Result of model fit to residue data for AE F130619 in soil Shuttleworth (pyrimidyl label).



3. Soil Orainville; phenyl label

Table B.8.1.1.2-9. Time course of AE F130619 and the formation and decline of its metabolites in Orainville loam under non-sterile aerobic conditions at 20 °C (% of applied radioactivity)

Time [days]	Phenyl radiolabeled components (PH)				
	AE F130619	AE F153745	Others	PH-NER	PH- ¹⁴ CO ₂
0	78.6	< LOD	11.3	11.4	na
0.33	49.5	< LOD	7.7	42.9	0.0
1	26.6	< LOD	5.3	61.9	0.1
3	10.9	< LOD	5.8	79.5	0.2
7	7.5	< LOD	6.3	75.6	0.1
14	0.9	< LOD	5.5	85.3	0.2
22	na	na	na	89.5	0.5
28	na	na	na	46.3	0.3
63	na	na	na	92.7	0.5
120	na	na	na	96.8	0.7

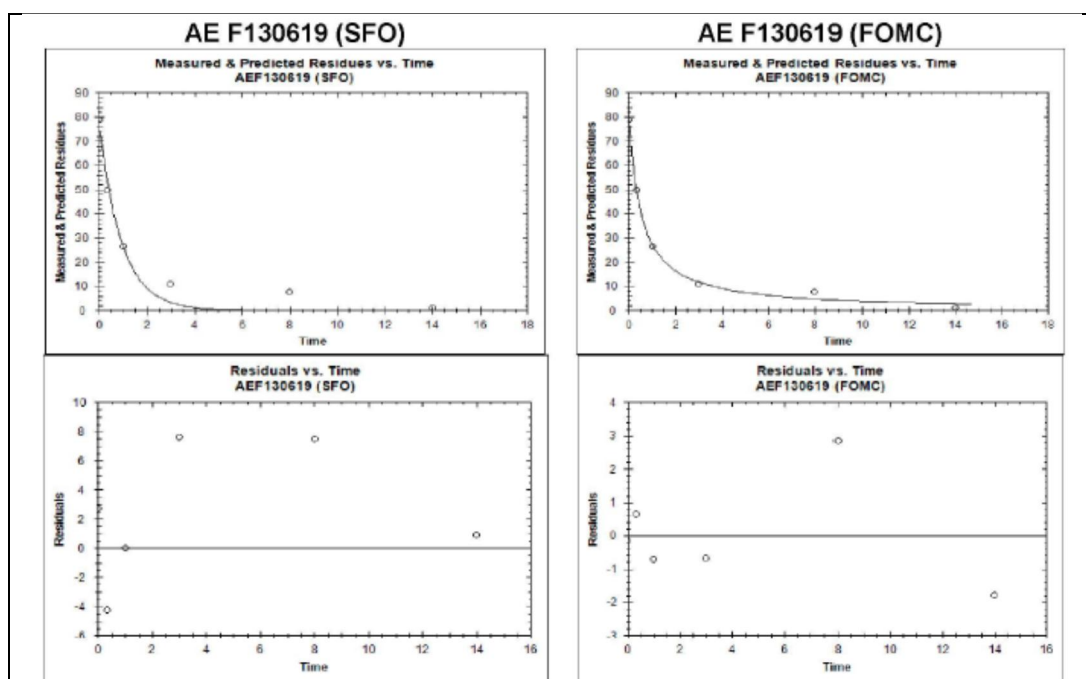
< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity na: Not analysed

Fitting the SFO model to the residue data did not lead to a visually acceptable fit to the observed data (Figure B.8.1.1.2-5) because of systematically varying residues. Therefore, alternatively a FOMC model was fitted to the data resulting in a significantly better visual fit (Figure B.8.1.1.2-5). Also the Chi²-error decreased strongly and was far below 15% (Table B.8.1.1.2-10). For the use in environmental fate simulations a pseudo SFO-DT₅₀ of 1.4 days was calculated from the derived DT₉₀.

Table B.8.1.1.2-10. Summary of the kinetic evaluation of the degradation of phenyl labelled AE F130619 in Orainville soil

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ ² [%]	prob > t	parameter CI	
									lower	upper
AE F130619	SFO	75.9		k = 1.0475	0.7	2.2	13.3	k: 0.0052	0.5971	1.498
AE F130619	FOMC	78.8		α = 1.0418 β = 0.5674	0.5	4.6	4.4	α = 0.0055 β = 0.0216	0.6813 0.2382	1.402 0.897
<p>Study conclusion (Schmitt & Mikolasch 2012):</p> <p>AE F130619 SFO: fit visually not acceptable, statistically acceptable (χ² 13.3%); (comment RMS: residual plot shows systematic deviations)</p> <p>AE F130619 FOMC: fit visually and statistically acceptable (comment RMS: agreed; 10% initial concentration was met within experimental period)</p> <p>Best fit model / trigger endpoint for AE F130619: FOMC / 0.5 d</p> <p>Modelling endpoint for AE F130619: Pseudo-SFO DT₅₀ = FOMC DT₉₀/3.32 / 1.4 d</p>										

Figure B.8.1.1.2-5. Result of model fit to residue data for AE F130619 in soil Oraiville (phenyl label).



3. Soil Orainville; pyrimidyl label

Table B.8.1.1.2-11. Time course of AE F130619 and the formation and decline of its metabolites in Orainville loam under non-sterile aerobic conditions at 20 °C (% of applied radioactivity)

Time [days]	Pyrimidyl radiolabeled components (PY)				
	AE F130619	AE F092944	Others	PY-NER	PY- ¹⁴ CO ₂
0	83.2	2.3	3.7	8.8	na
0.33	46.7	1.7	7.2	40.5	0.0
1	25.9	1.6	2.8	49.9	0.0
3	10.3	0.9	-	75.7	0.3
7	10.2	2.2	2.7	64.4	0.2
14	na	na	na	85.9	0.8
22	na	na	na	89.6	0.8
28	na	na	na	44.5	0.0
63	na	na	na	86.9	0.8
120	na	na	na	91.7	4.1

< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity

na: Not analysed

Fitting the SFO model to the residue data did not lead to an acceptable fit to the observed data (Figure B.8.1.1.2-6). Both, the statistical and the visual quality do not meet the criteria required by FOCUS (2006) (Table B.8.1.1.2-12). Therefore, alternatively a DFOP model was fitted to the data resulting in a significantly better visual fit (Figure B.8.1.1.2-6). Also the Chi²-error decreased strongly and was far below 15% (Table B.8.1.1.2-12). For the use in environmental fate simulations a pseudo SFO-DT₅₀ of 1.7 days was calculated from the derived DT₉₀.

Table B.8.1.1.2-12. Summary of the kinetic evaluation of the degradation of pyrimidyl labelled AE F130619 in Orainville soil

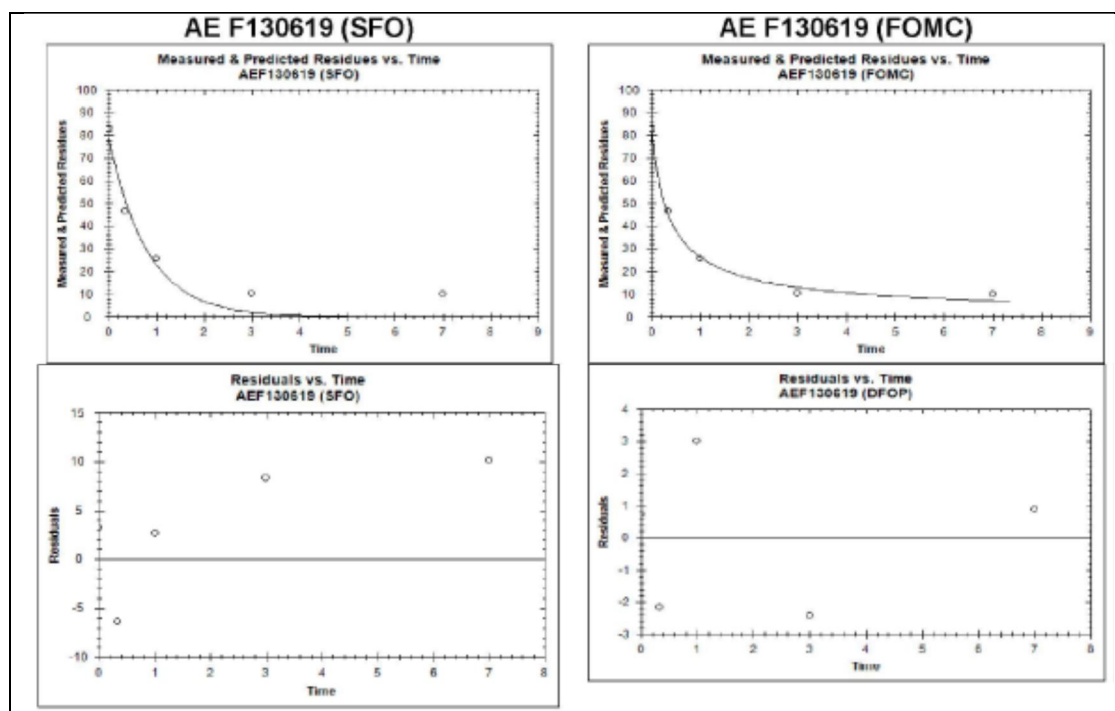
	kinetic model	M_0	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
AE F130619	SFO	79.9		$k = 1.2372$	0.6	1.7	15.5	0.0282		
AE F130619	FOMC	83.3		$\alpha = 0.7559$ $\beta = 0.2771$	0.4	5.6	4.8	$\alpha = 0.0210$ $\beta = 0.0640$	0.4423 0.0616	1.069 0.493

Study conclusion (Schmitt & Mikolasch 2012):

AE F130619 SFO: fit visually not acceptable, statistically not acceptable (χ^2 15.5%);
(comment RMS: residual plot shows systematic deviations)

AE F130619 FOMC: fit visually and statistically acceptable
(comment RMS: agreed; 10% initial concentration was met within experimental period)

Best fit model / trigger endpoint for AE F130619: FOMC / 0.4 d
Modelling endpoint for AE F130619: Pseudo-SFO DT50 = FOMC DT90/3.32 / 1.7 d

Figure B.8.1.1.2-6. Result of model fit to residue data for AE F130619 in soil Oraiville (pyrimidyl label).

4. Soil Chantepie; phenyl label

Table B.8.1.1.2-13. Time course of phenyl labelled AE F130619 and the formation and decline of its metabolites in Chantepie loam under non-sterile aerobic conditions at 20 °C (% of applied radioactivity)

Time [days]	Phenyl radiolabeled components (PH)				
	AE F130619	AE F148003	Others	PH-NER	PH- ¹⁴ CO ₂
0	79.9	2.3	10.0	9.1	na
0.33	45.8	1.0	11.7	37.4	0.0
1	29.3	< LOD	4.1	62.5	0.0
3	9.1	< LOD	5.6	81.7	0.1
7	6.6	< LOD	4.4	73.7	0.1
14	4.0	< LOD	6.3	87.3	0.1
22	na	na	na	92.8	0.2
29	na	na	na	30.3	0.1
63	na	na	na	95.4	0.4
120	na	na	na	99.9	0.7

< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity na: Not analysed

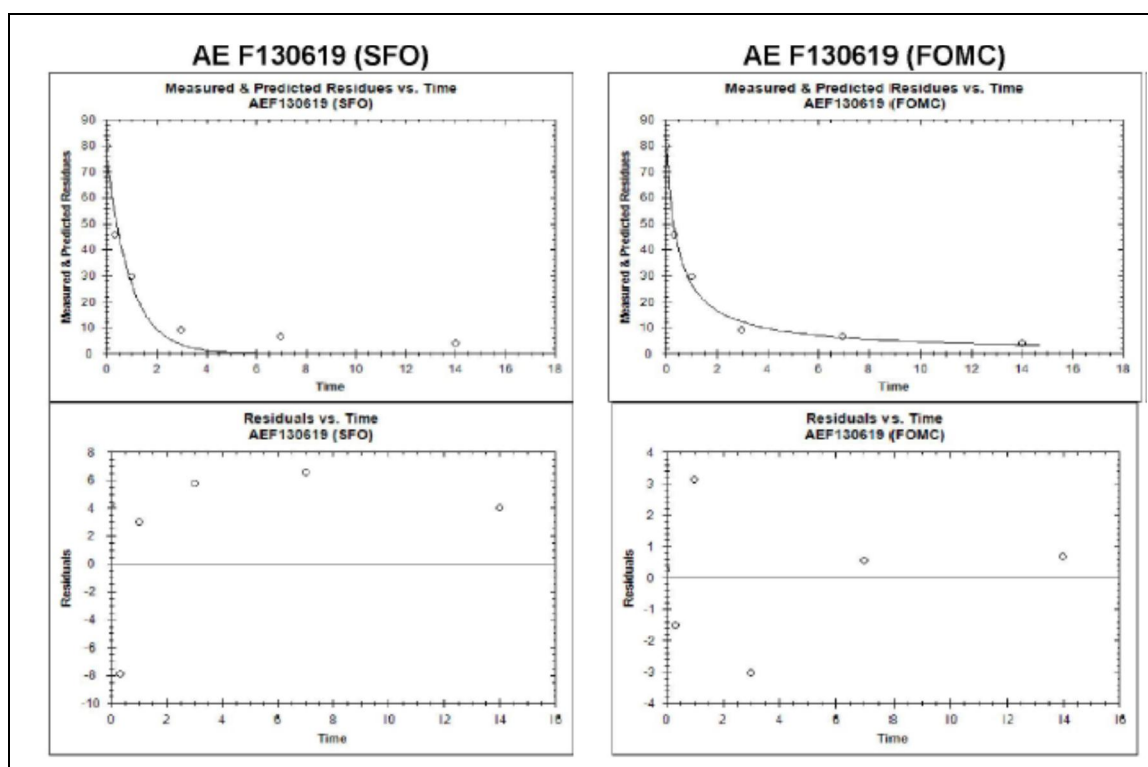
Fitting the SFO model to the residue data did not lead to a visually acceptable fit to the observed data (Figure B.8.1.1.2-7) because of systematically varying residues. Therefore, alternatively a FOMC model was fitted to the data resulting in a significantly better visual fit (Figure B.8.1.1.2-7). Also the Chi²-error decreased strongly and was far below 15% (Table B.8.1.1.2-14).

For the use in environmental fate simulations a pseudo SFO-DT₅₀ of 1.5 days was calculated from the derived DT₉₀.

Table B.8.1.1.2-14. Summary of the kinetic evaluation of the degradation of phenyl labelled AE F130619 in Chantepie soil

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ ² [%]	prob > t	CI	
									lower	upper
AE F130619	SFO	75.6		k = 1.0359	0.7	2.2	15.0	k = 0.0081	0.5282	1.544
AE F130619	FOMC	79.6		α = 0.8969 β = 0.4193	0.5	5.0	5.7	α = 0.0089 β = 0.0414	0.5262 0.0989	1.268 0.740
<p>Study conclusion (Schmitt & Mikolasch 2012):</p> <p>AE F130619 SFO: fit visually not acceptable, statistically acceptable (χ² 15 %); (comment RMS: residual plot shows systematic deviations)</p> <p>AE F130619 FOMC: fit visually and statistically acceptable (comment RMS: agreed; 10% initial concentration was met within experimental period)</p> <p>Best fit model / trigger endpoint for AE F130619: FOMC / 0.5 d Modelling endpoint for AE F130619: Pseudo-SFO DT₅₀ = FOMC DT₉₀/3.32 / 1.5 d</p>										

Figure B.8.1.1.2-7. Result of model fit to residue data for AE F130619 in soil Chantepie (phenyl label).



4. Soil Chantepie; pyrimidyl label

Table B.8.1.1.2-15. Time course of pyrimidyl labelled AE F130619 and the formation and decline of its metabolites in Chantepie loam under non-sterile aerobic conditions at 20 °C (% of applied radioactivity)

Time [days]	Pyrimidyl radiolabeled components (PY)				
	AE F130619	AE F092944	Others	PY-NER	PY- ¹⁴ CO ₂
0	74.6	3.8	13.8	7.4	na
0.33	46.8	4.3	17.6	31.6	0.0
1	29.0	6.3	8.9	52.4	0.0
3	10.3	1.3	13.3	76.1	0.1
7	5.8	1.5	11.8	70.9	0.3
14	2.5	1.5	11.8	83.3	0.6
22	5.2	1.7	14.7	80.0	0.3
29	< LOD	< LOD	12.2	25.2	0.9
63	0.4	8.0	2.5	85.8	2.0
120	< LOD	41.0	7.9	50.6	1.6

< LOD: Components less than limit of detection of 0.02% to 0.03% of applied radioactivity na: Not analysed

Fitting the SFO model to the residue data did not lead to an acceptable fit to the observed data (Figure B.8.1.1.2-8). Both, the statistical and the visual quality do not meet the criteria required by FOCUS (2006) (Table B.8.1.1.2-15). Therefore, alternatively a DFOP model was fitted to the data resulting in a significantly better visual fit (Figure B.8.1.1.2-8). Also the Chi²-error decreased strongly and was far below 15% (Table B.8.1.1.2-16).

For the use in environmental fate simulations a pseudo SFO-DT₅₀ of 1.6 days was calculated from the derived DT₉₀.

Table B.8.1.1.2-16. Summary of the kinetic evaluation of the degradation of pyrimidyl labelled AE F130619 in Chantepie soil

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
AE F130619	SFO	70.9		k = 0.9140	0.8	2.5	17.5	k: 0.0001	0.6269	1.201
AE F130619	FOMC	74.5		α = 1.0074 β = 0.5891	0.6	5.2	6.7	α = 0.0210 β = 0.0640	0.7465 0.3141	1.268 0.864

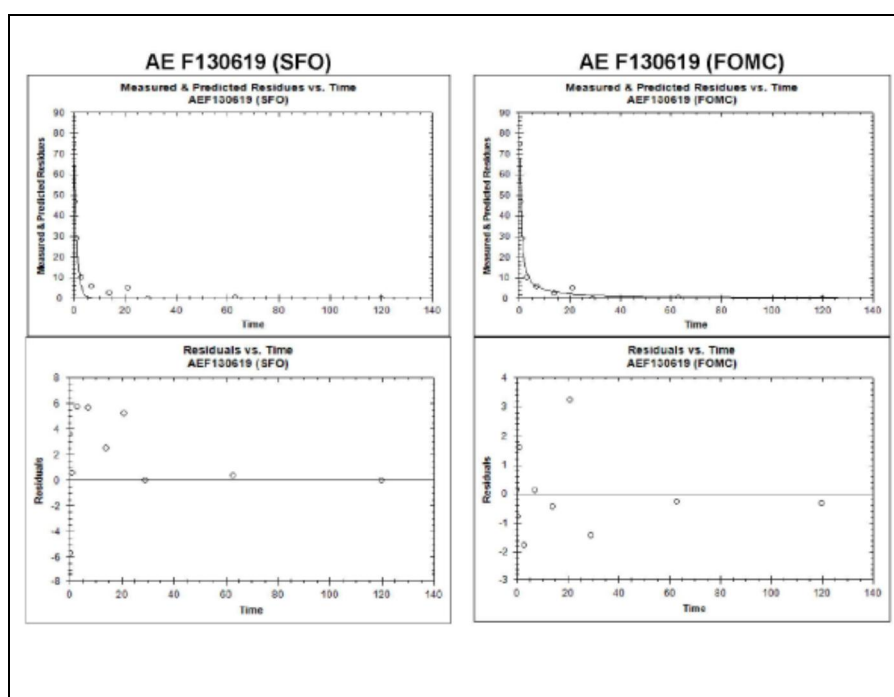
Study conclusion (Schmitt & Mikolasch 2012):

AE F130619 SFO: fit visually not acceptable, statistically not acceptable (χ^2 17.5 %);
(comment RMS: residual plot shows systematic deviations)

AE F130619 FOMC: fit visually and statistically acceptable
(comment RMS: agreed; 10% initial concentration was met within experimental period)

Best fit model / trigger endpoint for AE F130619: FOMC / 0.6 d
Modelling endpoint for AE F130619: Pseudo-SFO DT50 = FOMC DT90/3.32 / 1.6 d

Figure B.8.1.1.2-8. Result of model fit to residue data for AE F130619 in soil Chantepie (pyrimidyl label).



Calculation of non-normalised DT₅₀-values:

For metabolite AE F130619 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 (soil Illinois) 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 DT₅₀-values were back-calculated from the corresponding value of the DT₉₀ derived either by the FOMC or the DFOP fit. The results are summarised for AE F130619 in Table B.8.1.1.2-13.

Normalisation of DT₅₀-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 B.8.1.1.2-17. The values of half-lives resulting from normalisation are summarised in Table B.8.1.1.2-18.

Table B.8.1.1.2-17: 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	0.33 bar				Moisture	Temp.
			[% m/m]	[% m/m]				[-]	[-]
Judge, 2000c	Illinois	Sandy loam	52.3	19.7	20.9	-	20	1.04	1.00
	Shuttleworth	Sand	44.7	8.1	17.9	-	20	1.74	1.00
	Orainville	Loam	54.3	23.1	21.7	-	20	0.96	1.00
	Chantepie	Loam	57	26.3	22.8	-	20	0.90	1.00

Table B.8.1.1.2-18: DT₅₀ and DT₉₀ -values for metabolite AE F130619 in aerobic soil under laboratory conditions for use as modelling input parameters in environmental exposure assessments and for trigger evaluation (values highlighted in green are obtained from studies with the active substance evaluated under the Section B.8.1.1.1)

Soil	Label position	Non-Normalised DT ₅₀ (days) Modelling	Normalised DT ₅₀ (days) Modelling	Non-Normalised DT ₅₀ (days) Trigger	Non-Normalised DT ₉₀ (days) Trigger	Model
				Best fit	Best fit	
Shuttleworth (Study 1)	phenyl	6.5	4.4	6.5	21.6	SFO
Shuttleworth (Study 1)	pyrimidyl	-	-	-	-	-
Worst case		6.5	4.4	6.5	21.6	
Shuttleworth (Study 2)	phenyl	2.0	3.5	0.8	6.8	FOMC
Shuttleworth (Study 2)	pyrimidyl	1.8	3.1	0.6	6.0	FOMC
Mean (geometric)		1.9	3.6	0.7	6.4	
Orainville (Study 1)	phenyl	0.7	0.4	0.7	2.3	SFO
Orainville (Study 1)	pyrimidyl	0.9	0.5	0.9	3.0	SFO
Mean (geometric)		0.8		0.4	5.1	
Orainville (Study 2)	phenyl	1.4	1.3	0.5	4.6	FOMC
Orainville (Study 2)	pyrimidyl	1.7	1.6	0.4	5.6	FOMC
Mean (geometric)		1.5	0.8	1.5	5.1	
Chantepie (Study 1)	phenyl	0.2	0.1	0.2	0.7	SFO
Chantepie (Study 1)	pyrimidyl	-	-	-	-	-
Worst case		0.2		0.2	0.7	
Chantepie (Study 2)	phenyl	1.5	1.4	0.5	5.0	FOMC
Chantepie (Study 2)	pyrimidyl	1.6	1.4	0.6	5.2	FOMC
Mean (geometric)		1.5	0.6	0.5	5.1	
Illinois (Study 2)	phenyl	8.7	9.0	1.1	18.1	DFOP
Illinois (Study 2)	pyrimidyl	24.7	25.7	1.9	42.2	DFOP
Mean (geometric)		14.7	15.2	1.4	27.6	
Worst case for trigger evaluation				6.5	27.6	
Mean (geometric) for modelling:			2.3			

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

Conclusion

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 metabolite AE F130619 in aerobic soil under laboratory conditions was investigated with two positions of radiolabel. This resulted in eight reliably evaluable data sets (n=8) from four soils. For the kinetic evaluation of the degradation 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 DT₅₀'s were back-calculated from the corresponding DT₉₀-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 B.8.1.1.2-18.

RMS comments and conclusion

The study was performed according to guideline and is considered acceptable by the RMS. However, the carbon content in Chantepie and Illinois soils were 4.09% and 2.97% respectively, which is significantly higher than is recommended by guideline OECD TG 307 (2002). Since the DT₅₀ of

metabolite AE F130619 carried out in Chantepie and in Illinois soils seems not to be dependent on the carbon content, the results are considered acceptable.

Also the pH of Shuttleworth soil (pH=5) is slightly below the recommended scale (OECD TG 307, 2002). The pH of the rest soils were evenly distributed in the whole range of the recommended scale and the neutral and basic soils were tested as well (pH 5-7.4). Hence, the results are considered acceptable.

For the determination of the degradation rate, the data sets were analysed in accordance with the FOCUS Deg Kinetics Report (2006). For optimal goodness of fit, the initial value was allowed to be estimated by the model and all data points were weighted equally. The residues at time zero for metabolites formed from the applied substance was on the other hand kept fixed at a value of zero. Therefore the results can be considered acceptable.

The worst case values of non-normalised half-lives can be used for evaluation against persistence triggers and the geometric mean of normalised half-life of 2.3 days can be used as modelling endpoint. The Applicant has used SFO kinetics for comparison against persistence triggers and suggested a non-normalised worst case half-life of 14.7 days for soil Illinois associated with a DT₉₀ of 48.7 days from the same soil. However, since the residual plots showed systematic deviations in the SFO kinetics and the SFO fit was not acceptable, a worst case non-normalised half-life of 6.5 days is obtained for soil Shuttleworth and a non-normalised worst case DT₉₀ value of 27.6 days for soil Illinois. These values are used for persistence evaluation.

3) Kinetic evaluation of the degradation of the metabolite AE F153745

Reference:	KCA 7.1.2.1.2 /06; Shepherd, Ripperger, 2012 Degradation of of phenyl-UL-14C-AE F153745 in Four Soils under Laboratory Aerobic Conditions at 20°C.
Report No.:	MEFSL008
Document No.:	M-425904-01-1
Guideline:	OECD: Guideline 307; Aerobic and Anaerobic Transformation in Soil, April 24, 2002
GLP:	Yes
Previous evaluation:	Submitted for the purpose of renewal
	Acceptable

Material and Methods

1. Test Material: [Phenyl-UL-¹⁴C] 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. Physico-chemical characteristics are summarised in Table 8.1.1.2-19.

Table 8.1.1.2-19: Characteristics of test soils

Soil	Porterville	Springfield	Pikeville	Sanger
Geographic Location (City / State / Country)	Porterville / CA / US	Springfield / NE / US	Pikeville / NC / US	Sanger / CA / US
GPS coordinates	N 36° 00.492’ W 119° 04.525’	N 41.03725 W 96.15085	N 35° 29.312’ W 78° 02.443’	N 36° 42.2216’ W 119° 28.0012’
Pesticide use history	No use for previous 3 years	No pesticide use for previous 5 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 kandiodults	Hanford fine sandy loam, gravelly substrate
Texture Class (USDA)	sandy loam	silt loam	loamy sand	loamy sand
Sand [50 µm - 2 mm] (%)	65.8	13.2	79.2	80.3
Silt [2 µm - 50 µm] (%)	27.7	62.4	17.5	14.6
Clay [$< 2 \mu\text{m}$] (%)	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 ₂ (0.01 M)	7.2	6.4	5.4	6.7
Organic Matter ^A (%)	0.53	3.2	1.3	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)	74	433	81	140
Day 41 (final, duplicates)	63 / 66	437 / 433	63 / 63	140 / 147
CEC (meq/100 g)	9.1	15.2	4.2	5.7
55% of MWHC (g/100 g)	14.9	25.7	14.8	16.8
MWHC (g water /100 g soil)	27.1	46.8	26.9	30.5
Moisture at 0.1 bar = pF 2.0 (g water /100 g soil)	13.9	32.4	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

^A) % organic matter = % organic carbon × 1.724;

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

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 ¹⁴C-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 40 mL aqueous acetonitrile solution containing 0.1 M ammonium acetate (70:30:0.01, v/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 1 M ammonium bicarbonate (70:30:0.01, v/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 ¹⁴C-material balance was established for each sample by extraction, analysis of volatiles and combustion of non-extractable residues. Following quantitation of radioactivity in extracts by LSC, analysis was performed by reversed phase HPLC and ¹⁴C-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 peaks observed in various chromatograms in the course of the study.

A. Determination of degradation kinetics: Degradation data were kinetically evaluated by use of the software KinGui, 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 (χ^2) to be a minimum in the significance test.

Results and Discussion

A. Data: The results of aerobic biotransformation of [phenyl-UL-¹⁴C] foramsulfuron sulfonamide after incubation in four US soils are summarised in Tables from B.8.1.1.2-20 to Table B.8.1.1.2-23.

Table 8.1.1.2-20: Degradation of [phenyl-UL-¹⁴C]foramsulfuron sulfonamide in sandy loam soil Porterville under aerobic conditions (mean ± SD)

Component		Sampling interval (days)							
		0	1	2	5	7	9	14	23
Foramsulfuron sulfonamide (AE F153745)	Mean*	98.9	82.7	62.7	37.7	24.3	15.7	10.6	3.6
	SD	±4.6	±4.7	±1.7	±4.0	±0.7	±0.4	±4.3	±1.1
Foramsulfuron amino= sulfonamide (AE F148003)	Mean*	0.0	13.5	26.4	30.5	30.7	30.5	21.8	14.4
	SD	±0.0	±2.9	±0.8	±5.2	±0.2	±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	68.3	54.9	46.2	32.9	18.0
	SD	±4.6	±1.8	±0.9	±1.1	±0.9	±0.9	±6.3	±0.4
Non-extractable radioactivity	Mean*	2.7	3.7	13.9	33.6	50.0	54.3	70.5	80.1
	SD	±3.5	±0.0	±1.8	±2.8	±1.1	±1.0	±13.3	±0.3
¹⁴ CO ₂	Mean*	0.0	0.5	0.3	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	102.2	105.4	101.2	104.1	99.3
	SD	±1.1	±1.8	±0.9	±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 8.1.1.2-21: Degradation of [phenyl-UL-¹⁴C]foramsulfuron sulfonamide in silt loam soil Springfield 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	8.4
	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	53.6	28.9	21.7	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	47.5	72.5	77.6	81.0	94.3
	SD	±0.0	±1.9	±0.2	±0.5	±3.5	±1.0	±0.2
¹⁴ CO ₂	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

Table 8.1.1.2-22: Degradation of [phenyl-UL-¹⁴C]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	±0.2	±0.1
Foramsulfuron amino=Sulfonamide (AE F148003)	Mean*	0.0	41.3	41.5	32.0	24.7	21.2	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	0.8	0.0	0.0	0.7
	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	±0.1	±0.4	±0.0
Non-extractable radioactivity	Mean*	0.1	17.0	29.9	56.6	62.0	60.9	83.8
	SD	±0.0	±0.2	±0.0	±5.0	±3.6	±1.4	±7.2
¹⁴ CO ₂	Mean*	0.0	0.5	0.6	0.6	0.7	0.9	1.3
	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	±5.7	±3.5	±1.7	±7.2

Values given as percentages of initially applied radioactivity

SD = standard deviation; * Mean values of two replicates

Table 8.1.1.2-23: Degradation of [phenyl-UL-¹⁴C]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	24.6	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	±1.8	±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	±4.6	±1.6
¹⁴ CO ₂	Mean*	0.0	0.3	0.6	0.6	0.8	0.9	1.6
	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	±1.6	±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 B.8.1.1.2-24. Conclusively there were no signs for losses of radioactivity from sample work-up and processing.

Table 8.1.1.2-24: Total material balances of radioactivity of ¹⁴C-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
Rel. 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 B.8.1.1.2-25. 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).

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 8.1.1.2-25: Extractable and non-extractable residues of ^{14}C -AE F153745 in four US soils (mean \pm 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	8.4 ± 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	8.8 ± 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 ^{14}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 ($\leq 0.1\%$ 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 KCA 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 ^{14}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 and DFOP¹ for the test substance only with the quality of fits assessed according to FOCUS kinetic guidance. The initial concentration at time zero was 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 (χ^2) scaled-error to be a minimum and on the basis of visual assessment. The results of the kinetic evaluation and visual fits are provided in figures and tables below.

¹ SFO = Single first order; FOMC = First order multi compartment; DFOP = Double first order in parallel

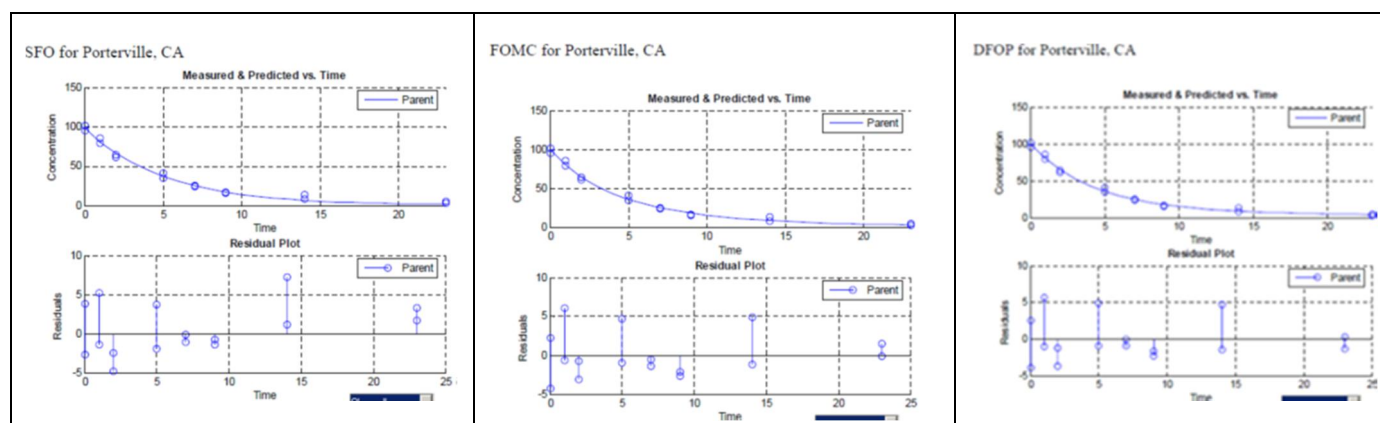
1. Soil Porterville

Fitting the model with SFO kinetics used to the residue data led to a visually acceptable fit (Figure B.8.1.1.2-9) also with good statistical measures (Table B.8.1.1.2-26). The resulting DT₅₀ was 3.5 days. However, the Applicant has still performed kinetic evaluation of degradation with FOMC and DFOP.

Table B.8.1.1.2-26. Summary of the kinetic evaluation of the degradation of [phenyl-UL-¹⁴C]foramsulfuron sulfonamide in Porterville soil

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
AE F153745	SFO	98.2		k = 0.1962	3.5	11.7	4.5	k: < 0.0001	0.1776	0.2148
AE F153745	DFOP	99.5		k ₁ = 0.0438 k ₂ = 0.2356 g = 0.1034	3.3	13.0	3.7	k ₁ : 0.346 k ₂ : 0.0007 g = 0.3313	-0.1921 0.1111 -0.4002	0.2798 0.3601 0.6070
AE F153745	FOMC	99.9		α = 4.7873 β = 20.9961	3.3	13.0	3.7	α = 0.0438 β = 0.0671	-0.8108 -7.3992	10.3855 49.3914
Study conclusion (Shepherd and Ripperger 2012):										
AE F153745 SFO: fit visually and statistically acceptable (χ^2 4.5 %) (comment RMS: agreed)										
Best fit model / trigger endpoint for AE F153745: DFOP / 3.3 d Modelling endpoint for AE F130619: SFO / 3.5 d										

Figure B.8.1.1.2-9. Result of model fit to residue data for AE F153745 in soil Porterville (phenyl label).



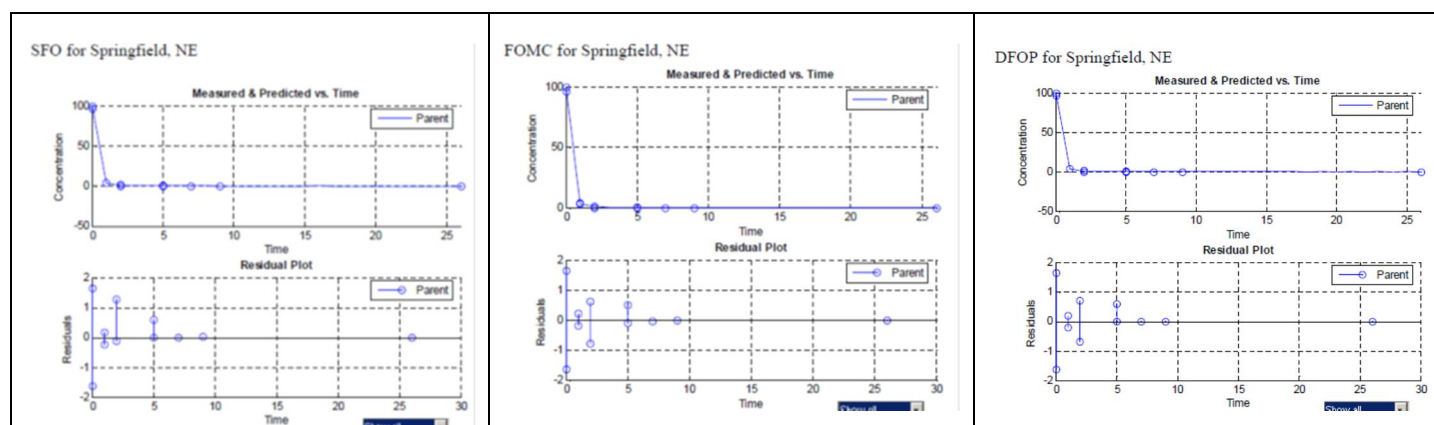
2. Soil Springfield

Fitting the model with SFO kinetics used to the residue data led to a visually acceptable fit (Figure B.8.1.1.2-10) also with good statistical measures (Table B.8.1.1.2-27). The resulting DT₅₀ was 3.2 days. However, the Applicant has still performed kinetic evaluation of degradation with FOMC and DFOP.

Table B.8.1.1.2-27. Summary of the kinetic evaluation of the degradation of [phenyl-UL-¹⁴C]foramsulfuron sulfonamide in Springfield soil

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
AE F153745	SFO	97.7		k = 3.3467	0.21	0.69	1.3	k: < 0.0001	2.9925	3.7010
AE F153745	DFOP	97.8		k ₁ = 9.1579 k ₂ = 1.5708 g = 0.8331	0.09	0.43	0.72	k ₁ : 0.50 k ₂ : 0.48 g: 0.47	<-1000 -66.9463 -22.0559	23.7221 70.0879 23.7221
AE F153745	FOMC	97.8		α = 2.7081 β = 0.4054	0.12	0.54	0.52	α = 0.1084 β = 0.2385	-1.8401 -0.8065	7.2522 1.6173
<p>Study conclusion (Shepherd and Ripperger 2012):</p> <p>AE F153745 SFO: fit visually and statistically acceptable (χ^2 1.3 %) (comment RMS: agreed)</p> <p>Best fit model / trigger endpoint for AE F153745: FOMC / 0.1 d</p> <p>Modelling endpoint for AE F153745: SFO / 0.2 d</p>										

Figure B.8.1.1.2-10. Result of model fit to residue data for AE F153745 in soil Springfield (phenyl label).



3. Soil Pikeville

Fitting a SFO model to the residue data did not lead to a visually acceptable fit to the observed data (Figure B.8.1.1.2-11) because of systematically varying residues and a χ^2 -error larger than 15%. Therefore, alternatively a FOMC model was fitted to the data resulting in a significantly better visual fit (Figure B.8.1.1.2-11). Also the χ^2 -error decreased strongly and was far below 15% (Table B.8.1.1.2-28). For the use in environmental fate simulations a pseudo SFO-DT₅₀ of 1.9 days was calculated from the derived DT₉₀.

Table B.8.1.1.2-28. Summary of the kinetic evaluation of the degradation of [phenyl-UL-¹⁴C]foramsulfuron sulfonamide in Pikeville soil

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
AE F153745	SFO	99.8		k = 0.6619	1.0	3.5	15.8	k: <0.0001	0.5169	0.8069
AE F153745	DFOP	101.8		k ₁ = 0.0962 k ₂ = 1.0285 g = 0.1862	0.88	6.6	4.2	k ₁ : 0.0032 k ₂ : <0.0001 g: 0.0003	0.0337 0.8586 0.1030	0.1587 1.1985 0.2693
AE F153745	FOMC	102.1		α = 1.1436 β = 0.9619	0.80	6.2	2.0	α : <0.0001 β : <0.0001	1.0221 0.7838	1.2650 1.1400

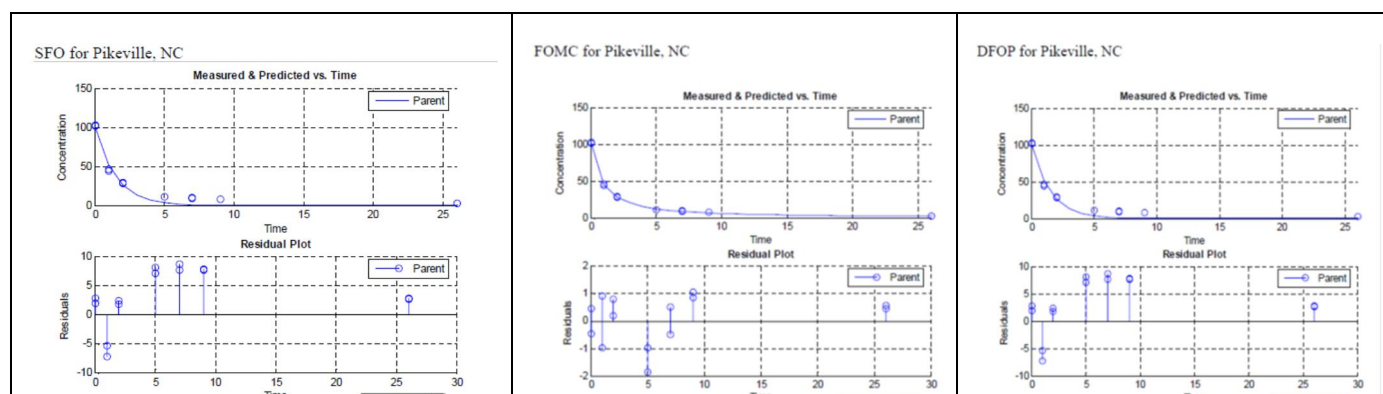
Study conclusion (Shepherd and Ripperger 2012):

AE F153745 SFO: fit visually and statistically not acceptable (χ^2 15.8 %) (comment RMS: residual plot shows systematic deviations and therefore not acceptable)

Best fit model / trigger endpoint for AE F153745: FOMC / 0.8 d

Modelling endpoint for AE F153745: Pseudo-SFO DT50 = FOMC DT90/3.32 / 1.9 d

Figure B.8.1.1.2-11. Result of model fit to residue data for AE F153745 in soil Pikeville (phenyl label)



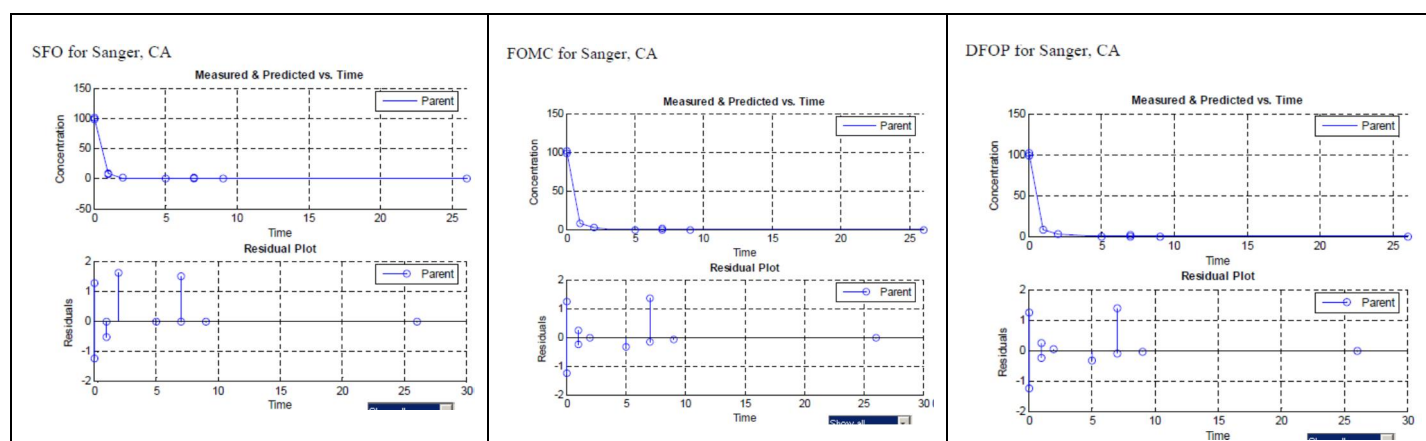
4. Soil Sanger

Fitting a model with SFO kinetics used to the residue data led to a visually acceptable fit (Figure B.8.1.1.2-12) also with good statistical measures (Table B.8.1.1.2-29). The resulting DT₅₀ was 0.3 days.

Table B.8.1.1.2-29. Summary of the kinetic evaluation of the degradation of [phenyl-UL-¹⁴C]foramsulfuron sulfonamide in Sanger soil

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
AE F153745	SFO	100.1		k = 2.4882	0.28	0.93	3.4	k: < 0.0001	2.3141	2.6623
AE F153745	DFOP	100.2		k ₁ = 0.6017 k ₂ = 3.0831 g = 0.0689	0.24	0.89	1.7	k ₁ : 0.1213 k ₂ : 0.0001 g: 0.2035	-0.4778 1.8483 -0.1085	1.6812 4.3178 0.2463
AE F153745	FOMC	100.1		α = 2.5742 β = 0.6012	0.19	0.87	1.4	α : 0.0031 β : 0.0302	0.8962 -0.0313	4.2522 1.2337
Study conclusion (Shepherd and Ripperger 2012): AE F153745 SFO: fit visually and statistically acceptable (χ^2 3.4 %) (comment RMS: residual plot shows systematic deviations and therefore not acceptable) Best fit model / trigger endpoint for AE F153745: FOMC / 0.2 d Modelling endpoint for AE F153745: SFO / 0.3 d										

Figure B.8.1.1.2-12. Result of model fit to residue data for AE F153745 in soil Sanger (phenyl label)



Conclusion

The fits describing degradation of foramsulfuron sulfonamide in the four soils resulted in low chi-square (χ^2) errors for all models applied with overall ranges of χ^2 -errors being marginal for all but one soil (exception for SFO in soil Pikeville; Table B.8.1.1.2-30). 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. 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 DT₉₀-values were 13.0 days (soil Porterville), 0.5 days (Springfield), 6.2 days (Pikeville) and 0.9 days (Sanger).

Table B.8.1.1.2-30: Kinetics of aerobic degradation of foramsulfuron sulfonamide in four soils at 20°C

Soil	Kinetic model	DT ₅₀ (days)	DT ₉₀ (days)	Chi ² Err (%)	Visual assessment
Porterville	SFO	3.5	11.7	4.5	+
	FOMC	3.3	13.0	3.7	+
	DFOP	3.3	13.0	3.7	+
Springfield	SFO	0.2	0.7	1.3	+
	FOMC	0.1	0.5	0.5	+
	DFOP	0.1	0.4	0.7	+
Pikeville	SFO	1.0	3.5	15.8	o
	FOMC	0.8	6.2	2.0	+
	DFOP	0.9	6.6	4.2	+
Sanger	SFO	0.3	0.9	3.4	+
	FOMC	0.2	0.9	1.4	+
	DFOP	0.2	0.9	1.7	+

Best fits according to the criteria set are marked bold.

Visual assessment: + good; o medium; - bad

Calculation of non-normalised DT₅₀-values:

For modelling for metabolite AE F153745 the kinetic evaluation of soil degradation tests using the SFO approach resulted in acceptable fits, except for Springfield soil for which DFOP was the optimal fit to describe the degradation data. For use as non-normalised data prior to normalisation to reference conditions, the DT₅₀-values were back-calculated from the corresponding value of the DT₉₀ derived by the DFOP fit. The results are summarised for AE F092944 in Table B.8.1.1.2-31.

Normalisation of DT₅₀-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 B.8.1.1.2-32. The values of half-lives resulting from normalisation are summarised in Table B.8.1.1.2-33.

Table B.8.1.1.2-32: Study conditions and correction factors used for moisture and temperature normalization

Study	Soil	Texture class (USDA)	Gravimetric water content		Actual moisture in test **	Reference moisture pF2 *	T [°C]	Corr. Factor	
			MHWC	0.33 bar				Moisture	Temp.
			[% m/m]	[% m/m]				[-]	[-]
Shepherd, Ripperger, 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 FOCUS, 2000; ** 75% of 0.33 bar or at 40% (55%) of MHWC

*** Values given in study report

Table B.8.1.1.2-33: DT₅₀ and DT₉₀ -values for metabolite AE F153745 in aerobic soil under laboratory conditions for use as modelling input parameters in environmental exposure assessments and for trigger evaluation

Soil	Label position	Non-Normalised DT ₅₀ /pseudoDT ₅₀ (days) Modelling	Normalised DT ₅₀ /pseudoDT ₅₀ (days) Modelling	Non-Normalised DT ₅₀ (days) Trigger	Non-Normalised DT ₉₀ (days) Trigger	Model
				Best fit	Best fit	
Porterville (Study 1)	phenyl	3.5	3.7	3.3	11.6	SFO
Springfield (Study 1)	phenyl	0.2	0.2	0.8	0.7	SFO
Pikeville (Study 1)	phenyl	1.9	2.5	0.8	6.2	FOMC
Sanger (Study 1)	phenyl	0.3	0.3	0.2	1.0	SFO
Worst case for trigger evaluation				3.3	11.6	
Mean (geometric) for modelling:			0.85			

Study: KCA 7.1.2.1.2 /03

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.

RMS comments

The study was performed according to the guideline and is considered acceptable by the RMS. However, the carbon content in Porterville soil and Sanger soil was lower (0.31% and 0.45%, respectively), than is recommended by guideline OECD 307. However, since the degradation seems not to be dependent on the carbon content, the results can be considered acceptable.

For the determination of the degradation rate, the data sets were analysed in accordance with the FOCUS Deg Kinetics Report (2006). The initial concentration was included in the parameter optimization procedure and all data points were weighted equally. For optimal goodness of fit, the initial value was also allowed to be estimated by the model. In Springfield and Sanger soils the metabolite foramsulfuron sulphonamide degraded so fast that five data points were not obtained before

the metabolite was almost completely degraded. However, according to the DegKinetics Report (2006), if with the available data points an acceptable fit can be obtained, the data points and the DT₅₀ values can be considered acceptable. This applies for both soils.

For use as modeling endpoint, an overall geometric mean of normalised half-life of 0.85 days was calculated for AE F153745. For comparison against trigger endpoints a worst case non-normalised half-life of 3.3 days was calculated for soil Porteville associated with a DT₉₀ of 11.6 days from the same soil. The degradation of foramsulfuron sulfonamide in four aerobic soils was fast to result in half-lives ranging from 0.1 to 3.3 days.

3) Kinetic evaluation of the degradation of the metabolite AE F092944

Reference:	KCA 7.1.2.1.2 /07; Voelkel, W. 2006 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 (partA) of the review programme referred to in article 8(2) of council directive 91/414/EEC - Volume 3, Annex, B.8.
Report No.:	384480
Document No.:	M-469999-01-1
Guideline:	OECD: Guideline 307; Aerobic and Anaerobic Transformation in Soil, April 24, 2002
GLP:	n.a.
Previous evaluation:	Submitted for the purpose of renewal
	Acceptable

In the following study degradation data in aerobic soil is presented for metabolite AE F092944. AE F092944 is a common metabolite of the active substances foramsulfuron and nicosulfuron. The submitted 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 ¹⁴C-labelled AE F092944 thus generated information on the degradation in aerobic soil independent from their parent molecules.

Material and Methods

1. Test Material: [pyrimidine-¹⁴C]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 B.8.1.1.2-34.

Table B.8.1.1.2-34: 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	7.3
Organic carbon (%)	0.98	2.294	1.96
CEC (meq/100g)	8.7	9.7	10.4
Max. water holding capacity (%)	44.2	44.3	53.4
Biomass (mg C/100g soil)			
Start	48.3	51.3	80.5
Completion of incubation	34.4	44.8	54.4

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

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 ^{14}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 TLC 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.

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 $^{14}\text{CO}_2$ 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 B.8.1.1.2-35.

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 B.8.1.1.2-35: Degradation of [pyrimidine-¹⁴C] 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	79.0	85.2
3	45.1	58.5	69.9
7	14.7	39.1	51.8
14	6.1	20.7	36.8
28	3.7	11.5	19.0
56	3.6	5.9	12.5
104	0.8	4.7	8.3

Summary of the kinetic evaluation of the degradation of [pyrimidine-¹⁴C] AE F092944 in the three studied soils are given in Tables from B.8.1.1.2-36 to B.8.1.1.2-39.

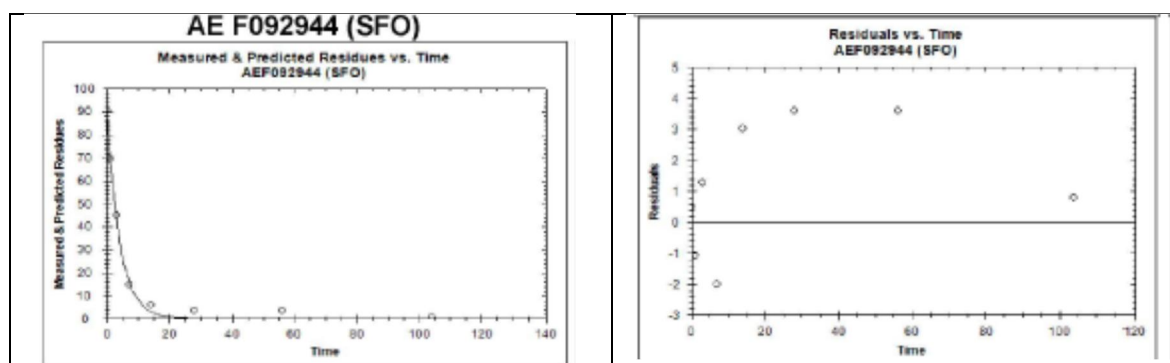
1. Soil Collombey; pyrimidyl label

Fitting the model with SFO kinetics used to the residue data led to a visually acceptable fit (Figure B.8.1.1.2-13) also with good statistical measures (Table B.8.1.1.2-36). The resulting DT₅₀ was 2.9 days.

Table B.8.1.1.2-36. Summary of the kinetic evaluation of the degradation of [pyrimidine-¹⁴C]AE F092944 in Collombey soil

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
AE F092944	SFO	90.3		k = 0.2411	2.9	9.5	6.3	k: <0.0001	0.20905	0.273
<p>Study conclusion (Schmitt & Mikolasch 2012):</p> <p>AE F092944 SFO: fit visually and statistically acceptable (χ^2 6.3 %) (comment RMS: agreed)</p> <p>Best fit model / trigger endpoint for AE F092944: SFO DT50 / 2.9 d</p> <p>Modelling endpoint for AE F092944: SFO DT50 / 2.9 d</p>										

Figure B.8.1.1.2-13. Result of model fit to residue data for AE F092944 in soil Collombey (pyrimidyl label)



2. Soil Speyer 2.2; pyrimidyl label

Fitting a SFO model to the residue data did not lead to a visually acceptable fit to the observed data (Figure B.8.1.1.2-14) because of systematically varying residues. Therefore, alternatively a FOMC model was fitted to the data resulting in a significantly better visual fit (Figure B.8.1.1.2-14). Also the χ^2 -error decreased strongly and was far below 15% (Table B.8.1.1.2-32). For the use in environmental fate simulations a pseudo SFO-DT₅₀ of 10.5 days was calculated from the derived DT₉₀.

Table B.8.1.1.2-32. Summary of the kinetic evaluation of the degradation of [pyrimidine-14C]AE F092944 in Speyer 2.2.soil

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ ² [%]	prob > t	parameter CI	
									lower	upper
AE F092944	SFO	93.7		k = 0.1130	6.1	20.4	9.3	k: <0.0002	0.0824	0.144
AE F092944	FOMC	94.0		α = 1.2496 β = 6.5530	4.9	34.8	2.3	α = 0.0001 β = 0.0009	0.9963 4.4473	1.503 8.659

Study conclusion (Schmitt & Mikolasch 2012):

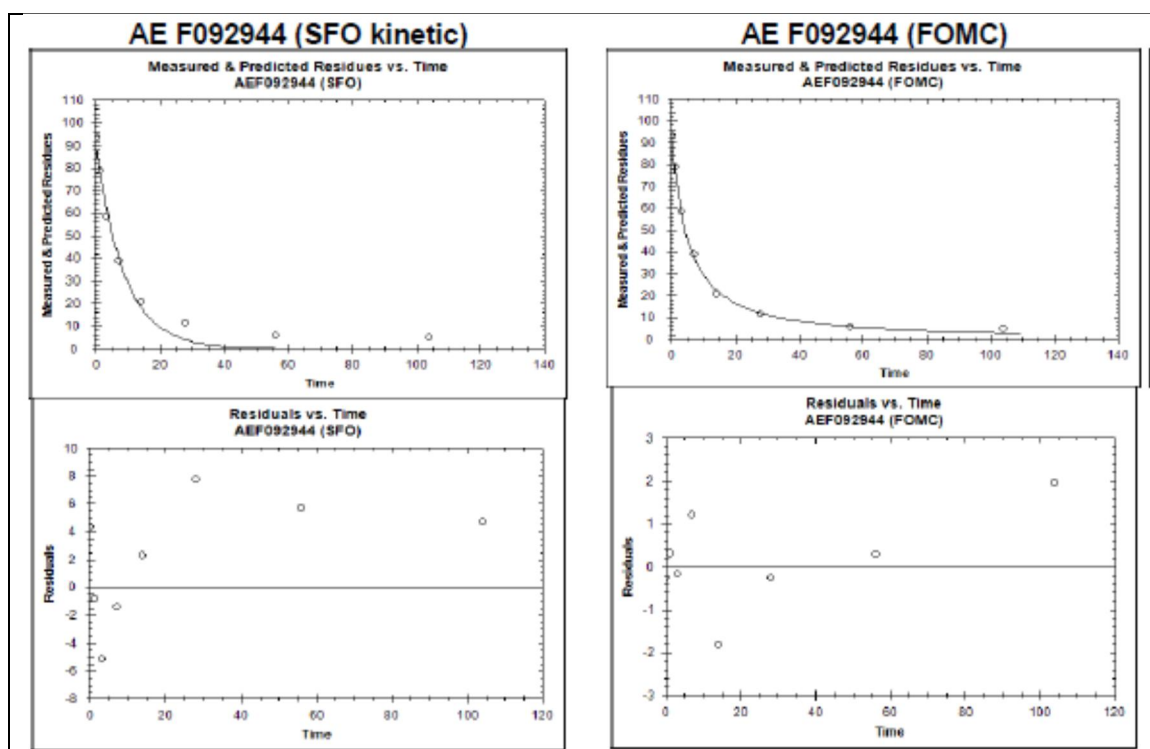
AE F092944 SFO: fit visually not acceptable, statistically acceptable (χ²9.3 %);
(comment RMS: residual plot shows systematic deviations)

AE F092944 FOMC: fit visually and statistically acceptable
(comment RMS: agreed; 10% initial concentration was met within experimental period)

Best fit model / trigger endpoint for AE F092944: FOMC DT50 / **4.9 d**

Modelling endpoint for AE F092944: Pseudo-SFO DT50 = FOMC DT90/3.32 / **10.5 d**

Figure B.8.1.1.2-14. Result of model fit to residue data for AE F092944 in soil Speyer 2.2. (pyrimidyl label)



3. Soil Les Evouettes; pyrimidyl label

Fitting a SFO model to the residue data did not lead to a visually acceptable fit to the observed data (Figure B.8.1.1.2-15) because of systematically varying residues. Therefore, alternatively a FOMC model was fitted to the data resulting in a significantly better visual fit (Figure B.8.1.1.2-15). Also the χ^2 -error decreased strongly and was well below 15% (Table B.8.1.1.2-33). For the use in environmental fate simulations a pseudo SFO-DT₅₀ of 21.8 days was calculated from the derived DT₉₀.

Table B.8.1.1.2-33. Summary of the kinetic evaluation of the degradation of [pyrimidine-14C]AE F092944 in Les Evouettes soil

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
AE F092944	SFO	88.0		k = 0.0611	11.3	37.7	9.1	k: <0.0001	0.0419	0.08
AE F092944	FOMC	92.7		α = 1.1029 β = 10.249	9.0	72.4	2.6	α = 0.0003 β = 0.0026	0.8234 6.0125	1.382 14.486

Study conclusion (Schmitt & Mikolasch 2012):

AE F092944 SFO:

fit visually not acceptable, statistically not acceptable (χ^2 17.5 %);
(comment RMS: residual plot shows systematic deviations)

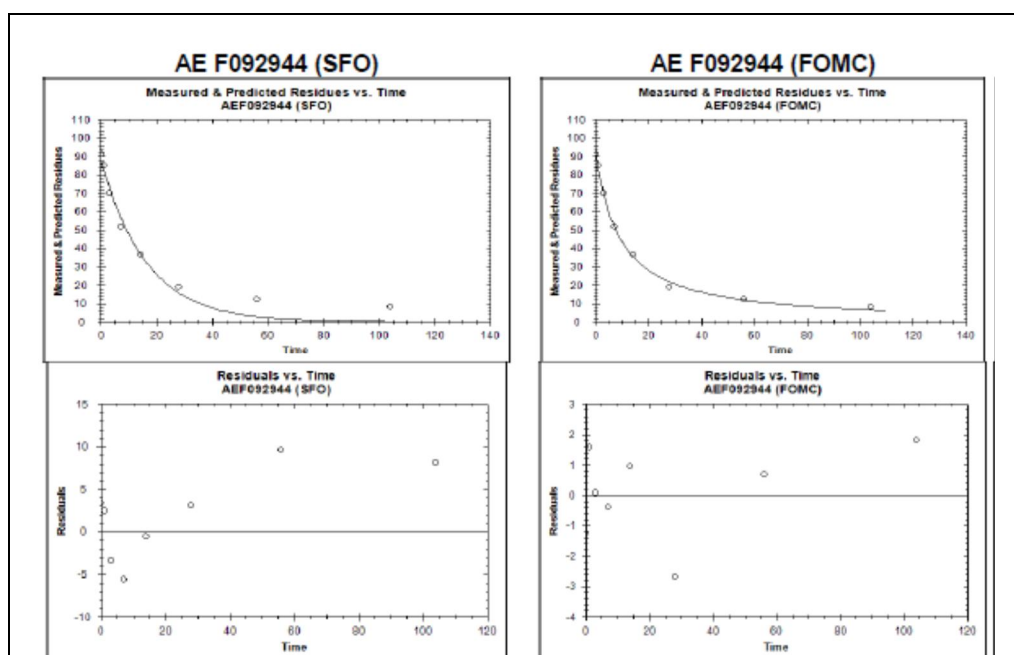
AE F092944 FOMC:

fit visually and statistically acceptable
(comment RMS: agreed; 10% initial concentration was met within experimental period)

Best fit model / trigger endpoint for AE F092944: FOMC DT50 / 9.0 d

Modelling endpoint for AE F092944: Pseudo-SFO DT50 = FOMC DT90/3.32 / 21.8 d

Figure B.8.1.1.2-15. Result of model fit to residue data for AE F092944 in soil Les Evouettes (pyrimidyl label)



The resulting DT_{50} and DT_{90} values of AE F092944 following kinetic evaluation are summarised in Tables B.8.1.1.2-34.

Table B.8.1.1.2-34: Kinetics of aerobic degradation of AE F092944 in three soils at 20°C

Soil	Kinetic model	DT_{50} (days)	DT_{90} (days)	Chi2 Err (%)	Visual assessment
Collombey	SFO	2.9	9.5	6.3	+
Speyer 2.2	SFO	6.1	20.4	9.3	o
	FOMC	4.9	34.8	2.3	+
Les Evouettes	SFO	11.3	37.7	9.1	o
	FOMC	9.0	72.4	2.6	+

Best fits according to the criteria set are marked bold.

Visual assessment: + good; o medium; - bad

Conclusion

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

Calculation of non-normalised DT₅₀-values:

For metabolite AE F092944 the kinetic evaluation of soil degradation tests using the SFO approach resulted in acceptable fits for one soil, while FOMC was more appropriate for additional two soils. For use as non-normalised data prior to normalisation to reference conditions, the DT₅₀-values were back-calculated from the corresponding value of the DT₉₀ derived by the FOMC fit. The results are summarised for AE F092944 in Table B.8.1.1.2-36. For metabolite AE F092944 two more reliable half-lives could be derived from degradation study with the active substance in two soils based on SFO kinetics.

Normalisation of DT₅₀-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 B.8.1.1.2-35. The values of half-lives resulting from normalisation are summarised in Table B.8.1.1.2-36.

Table B.8.1.1.2-35: Study conditions and correction factors used for moisture and temperature normalization

Study	Soil	Texture class (USDA)	Gravimetric water content		Actual moisture in test **	Reference moisture pF2 *	T [°C]	Corr. Factor	
			MHWC	0.33 bar				Moisture	Temp.
			[% m/m]	[% m/m]				[-]	[-]
Judge, 2000a	Shuttleworth	Sandy loam	27	-	10.8	19	20	0.67	1.00
	Chantepie	Clay loam	32	-	12.8	28	20	0.58	1.00
DAR, 2006	Collombey	Loamy sand	44.2	-	17.7	14	20	1.18	1.00
	Speyer 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

* Calculated values according to FOCUS, 2000 ** 75% of 0.33 bar or at 40% (55%) of MWHC

Table B.8.1.1.2-36: DT₅₀ and DT₉₀ -values for metabolite AE F092944 in aerobic soil under laboratory conditions for use as modelling input parameters in environmental exposure assessments and for trigger evaluation (values highlighted in green are obtained from studies with the active substance evaluated under the Section B.8.1.1.1)

Soil	Label position	Non-Normalised DT ₅₀ /pseudoDT ₅₀ (days) Modelling	Normalised DT ₅₀ / pseudoDT ₅₀ (days) Modelling	Non-Normalised DT ₅₀ (days) Trigger	Non-Normalised DT ₉₀ (days) Trigger	Model
Shuttleworth (Study 1)	pyrimidyl	141.7	94.9	141.7	470.4	SFO
Chantepie (Study 1)	pyrimidyl	254.4	147.6	254.4	844.6	SFO
Collombey (Study 3)	pyrimidyl	2.9	3.4	2.9	9.6	SFO
Speyer 2.2 (Study 3)	pyrimidyl	10.5	12.4	4.9	34.8	FOMC
Les Evouettes (Study 3)	pyrimidyl	21.8	19.6	9.0	72.4	FOMC
Geometric mean for modelling			25.9			
Overall worst case for trigger evaluation (Best fit)		254			845	

Study 1: KCA 7.1.2.1.1 /01; Study 3: KCA 7.1.2.1.2 /07

RMS comments and conclusion

The study was performed according to the guideline and is considered acceptable by the RMS. For the determination of the degradation rate, the data sets were analysed in accordance with the FOCUS Deg Kinetics Report (2006). The initial concentration was included in the parameter optimization procedure and all data points were weighted equally. For optimal goodness of fit, the initial value was also allowed to be estimated by the model. For use as modeling endpoint, an overall geometric mean of normalised half-life of 25.9 days was calculated for AE F092944. For comparison against persistence triggers a non-normalised worst case half-life of 254 days was calculated in soil Chantepie associated with a DT₉₀ of 845 days. This value was obtained in a study with the active substance foramsulfuron.

Overall conclusion on metabolites

The end point values for modelling and for comparison with trigger values for all metabolites are summarized in Table B.8.1.1.2-37 and the characteristics of soils used in the degradation studies are given in Table B.8.1.1.2-38.

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 DT₉₀ 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 DT₉₀ range from 2.6 days to 42.2 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 DT₉₀ range from 0.7 days to 11.6 days for the same soils.

Table B.8.1.1.2-37: DT₅₀ and DT₉₀ -values for metabolites AE F092944, AE F130619 and AE F153745 in aerobic soil under laboratory conditions for use as modelling input parameters in environmental exposure assessments and for trigger evaluation

Substance	Normalised DT₅₀ / pseudoDT₅₀ (days) Modelling	Worst case non-Normalised DT₅₀ (days) Trigger	Worst case non-Normalised DT₉₀ (days) Trigger
AE F092944	25.9	254	845
AE F130619	2.3	6.5	42.2
AE F153745	0.9	3.3	11.6

Table B.8.1.1.2-38: Characteristics of soils used in the degradation studies

Study	Soil	Texture Class (USDA)	Sand [%]	Silt [%]	Clay [%]	MHWC [% w/w]	Org. carbon	pH (CaCl ₂)	CEC [meq/100g]
Judge, 2000a	Shuttleworth	Sandy loam	77.7	13.5	8.8	-	2.28	5.0	9.09
	Orainville	Clay loam	29.8	38.0	32.2	-	1.99	7.4	7.99
	Chantepie	Clay loam	25.1	37.7	37.2	-	4.09	6.3	13.77
Judge, 2000c	Illinois	Sandy loam	67	27	6	52.3	2.97	7.2	19.0
	Shuttleworth	Sand	87	7	6	44.7	1.57	5.0	7.8
	Orainville	Loam	36	38	26	54.3	2.03	7.3	13.9
	Chantepie	Loam	32	42	26	57.0	1.80	6.3	10.5
DAR, 2006	Collombey	Loamy sand	83.1	15.8	1.1	44.2	0.98	7.6	8.7
	Speyer 2.2	Loamy sand	89.3	5.6	5.1	44.3	2.29	6.0	9.7
	Les Evouettes	Loam	47.3	43.4	9.3	53.4	1.96	7.3	10.4
Shepherd Ripperger, 2011	Porterville	Sandy loam	65.8	27.7	6.5	27.1	0.31	7.2	9.1
	Springfield	Silt loam	13.2	62.4	24.4	46.8	1.8	6.4	15.2
	Pikeville	Loamy sand	79.2	17.5	3.3	26.9	0.75	5.4	4.2
	Sanger	Loamy sand	80.3	14.6	5.1	30.5	0.45	6.7	5.7

B.8.1.2 Anaerobic degradation

Reference:	KCA 7.1.1.2 /01; Meyer, B. N.; Pate, M. C.; 2000; M-238343-02; Amended: 2000-02-29
Report No.:	B002603
Guideline:	EU (=EEC): Annex II Point 7.1.1.1.2; PMRA: T-1-255; USEPA (=EPA): 162-2
GLP:	Yes
Previous evaluation:	In DAR (2001)
	Acceptable

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

- 1 flooded soil at 20°C following application of phenyl-UL-¹⁴C- and pyrimidyl-2-¹⁴C- labeled active substance (KCA 7.1.1.2 /01).

The data requirement was evaluated within the process for Annex I inclusion and was considered acceptable by the RMS Germany. The study was not re-evaluated, since the study was performed according to the USEPA: 162-2 which is in line with OECD test guideline No. 307: Aerobic and Anaerobic Transformation in Soil.

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).

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 AE F092944 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. However, the low level of metabolites formed resulting in scattering data did not allow for kinetic evaluation to determine degradation rates under anaerobic conditions.

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.

RMS comments and conclusion:

RMS agrees with the conclusion that anaerobic conditions do not prevail for extended time periods and usually not on a full field plot scale.

B.8.1.3 Photodegradation on soil

Reference:	KCA 7.1.1.3 /01;Burri, R.;2000;M-194958-01 Photolysis of 14C-AE F130360 on soil surface under laboratory conditions
Report No.:	C006964
Guideline:	SETAC: Part 1, 2.; USEPA (=EPA): Subdiv. N, § 161-3;
GLP:	Yes
Previous evaluation:	In DAR (2001) Acceptable

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-2-¹⁴C-labeled active substance (KCA 7.1.1.3 /01).

The data requirement was evaluated within the process of evaluation for Annex I inclusion and was considered acceptable by the RMS Germany. The study was not re-evaluated, since it was performed according to the US EPA: 161-3.

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-¹⁴C-labeled active substance as the second position of radiolabel.

Reference:	KCA 7.1.1.3 /02; Hall L. R.;2012; M-422619-01-1 [Phenyl-UL-14C]foramsulfuron: Phototransformation on soil
Report No.:	MEFSL009
Guideline:	US EPA Fate, Transport and Transformation Guidelines. OPPTS 835.2410; OECD Guidelines for the Testing of Chemicals. 2002 Draft Document. Phototransformation of Chemicals on Soil Surfaces
GLP:	Yes
Previous evaluation:	Submitted for the purpose of renewal
	Acceptable

Materials

1. Test Material: [phenyl-UL-¹⁴C]Foramsulfuron

Specific radioactivity: 4.44 MBq/mg (54.29 mCi/mmol, 266,386 dpm/μg)

Radiochemical purity: 98.3%

Sample ID: C-1138

2. Soil: The soil was collected from Springfield, Nebraska, US

Table B.8.1.3-1: Characteristics of soil used for the photolysis study

Geographic Location (City / Farm / Country)	Springfield / Nebraska / US
Sampling depth	0 – 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 ₂	6.6
pH in Water	7.0
pH in saturated paste	6.8
Organic Matter ^A (%)	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

^A) % organic matter = % organic carbon × 1.724; CEC: Cation exchange capacity

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- ^{14}C]Foramsulfuron (100 μL) was applied to the soil surface area of 12.57 cm^2 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^2 . Considering light conditions at summer solstice at Phoenix, AZ, US in June expressed by its global radiation, one solar outdoor day was equivalent to 7.883 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 ^{14}C -carbon dioxide (2 M aqueous KOH). The samples were irradiated at $20 \pm 2^\circ\text{C}$ 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, 2, 4, 7 and 10 days of incubation. Soil moisture was checked at each sampling interval to result in negligible losses during incubation. Traps for ^{14}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).

Results and Discussion

The results have summarized in Table B.8.1.3-2.

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 $96.8\% \pm 3.6\%$ (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 $96.6 \pm 2.5\%$.

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 (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 $^{14}\text{CO}_2$. Determination of $^{14}\text{CO}_2$ 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%, 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 12.2% 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 AE 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 AE F130619 (foramsulfuron amine) which is well in line with the results of aerobic soil degradation. AE 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.

Table B.8.1.3-2: Photo-transformation of Foramsulfuron on soil surfaces, expressed as percentage of AR (mean \pm SD)

Compound		Sampling time (days)					
		0	1	2	4	7	10
Foramsulfuron	irradiated	94.7 \pm 0.4	76.8 \pm 1.5	75.3 \pm 2.1	55.4 \pm 4.1	67.8 \pm 4.0	58.6 \pm 4.7
	dark	94.9 \pm 1.9	50.8 \pm 0.5	33.4 \pm 0.0	19.3 \pm 4.1	14.3 \pm 4.6	12.2 \pm 4.5
A	irradiated	0.2 \pm 0.3	0.0 \pm 0.0	0.0 \pm 0.0	0.8 \pm 0.9	1.2 \pm 0.3	0.9 \pm 0.0
	dark	0.3 \pm 0.1	0.0 \pm 0.0	0.4 \pm 0.6	1.2 \pm 0.1	1.3 \pm 0.1	1.9 \pm 0.0
B	irradiated	0.0 \pm 0.0	0.0 \pm 0.0	0.1 \pm 0.2	0.2 \pm 0.3	0.0 \pm 0.0	0.2 \pm 0.3
	dark	0.0 \pm 0.0	0.2 \pm 0.3	0.2 \pm 0.2	0.2 \pm 0.3	0.2 \pm 0.3	0.2 \pm 0.3
AE F130619 (Foramsulfuron amine)	irradiated	0.0 \pm 0.0	2.3 \pm 0.1	2.5 \pm 0.0	1.1 \pm 1.6	1.6 \pm 0.4	2.0 \pm 0.3
	dark	0.0 \pm 0.0	30.3 \pm 0.4	38.7 \pm 1.5	34.6 \pm 0.4	22.4 \pm 2.1	17.3 \pm 6.3
D	irradiated	0.0 \pm 0.0	0.0 \pm 0.0	0.3 \pm 0.4	0.3 \pm 0.4	0.6 \pm 0.8	0.5 \pm 0.1
	dark	0.0 \pm 0.0	0.0 \pm 0.0	0.0 \pm 0.0	0.0 \pm 0.0	0.0 \pm 0.0	0.0 \pm 0.0
E	irradiated	0.0 \pm 0.0	0.1 \pm 0.2	0.4 \pm 0.1	0.5 \pm 0.1	0.7 \pm 0.0	0.5 \pm 0.2
	dark	0.0 \pm 0.	0.0 \pm 0.0	0.0 \pm 0.0	0.0 \pm 0.0	0.0 \pm 0.0	0.0 \pm 0.0
AE F153745 (Foramsulfuron sulfonamide)	irradiated	1.8 \pm 0.0	5.0 \pm 1.2	2.8 \pm 0.6	10.4 \pm 1.4	4.0 \pm 1.0	4.5 \pm 0.8
	dark	2.0 \pm 0.1	0.4 \pm 0.0	0.1 \pm 0.2	0.2 \pm 0.2	0.2 \pm 0.3	0.5 \pm 0.3
G	irradiated	0.1 \pm 0.2	0.5 \pm 0.1	0.2 \pm 0.2	1.6 \pm 0.3	0.4 \pm 0.3	0.4 \pm 0.1
	dark	0.0 \pm 0.0	0.9 \pm 0.2	0.7 \pm 0.0	0.6 \pm 0.1	0.6 \pm 0.1	0.3 \pm 0.4
H	irradiated	0.2 \pm 0.2	0.0 \pm 0.0	0.0 \pm 0.0	0.3 \pm 0.0	0.5 \pm 0.0	0.6 \pm 0.1
	dark	0.0 \pm 0.0	0.0 \pm 0.0	0.0 \pm 0.0	0.0 \pm 0.0	0.0 \pm 0.0	0.0 \pm 0.0
I	irradiated	0.0 \pm 0.0	0.5 \pm 0.1	0.6 \pm 0.0	0.6 \pm 0.3	1.1 \pm 0.1	0.8 \pm 0.2
	dark	0.0 \pm 0.0	0.0 \pm 0.0	0.0 \pm 0.0	0.0 \pm 0.0	0.0 \pm 0.0	0.0 \pm 0.0
Total extractable residues	irradiated	97.1 \pm 0.0	85.3 \pm 2.4	82.2 \pm 2.1	71.2 \pm 2.5	77.7 \pm 4.7	68.9 \pm 3.8
	dark	97.1 \pm 1.9	82.5 \pm 1.3	73.5 \pm 0.6	56.1 \pm 4.5	39.0 \pm 2.6	32.4 \pm 1.4
Non-extractable residues	irradiated	2.9 \pm 0.9	14.6 \pm 0.8	15.3 \pm 0.6	22.4 \pm 1.5	18.8 \pm 1.4	21.8 \pm 4.3
	dark	2.9 \pm 1.2	12.8 \pm 0.6	24.0 \pm 1.7	41.5 \pm 7.1	56.5 \pm 0.8	61.2 \pm 0.7

Compound		Sampling time (days)					
		0	1	2	4	7	10
CO ₂ 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 ± 0.1
	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	97.6 ± 3.4	91.6 ± 0.4
	dark	100.0 ± 0.7	95.2 ± 0.7	97.5 ± 2.3	97.7 ± 2.6	95.6 ± 1.8	93.7 ± 2.0

SD = standard deviation; Letters in table above represent unidentified radioactive compounds.

E. Kinetic analysis of data: For irradiated samples, degradation of foramsulfuron was slow to result in values of the experimental DT₅₀, DT₇₅ and DT₉₀ of 15.9, 31.9, and 52.9 days, respectively, when following the simple first order kinetic model (Table B.8.1.3-3). 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 DT₅₀, DT₇₅ and DT₉₀ of 1.6, 3.1, and 5.1 days, respectively, again following the simple first order kinetic model.

Table B.8.1.3-3: Kinetic analysis of photolytic degradation of foramsulfuron on soil surfaces

Test Matrix	Kinetic Model	Rate Constant (<i>k</i> ; day ⁻¹)	DT ₅₀ (days)	DT ₇₅ (days)	DT ₉₀ (days)	χ ² test error (%)	t-test* (Prob> t)	Corr. of Det. (r ²)
Irradiated	SFO	0.0435	15.9	31.9	52.9	9.2	0.0024	0.578
Dark controls	SFO	0.4476	1.55	3.10	5.14	15.8	0.00001	0.956
Net Phototrans-formation rate	na	-0.4041	n.c.	n.c.	n.c.	n.a.	n.a.	n.a.

n.a. = not applicable

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

Net phototransformation rate = $k_{\text{irradiated soil}} - k_{\text{dark control soil}}$

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-¹⁴C-phenyl-labeled foramsulfuron resulted in an experimental DT₅₀ of 15.9 days. This is equivalent to 30.5 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 DT₅₀ of 1.6 day in dark control). 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-¹⁴C-phenyl-labeled foramsulfuron was accompanied by the formation of AE F153745 (foramsulfuron sulfonamide) as a major (i.e. >10% AR), but transient degradation product.

RMS comment

The study was performed according to the OECD draft guideline and is considered acceptable by the RMS.

RMS overall conclusion on 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-¹⁴C-labeled active substance the formation of AE F153745 (foramsulfuron sulfonamide) was observed as a major, but transient degradation product while tests with pyrimidine-2-¹⁴C-labeled foramsulfuron resulted in the formation of AE F099095 as a minor degradation product observed at <10% of AR.

B.8.1.4 Field dissipation data

B.8.1.4.1 Soil dissipation studies

Reference:	KCA 7.1.2.2.1 /01; Norris, F. A.;2000;M-238506-02 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 00 WG50 A107
Report No.:	B004767
Document No.:	M-238506-02-1
Guideline:	USEPA (=EPA): 164-1;Deviation not specified
GLP:	Yes
Previous evaluation:	In DAR (2001)
	Acceptable

The data requirement was evaluated within the process of Annex I inclusion as published in the corresponding Monograph of RMS Germany (April 01, 2001) and its amendments. The study was performed to fulfill specific US data registration requirements. Within the EU Annex I inclusion process the study was regarded as supportive data with no consideration for environmental risk assessments. The evaluation revealed that the DT₅₀-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 8.1.1.1.

B.8.1.4.2 Soil accumulation studies

The data requirement was 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 DT₉₀ 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 8.1.1.1.

B.8.1.5 Summary of studies on route and rate of degradation in soil

Please see Vol 1, Level 2, section 2.8.1 for a summary of route and rate of degradation in soil.

B.8.2 Adsorption, desorption and mobility in soil**B.8.2.1 Adsorption/desorption studies****B.8.2.1.1. Adsorption/desorption of the active substance**

Reference:	KCA 7.1.3.1.1 /01; Allan, J. P.; Pate, M. C.; Allan, J. G.; Pate, M. C.; 2000; M-141563-02; Amended: 2000-03-08
Report No.:	The adsorption/desorption of (14C)-AE F130360 on five soils Code: AE F130360 A57846
Guideline:	OECD: 106; USEPA (=EPA): PAG-N 163-1; Deviation not specified
GLP:	Yes
Previous evaluation:	In DAR (2001)
	Acceptable

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-14C- labeled active substance (KCA 7.1.3.1.1 /01).

The data requirement has been evaluated within the process of Annex I inclusion and were considered acceptable by the RMS Germany (2001). The study was not re-evaluated by RMS, since the OECD test guideline No.106: Adsorption -- Desorption Using a Batch Equilibrium Method has not been revised after Annex I inclusion.

The evaluation revealed that the active substance foramsulfuron was weakly adsorbed to soil. Values for the adsorption K_{FOC} 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 B.8.2.1.1-1.

Table B.8.2.1.1-1: Sorption behaviour of foramsulfuron (AE F130360) in 5 soils

Soil	%OC	% Clay	pH (CaCl ₂)	CEC	Ads KF (mL/g)	Ads K _{OC} (mL/g)	Ads 1/n
Maquoketa, US (EFS-16)	1.73	29.2	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	6.0	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
Geometric mean Ads K_{OC} and arithmetic mean of 1/n						69.7	0.87

CEC = Cation Exchange Capacity

The data for K_F , $K_{F,OC}$ 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.

RMS comments and conclusion

RMS considers the study as acceptable. There is no clear correlation either with organic matter, clay or pH.

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.

B.8.2.1.2. Adsorption/desorption of the metabolites

Reference:	KCA 7.1.3.1.2 /01; Reynolds, J. L.; 1999; M-238339-01 Adsorption and desorption of [14-C]-AE F153745 in US and European soils
Report No.:	B002593
Guideline:	EU (=EEC): Point 7.1.2; OECD: 106; USEPA (=EPA): 163-1; Deviation not specified
GLP:	Yes
Previous evaluation:	In DAR (2001) Acceptable

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-¹⁴C-labeled test substance (KCA 7.1.3.1.2 /01).

The data requirement has been evaluated within the process of Annex I inclusion and were considered acceptable by the RMS Germany (2001). The study was not re-evaluated by RMS, since the OECD test guideline No.106: Adsorption -- Desorption Using a Batch Equilibrium Method has not been revised after Annex I inclusion.

The evaluation revealed that metabolite AE F153745 was weakly adsorbed to soil to result in values for the adsorption K_{FOC} to range from 35 to 63 mL/g. Values for Freundlich coefficients 1/n were from 0.92 to 1.00. The data have been summarised in Table B.8.2.1.2-1.

Table B.8.2.1.2-1: Sorption behaviour of AE F153745 in 4 soils

Soil	%OC	% Clay	pH (CaCl ₂)	CEC	Ads K _F (mL/g)	Ads K _{OC} (mL/g)	Ads 1/n
Shuttleworth, US	0.81	6.0	6.9	3.67	0.51	63	0.98
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	10.61	0.99	48	1.00
Geometric mean Ads K_{OC} and arithmetic mean of 1/n						48	0.97

CEC = Cation Exchange Capacity

RMS comments and conclusion

RMS considers the study as acceptable. There is no clear correlation either with organic matter, clay or pH.

Reference:	KCA 7.1.3.1.2 /02;Allan, J. G.; Pate, M. C.;2000;M-238202-01 The adsorption/desorption of [14C]-AE F130619 in US and European soils: AE F130619
Report No.:	B002457
Guideline:	OECD: 106; USEPA (=EPA): 163-1;Deviation not specified
GLP:	Yes
Previous evaluation:	In DAR (2001)
	Acceptable

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-¹⁴C-labeled test substance (KCA 7.1.3.1.2 /02).

The data requirement has been evaluated within the process of Annex I inclusion and were considered acceptable by the RMS Germany (2001). The study was not re-evaluated by RMS, since the OECD test guideline No.106: Adsorption -- Desorption Using a Batch Equilibrium Method has not been revised after Annex I inclusion.

The evaluation revealed that metabolite AE F130619 was weakly adsorbed to soil with values for the adsorption K_{FOC} to range from 40-144 mL/g. Values for Freundlich coefficients 1/n were from 0.90 to 0.94. The data have been summarised in Table B.8.2.1.2-2.

Table B.8.2.1.2-2: Sorption behaviour of AE F130619 in 4 soils

Soil	%OC	% Clay	pH (CaCl ₂)	CEC	Ads K _F (mL/g)	Ads K _{OC} (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	32.2	7.4	7.99	0.79	40	0.90
Pikeville, US	2.07	19.8	4.5	10.61	2.98	144	0.94
Geometric mean Ads K_{OC} and arithmetic mean of 1/n						63.2	0.93

CEC = Cation Exchange Capacity

The data for K_F, K_{FOC} and 1/n for AE F130619 as presented above were also published in SANCO/10324/2002-Final as of Nov 2002.

RMS comments and conclusion

RMS considers the study as acceptable. There is no clear correlation either with organic matter, clay or pH.

Reference:	KCA 7.1.3.1.2 /03;Schollmeier, M.; Eyrich, U.;1992;M-136973-01 Adsorption/Desorption of 2-Amino-4,6-dimethoxypyrimidine (Hoe 092944) in the system soil/water
Report No.:	A48097
Guideline:	OECD: 106; USEPA (=EPA): 163-1;Deviation not specified
GLP:	Yes
Previous evaluation:	In DAR (2001)
	Acceptable

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).

The data requirement has been evaluated within the process of Annex I inclusion and were considered acceptable by the RMS Germany (2001). The study was not re-evaluated by RMS, since the OECD test guideline No.106: Adsorption -- Desorption Using a Batch Equilibrium Method has not been revised after Annex I inclusion.

The evaluation revealed that metabolite AE F092944 was found to be strongly adsorbed to soil with values for the adsorption K_{FOC} 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 B.8.2.1.2-3.

Table B.8.2.1.2-3: Sorption behaviour of AE F092944 in 8 soils

Soil	%OC	% Clay	pH (CaCl ₂)	CEC	Ads K _F (mL/g)	Ads K _{OC} (mL/g)	Ads 1/n
S 2.1, D	1.17	3.50	5.0	3.95	2.47	211	0.69
LS 2.2, D	2.91	5.70	5.0	10.59	2.59	89	0.86
SL 2.3, D	1.32	8.90	4.7	4.68	8.25	625	0.65
Arizona A, US	0.16	8.75	8.0	3.39	1.05	663	0.52
Arizona B, US	0.26	19.47	7.95	10.78	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	18.10	5.6	16.10	81.30	11289	0.58
Kanada, Canada	1.80	56.47	7.7	39.54	16.50	917	0.62
Geometric mean Ads K_{OC} and arithmetic mean of 1/n						621.1	0.67

CEC = Cation Exchange Capacity

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

RMS comments and conclusion

RMS considers the study as acceptable. There is no clear correlation either with organic matter, clay or pH.

B.8.2.2 Leaching studies

Column leaching of the active substance

Column leaching studies with the active substance AE F130360 were not performed as the data on its persistence under aerobic conditions (e.g. DT₅₀) and its adsorption coefficients determined in laboratory study allow for full assessment of the mobility of foramsulfuron in different soils. Such data are sufficient enough for further environmental risk assessment.

Column leaching studies with soil metabolites of foramsulfuron were not performed. This data requirement had been 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-born residues in environmental risk assessments. Column leaching studies with metabolites are therefore regarded as not necessary.

B.8.2.3 Field leaching/lysimeter studies

Reference:	KCA 7.1.4.2 /01; Mackenzie, E.; 2000; M-194838-01 [2- ¹⁴ C-pyrimidyl]-AE F130360: Leaching in outdoor Lysimeters [2-4C-pyrimidyl]-AE F130360
Report No.:	C006906
Guideline:	BBA: IV 4-3 1990; Deviation not specified
GLP/GEP:	Yes
Previous evaluation:	In DAR (2001)
	Acceptable

The leaching of foramsulfuron (AE F130360) under semi-field outdoor conditions was investigated in 2-year study (July 1997 – July 1999) in one soil in two lysimeters following application of pyrimidyl-2-¹⁴C-labeled active substance. Evaluations of this experiment revealed that even under the worst case realistic conditions for leaching, neither foramsulfuron nor any of its soil metabolites were found to leach at concentrations that could pose a risk to ground water.

This data requirement has been 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.

Another lysimeter study was performed since June 1997 till August 2000 in accordance with BBA Lysimeter Guideline, part IV 4-3 1990:

Reference:	KCA 7.1.4.2./02 (Burr, Mackenzie, 2001, M-207434-01) [2- ¹⁴ C-Pyrimidyl] - AE F130360 Leaching in Outdoor Lysimeters
Report No.:	C014861
Guideline:	BBA Lysimeter Guideline part IV 4-3 1990; 91/414/EEC
GLP/GEP:	Yes
Previous evaluation:	Submitted for the purpose of renewal
	Acceptable

Material and Methods

The fate and mobility of pyrimidyl-2-¹⁴C-labelled foramsulfuron ([¹⁴C]-AE F130360) was investigated in 3-year experiment in two lysimeters (L22 and L25). An additional lysimeter, L20, served as control being a source for untreated leachates.

Undisturbed soil monoliths for this study were collected from agricultural land (Shuttleworth Estate Farm, Old Warden, Bedfordshire, Great Britain) in October 1995. Soil of the monoliths was classified as loamy sand with low organic matter content and was uniform throughout the whole profile. Basic characteristics of the soil are summarized in Table B.8.2.3-1.

Table B.8.2.3-1: 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	63– 106 μm	2– 63 μm	<2 μm			
Ap	0-23	0.72	61.33	29.15	1.14	3.20	4.46	7.2	2.7	0.6
Bw/Cu	23-81	0.17	77.60	18.81	0.44	0.91	2.07	7.0	1.1	0.1
Cu	81-129	0.46	68.05	26.83	0.48	1.15	3.04	7.1	0.6	<0.05

* ADAS classification scheme.

Following collection the soil monoliths were installed in a specially constructed underground test facilities located at Aventis CropScience UK Ltd, Chesterford Park, Essex, UK. The lysimeters and the surrounding buffer area were managed in the same way with any agronomic applications of commercially available pesticides (required to keep crops free of undesirable infestations). Sowing and fertiliser applications were made to each lysimeter individually and separately to the buffer zones to ensure that an even distribution was achieved. The surrounding area was always cultivated with the same crop as the concerned lysimeter to avoid edge effects and to achieve an identical microclimate consistent with the field situation.

Applications of [^{14}C]-AE F130360 at a target rate of 2 x 45 g/ha per season were made to the intended crop – maize, together with the non-labelled safener compound AE F122006 (Isoxadifen). 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 season, i.e. on July 2 and August 7, 1998, by application of the same rates.

The radiochemical purity of [^{14}C]-AE F130360 applied to the lysimeters was > 95% on each occasion. The radio-labelled compound was diluted with non-labelled AE F130360 to result in a specific radioactivity of 100 $\mu\text{Ci}/\text{mg}$ (about 4.870 MBq/mg).

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

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

Precipitation and supplemental irrigation (P&I) were recorded daily. Supplemental irrigation was carried out to ensure that the total precipitation received was *ca.* 800 mm/year. Irrigation was also carried out for agronomic reasons as required.

Leachate from each lysimeter was continuously collected and further characterized by HPLC analysis when total radioactivity (TR), as determined by LSC, exceeded 0.1 $\mu\text{g a.s.}-\text{equiv.}/\text{L}$. The leachates were pooled on a calendar monthly basis.

Crops (maize and wheat), Weeds and Thinnings (above ground parts of the plants) harvested from the lysimeters were analysed for total radioactive residues (TRR) by combustion/LSC. Maize and wheat, as subsequent crops, were maintained and harvested according to GAP as far as possible (November 4, 1997; September 24, 1998 and August 31, 1999). The final crops of both lysimeters were harvested immature on 12th August 2000.

Following harvest of the crops intermediate soil cores were sampled from each lysimeter to a depth of 15 cm yearly. The soil cores were sectioned according to depth (0 – 5 cm, 5 – 10 cm, 10 – 15 cm) extracted and the extracts analysed by HPLC. Unextractable soil residue was determined by combustion/LSC.

At the end of the third experimental year (August 14, 2000) lysimeters were removed from the facility and the soil monoliths were segmented into 10 cm layers. The total radioactivity in each segment was determined by combustion/LSC followed by extraction of the top three (L25) and four (L22) layers respectively and HPLC analysis for foramsulfuron and its degradation products. The unextractable remaining was fractionated to quantify the amount of radioactivity associated with the humic acids, fulvic acids and humin fractions.

Results and discussion

Radioactivity in Plants

The total radioactivity in maize (tinnings including) and wheat harvested from the lysimeters during the course of the study was 2.9 % of Applied Radioactivity (% AR) recovered from L25 and 6.5% AR recovered from L22 over the three year period of the study.

Radioactivity in soil

After three experimental years the majority of [¹⁴C]-AE F130360 residue was found in the top 30 cm of the soil monoliths amounting to 41.9% AR in L22 and 38.1% AR in L25. Highly predominant portion of detected radioactivity related to unextractable fractions bonded to humin, humic acids and fulvic acids. Analysis of soil-extractable fractions revealed, that detected radioactivity related predominantly to the metabolite AE F092944 (<1.5% AR). The parent compound – foramsulfuron (<0.2% AR), metabolites AE F099095 (<0.6% AR) and AE F130619 (<0.2% AR) were detected as additional minor components.

Radioactivity was below the limit of quantification (1.4% of AR) in soil monoliths below 30 cm in case of L25 and 40 cm in L22.

Radioactivity in Leachates

The annual averages concentrations of [¹⁴C]-AE F130360 residues in leachates are summarised in Table B.8.2.3-2. Total radioactivity cumulated in leachates after three experimental years was 4.91% (L25) and 3.85% 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). Due to repeated 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 0.527 µg a.s.-equiv./L for L22 and 0.246 µg a.s.-equiv./L for L25.

Table B.8.2.3-2: Total radioactivity in leachates from L25 and L22

Year of experiment	Lysimeter L25					Lysimeter L22				
	Application: Treatment1: June 17, 1997 (45.0 g/ha) Treatment 2: July 19, 1997 (45.0 g/ha)					Application, Year 1: Treatment1: June 17, 1997 (45.0 g/ha) Treatment 2: July 19, 1997 (45.0 g/ha)				
						Application, Year 2: Treatment1: July 2, 1998 (45.0 g/ha) Treatment 2: August 7, 1998 (45.0 g/ha)				
	Total P&I* (mm)	Leachate		Total radioactivity		Total P&I* (mm)	Leachate		Total radioactivity	
		(mm)	(% of Total P&I)	Cumulative (% AR ¹)	Mean concentration (µg a.s.-equiv./L)		(mm)	(% of Total P&I)	Cumulative (% AR ²)	Mean concentration (µg a.s.-equiv./L)
1 st	951	434	45.6	2.031	0.428	951	439	46.1	0.918	0.374
2 nd	964	380	39.5	3.542	0.347	957	359	37.5	2.278	0.678
3 rd	855	551	64.5	4.910	0.246	855	532	62.2	3.847	0.527

* P&I – Precipitation and Irrigation

1st year of the experiment: 17th June 1997 to 8th August 19982nd year of the experiment: 9th August 1998 to 14th August 19993rd year of the experiment: 15th August 1999 to 14th August 2000¹ Calculation based on total AR applied to L25 in 1997² Calculation based on total AR applied to L22 in 1997 and 1998

The radioactivity in leachates was 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.

The results of HPLC analysis including fraction collection/LSC shown in terms of annual average concentrations for the various components and regions separated are summarised in Table B.8.2.3-3 (L25) and Table B.8.2.3-4 (L22). The total radioactivity observed in HPLC runs was separated into known compounds (i.e. foramsulfuron and 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).

Table B.8.2.3-3: Distribution of radioactivity in leachates from L25
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	0.0001-0.004
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	0.010	0.007	0.012	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 B.8.2.3-4: Distribution of radioactivity in leachates from L22
Annual average concentrations [$\mu\text{g a.s.-equiv./L}$]

Year	AE F130360	AE F130619	Early eluting	Region A	Region B	Region C	Region D*	Peak 2*	Others*
1	nd	0.003	0.160	0.121	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.

For both lysimeters and for any defined single compounds, the mean annual average concentration in leachates did not exceed 0.03 $\mu\text{g a.s.-equiv./L}$.

However, the total mean annual average concentration of radioactivity in leachates was higher than 0.1 $\mu\text{g a.s.-equiv./L}$ for a number of regions observed in chromatographic profiles. Further efforts were consequently made to demonstrate that radioactivity in this 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 any reference materials available and no individual component exceeded 0.1 $\mu\text{g a.s.-equiv./L}$ on an annual average basis. Unknown component 'Peak 2' eluted within 'Region A' as the largest single component was found to reach a maximum annual average concentration of 0.028 $\mu\text{g a.s.-equiv./L}$.

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.

Conclusion

For lysimeters L25 and L22 ca. 5% and ca. 4%, respectively, of applied radioactivity was detected in the leachate over the three-year study. The concentrations in leachate for L25, treated in the first season only, reached a peak of 0.629 $\mu\text{g a.s.-equiv./L}$ in the first year (January 98). The concentrations in the leachate for L22, treated in 2 seasons, reached a maximum of 0.858 $\mu\text{g a.s.-equiv./L}$ during year 2 (November 1998). The average concentration in leachate over the three-year study was 0.335 $\mu\text{g a.s.-equiv./L}$ in L25 and 0.517 $\mu\text{g a.s.-equiv./L}$ in L22.

Low levels of the parent compound, AE F130360, were detected in initial leachate samples from L25, at a maximum concentration was 0.011 $\mu\text{g/L}$, this was due to an incident of bypass or non-chromatographic flow. The mean annual concentration was 0.005 $\mu\text{g/L}$ in the first year with none detected in subsequent years. AE F130360 was not detected in any leachates from L22.

HPLC analysis of leachate samples showed that AE F130619 was found to reach a maximum annual average concentration of 0.003 µg a.s.-equiv./L in each lysimeter, with a maximum peak concentration of 0.011 µg/L in L25 and 0.006 µg/L in L22.

No other known metabolites were detected in any leachate sample. The average yearly concentration of any single component in the leachates did not exceed 0.03 µg a.s.-equiv./L. The remainder of radioactivity was composed of highly polar components or material that co-eluted with UV associated organic material.

The majority of radioactivity remaining in the soil after three years was located in the top 30 cm of the soil profile (up to ca. 40% of applied radioactivity). Levels of radioactivity below 30 cm in L25 and below 40 cm in L22 were less than the limit of quantification (1.4% AR). Of the radioactivity that was extractable from the top 30 cm of the soil, the largest component (<1.5 % of applied radioactivity) was the metabolite AE F092944. Only small amounts of parent compound (<0.2% of applied radioactivity) and the soil metabolites AE F130619 and AE F099095 (at <0.2 % and <0.6 %, respectively) could be detected in the soil segments.

This study has shown that even under realistic worst case conditions for leaching, neither AE F130360 nor any of its major soil metabolites will pose a risk to ground water at a depth of one metre or more.

RMS comments and conclusion

Some inaccuracies were noted in rainfall recorded and the total year precipitation differed in more than 10% within the span of experiment (951/964/855 mm/experimental year, respectively (see Table B.8.2.3-4) what is equal to 832/948/853 mm/365 days, respectively). However, the higher precipitation increases the leaching and the study is considered as acceptable by RMS. For both lysimeters and for foramsulfuron and AE F130619 and for other known metabolites, the mean annual average concentration in leachates did not exceed 0.01 µg a.s.-equiv./L. However, the total mean annual concentration of radioactivity in leachates representing the sum of active substance and its metabolites, degradation and reaction products, was higher than 0.5 µg a.s.-equiv./L in 2nd and 3rd year of the experiment in case of L22. The study shows that radioactivity is leached in mean annual concentration of max 0.678 µg/L and is dependent on the yearly application. The leachate analysis, however, shows that neither foramsulfuron nor any other known metabolites are found in the leachate in concentration above 0.01 µg/L. This conclusion is supported by the PECgw modelling.

Table B.8.2.3-4: Year total precipitation and irrigation overview

Period	P&I		Year of the experiment	P&I	
	L25	L22		L25	L22
06/1997 – 12/1997	515.6	515.6			
01/1998 – 12/1998	885.5	882.5	1 st : 17/06/1997 – 08/08/1998	951.1	951.1
01/1999 – 12/1999	875.5	875.5	2 nd : 09/08/1998 – 14/08/1999	963.8	956.7
01/2000 – 08/2000	444.4	444.4	3 rd : 15/08/1999 – 14/08/2000	854.9	854.9

Several other discrepancies have been identified further in between the same data listed in different tables and relevant appendices. To the most significant one belong differences in volumes of total precipitation as stated in Tables 7 and 8 comparing to the volumes stated in Table 4 of the study:

Table B.8.2.3-5: Comparison of “Total precipitation” data as quoted in Table 4 and Tables 7 and 8 of the study

Experimental year	Total precipitation listed in Table 4		Total precipitation listed in Tables 7 and 8	
	L22	L25	L22	L25
1 st : 17/06/1997 – 08/08/1998 (417 days)	951.1	951.1	949	949
2 nd : 09/08/1998 – 14/08/1999 (371 days)	956.7	963.8	866	873
3 rd : 15/08/1999 – 14/08/2000 (366 days)	854.9	854.9	855	855

B.8.2.4. Summary and assessment of adsorption, desorption and mobility in soil

Please see Vol 1, Level 2, section 2.8.1 for a summary of the adsorption, desorption and mobility in soil.

B.8.3 Predicted environmental concentrations in soil (PEC_s)

Please see separate Annex B.8 for product data.

B.8.4 Fate and behaviour in water**B.8.4.1 Abiotic degradation in water****B.8.4.1.1 Hydrolysis**

Reference:	KCA 7.2.1.1 /01;Allan, J. G.; Allen, R.;2000;M-238210-01 The hydrolysis of [14C]-AE F130360 in aqueous buffer at pH 4,5, 7, and 9: AE F130360
Report No.:	B002464
Guideline:	OECD: 111; USEPA (=EPA): 161-1;Deviation not specified
GLP:	Yes
Previous evaluation:	In DAR (2001)
	Acceptable

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-14C- and pyrimidyl-2-14C-labeled active substance following incubation at 25°C and 40°C in the dark

This data requirement has been evaluated within the process of Annex I inclusion (2001) and was considered acceptable by RMS Germany. The study was not re-evaluated by RMS, since the study was performed according to the OECD test guideline No.111: Hydrolysis as a Function of pH. The test guideline has been revised in 2004, but the main principles of the test remained.

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 are summarised in Table B.8.4.1.1-1.

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.

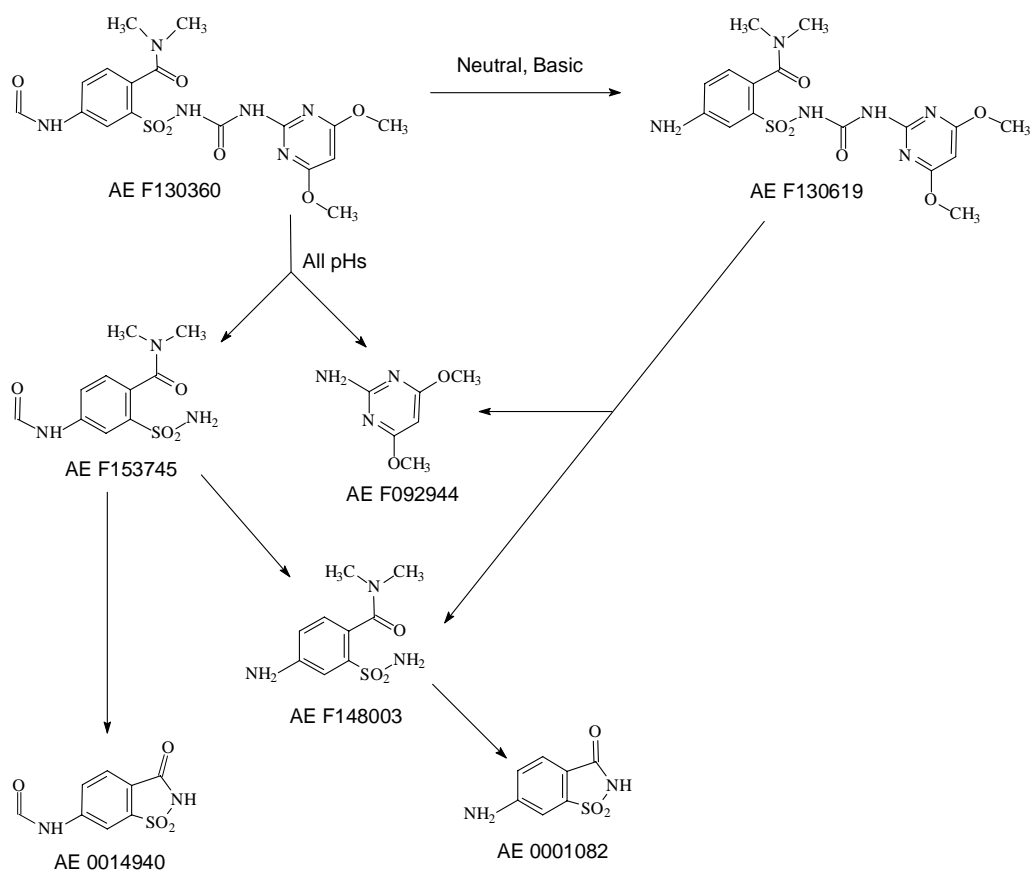
Table B.8.4.1.1-1: Half-lives of foramsulfuron in sterile aqueous buffer at 25°C and 40°C

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

Foramsulfuron was found 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 assessment.

The proposed hydrolysis pathway of foramsulfuron in sterile aqueous buffer is summarised in Figure B.8.4.1.1-1.

Figure B.8.4.1.1-1: Proposed hydrolysis pathway of foramsulfuron in sterile aqueous buffer

B.8.4.1.2.1 Direct photochemical transformation in water

Reference:	KCA 7.2.1.2 /01;Schmidt, W.; Buerkle, L. W.;1999;M-194828-01 Aqueous photolysis under laboratory conditions Code: (U-14C-phenyl)-AE F130360
Report No.:	C006901
Guideline:	OECD: Guidance on Phototransf.; USEPA (=EPA): § 161-2;Deviation not specified
GLP:	Yes
Previous evaluation:	In DAR (2001)
	Acceptable

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

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

The direct photochemical transformation in water was evaluated within the process for Annex I inclusion and were considered acceptable by RMS Germany. The study was not re-evaluated by RMS, since the study was performed according to the US EPA: 161-2 which is in line with the OECD Test No. 316: Phototransformation of Chemicals in Water – Direct Photolysis (2008).

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.

However, new information generated and presented under Point B.8.4.1.2.2 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.

In view of the observations made in the new photolysis study, the quantum yield was determined in addition.

Reference:	KCA 7.2.1.2 /02;Hall, L. R.;2012;M-425561-01 Phototransformation of [14C]foramsulfuron in aqueous pH 7 buffer
Report No.:	MEFSL011
Guideline:	US EPA Fate, Transport and Transformation Test Guidelines OPPTS 835.2240, Photodegradation in Water, US EPA, October 2008
GLP:	Yes
Previous evaluation:	Submitted for the purpose of renewal
	Acceptable

Material and Methods

A. Materials

1. Test Material: [Phenyl-UL-¹⁴C]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-1138

[Pyrimidine-2-¹⁴C] Foramsulfuron (label 2)

Specific radioactivity: 4.51 MBq/mg (55.15 mCi/mmol; 270606 dpm/μg)

Radiochemical purity: 100%

Chemical purity: not reported

Sample ID: C-1145

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 ¹⁴C-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-¹⁴C- (label 1) and pyrimidine-2-¹⁴C]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 [®]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/m² 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 conditions of Athens, Greece, 30 environmental days were reached after 152.6 experimental (Suntest) hours.

Duplicates of irradiated samples containing phenyl-UL-¹⁴C-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-¹⁴C-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-2-¹⁴C-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 ¹⁴C-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 and DFOP² for fitting. Values for half-lives and DT₉₀ were calculated for each set of data originating from the ¹⁴C-phenyl- and ¹⁴C-pyrimidine-labeled test substances, respectively. The quality of fits was evaluated by visual assessment and comparison to result in a minimum of Chi² errors.

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 B.8.4.1.2.1-1 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 B.8.4.1.2.1-2.

For pyrimidine-labelled foramsulfuron, the mean material balances were 100.4% ± 1.3% AR for irradiated samples and 100.7% ± 1.0% for dark controls. The results including material balances and distribution of radioactivity are summarised in Table B.8.4.1.2.1-3 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. Experiences from other tests had shown that no formation of ¹⁴C-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

² SFO = Single First Order; FOMC = First Order Multi Compartment; DFOP = Double First Order in Parallel

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 B.8.4.1.2.1-1 and Table B.8.4.1.2.1-3).

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 B.8.4.1.2.1-4.

The resulting proposed photolytic pathway is summarised in Figure B.8.4.1.2.1-1.

Figure B.8.4.1.2.1-1: Photolysis of foramsulfuron in sterile aqueous buffer solution

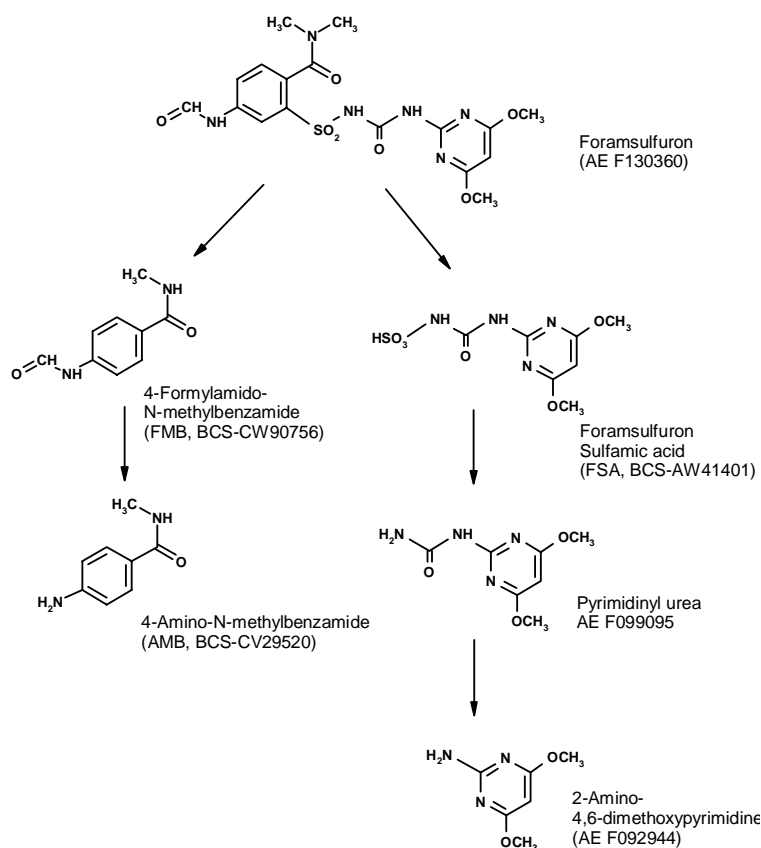


Table B.8.4.1.2.1-1: Phototransformation of [phenyl-UL-¹⁴C]foramsulfuron in sterile aqueous buffer, expressed as percentage of total applied radioactivity

Component		Sampling interval (days)							
		0.00	1.00	1.42	2.00	3.00	4.01	4.97	6.00
		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 ± 1.3
	Dark control	97.6	99.0	-	96.1	94.9	94.7	92.8	95.0
4-Formylamido-N-methylbenzamide (FMB)	Irradiated	0.0 ± 0.0	2.3 ± 3.3	6.9 ± 0.1	8.7 ± 2.3	11.7 ± 0.2	14.4 ± 0.9	16.6 ± 1.0	16.5 ± 0.0
	Dark control	0.0	0.0	-	0.0	0.0	0.0	0.2	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 ± 0.1	5.3 ± 0.2	7.2 ± 1.7	10.2 ± 0.5
	Dark control	0.0	0.0	-	0.0	0.0	0.0	0.0	0.0
Total unidentified radioactivity (each <7%)	Irradiated	1.1 ± 0.3	20.3 ± 3.3	31.6 ± 11.2	32.0 ± 2.8	38.2 ± 1.0	45.2 ± 5.2	50.7 ± 0.2	53.4 ± 0.4
	Dark control	2.2	3.2	-	3.2	6.0	5.9	7.0	7.7
Total number of individual unknown transformation products	Irradiated	2	8	13	14	18	15	19	18
	Dark control	3	4	-	6	5	6	9	6
Highest value for individual unknown transformation products	Irradiated	0.6	3.2	3.8	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	100.2 ± 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
¹⁴ C-Carbon dioxide	Irradiated	n.d. n.d.	n.d. n.d.	n.d. n.d.	n.d. n.d.	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.	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-formamido-N-methylbenzamide = BCS-CW90756

Table B.8.4.1.2.1-2: Transformation of [phenyl-UL-¹⁴C]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	3.2	8.0	8.8	8.5	8.7
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
¹⁴ 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	100.9	100.9	101.0	100.3	97.7

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

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

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

Table B.8.4.1.2.1-3: Phototransformation of [pyrimidine-2-¹⁴C]foramsulfuron in sterile aqueous buffer, expressed as percentage of total applied radioactivity

Component		Sampling interval (days)					
		0.00	0.33	1.00	1.92	3.00	4.00
		0.00	0.33	1.00	1.92	3.00	4.00
Foramsulfuron (Parent compound)	Irradiated	100.3 ± 0.9	92.5 ± 0.0	83.2 ± 3.0	67.9 ± 2.4	53.0 ± 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 ± 0.2	96.3 ± 1.4
Foramsulfuron sulfamic acid (FSA)	Irradiated	0.0 ± 0.0	1.4 ± 0.1	3.5 ± 0.8	6.7 ± 0.0	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	9.8 ± 0.7	16.9 ± 0.9	22.0 ± 1.6	29.2 ± 4.5
	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	0.6 ± 0.2	1.7 ± 0.1	2.8 ± 0.0	4.1 ± 0.1	4.7 ± 0.0
	Dark control	0.3 ± 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 ± 0.2	1.5 ± 0.2	3.3 ± 0.8	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	4	7	10	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	0.0	0.9	1.4	2.3	2.7
Total extractable	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
¹⁴ C-Carbon dioxide	Irradiated	n.d. n.d.	n.d. n.d.	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. 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.	n.d. n.d.	n.d. n.d.
	Dark control	n.d. n.d.	n.d. n.d.	n.d. n.d.	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

Table B.8.4.1.2.1-3: Continued: Phototransformation of [pyrimidine-2-¹⁴C]foramsulfuron in sterile aqueous buffer, expressed as percentage of total applied radioactivity.

Component		Sampling interval (days)		
	Irradiated	5.00	6.00	7.00
	Dark control	5.00	6.00	7.00
Foramsulfuron (Parent compound)	Irradiated	33.5 ± 5.0	23.6 ± 4.8	21.4 ± 2.7
	Dark control	99.5 ± 0.7	97.0 ± 1.5	99.5 ± 0.4
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	34.3 ± 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 ± 1.5	20.8 ± 1.3	21.6 ± 2.3
	Dark control	0.3 ± 0.0	0.4 ± 0.0	0.0 ± 0.0
Total number of individual unknown transformation products	Irradiated	14	15	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	100.0 ± 1.8	98.0 ± 2.8
	Dark control	100.9 ± 0.7	98.6 ± 1.5	101.4 ± 0.3
¹⁴ 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 ± 0.7	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

Table B.8.4.1.2.1-4: Products of phototransformation of ¹⁴C-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-AW41401)	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 DT₅₀-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 DT₅₀ of 83 days. Following determination of the 'net' phototransformation rate thus excluding biotic degradation processes the experimental DT₅₀ has been calculated to 2.46 days (Table B.8.4.1.2.1-5). 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).

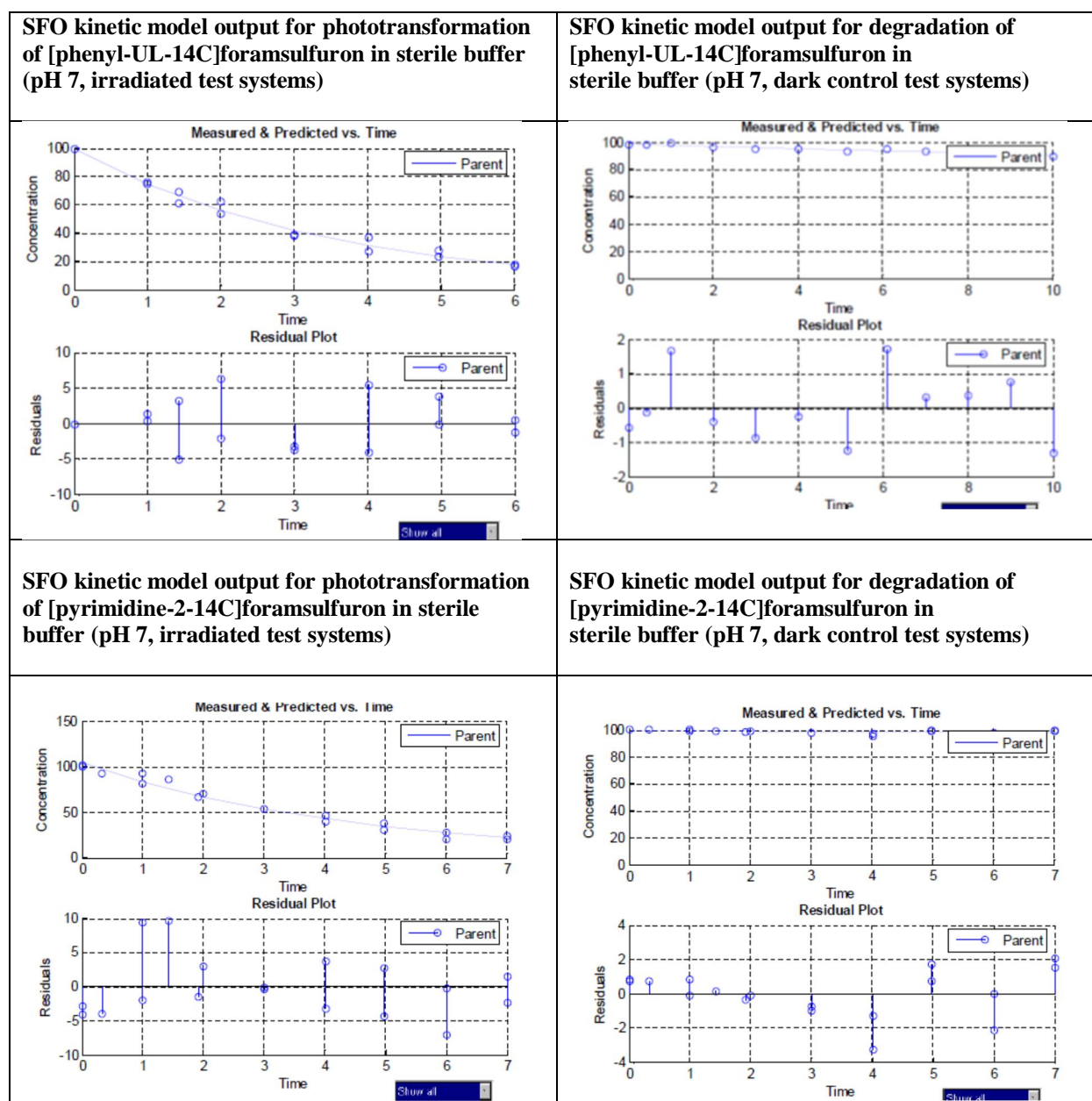
For pyrimidine-labelled foramsulfuron the experimental half-life was determined to 3.12 days for irradiated samples while degradation was again slow in dark controls (DT₅₀ of 253 days). Considering the net phototransformation rate thus excluding biotic degradation processes resulted in an experimental DT₅₀ of 3.16 days (Table B.8.4.1.2.1-5). 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). The visual fits are given in Figure B.8.4.1.2.1-2.

Table B.8.4.1.2.1-5: Kinetics of photolysis of foramsulfuron in sterile aqueous buffer at pH 7

Single First Order Model					Calculated for natural light conditions at			
					Phoenix, USA		Athens, Greece	
Test system	Experimental DT ₅₀ (days)	Rate constant (days ⁻¹)	Chi ² Err	Prob > t	DT ₅₀ (days)	DT ₉₀ (days)	DT ₅₀ (days)	DT ₉₀ (days)
Irradiated, phenyl	2.39	0.2898	2.6157	<0.0001	7.28	24.19	-	-
Dark control, phenyl	83.0	0.0084	0.8285	<0.0001	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	<0.0001	9.49	31.52	-	-
Dark control, pyrimidine	253	0.0027	0.8976	0.0375	n.a.	n.a.	n.a.	n.a.
'Net' transformation rate *	3.16	0.2197			9.6	31.9	14.9	49.5

* (k irradiated) minus (k dark)

Figure B.8.4.1.2.1-2: The visual fits



Conclusion

The photolytic degradation of foramsulfuron in sterile aqueous buffer solution was moderate to result in photolytic half-lives of 11.6 and 14.9 days for phenyl and pyrimidyl labelled active substance, respectively, when being referenced to natural light conditions of Athens, Greece, and considering 12 hours day/night intervals.

Irradiation of phenyl-UL-¹⁴C-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. Irradiation of pyrimidine-2-¹⁴C-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.

RMS comments and conclusion

The use of 0.01 M aqueous phosphate buffer solution with pH 7 in the test is acceptable since foramsulfuron is hydrolytically stable at this pH. The study followed the OECD test guideline 316: Phototransformation of Chemicals in Water – Direct Photolysis, except that duplicate samples were continuously irradiated in a @Suntest system at 25 ± 1 °C with simulated sunlight with range of wave length spectrum 290 – 3000 nm though it should be with range of wave length spectrum 290-800 nm. However, the UV-VIS absorption spectra of foramsulfuron showed one adsorption maximum at 249 nm. Therefore RMS considers the study as acceptable.

The results show that direct photolysis may therefore contribute to some extent to degradation of foramsulfuron in the aquatic environment, at least in alkaline environment where hydrolysis is not relevant. Therefore the major metabolites have to be considered in the aquatic risk assessment.

Reference:	KCA 7.2.1.2 /03;Heinemann, O.;2013;M-460124-01 Foramsulfuron: Determination of the quantum yield and assessment of the environmental half-life of the direct photo-degradation in water
Report No.:	EnSa-13-0305
Guideline:	OECD Test Guideline 316, 2008;not specified
GLP:	Yes
Previous evaluation:	Submitted for the purpose of renewal
	Acceptable

Material and Methods

A. Materials

- 1. Test Material:** Company code: Foramsulfuron (AE F130360)
Chemical purity: 98.3%
Sample ID: AZ16639, Batch AE F130360 00 1B 99 0003
- 2. Solutions:** Solutions of 11.3 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.

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 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.

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 ϵ 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 6.18×10^{-4} for the quantum yield Φ (Φ =the proportion of light quanta absorbed by a substance resulting in a transformation of the molecule).

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 B.8.4.1.2.1-6). The results from computations according to the approach by Frank and Kloeppfer are presented in Table B.8.4.1.2.1-7.

Table B.8.4.1.2.1-6: Environmental half-lives for the direct photolytic degradation of foramsulfuron according to the software GC SOLAR

Season	Environmental DT ₅₀ (days)			
	30 th degree latitude	40 th degree latitude	50 th degree latitude	60 th 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, 10th degree longitude, clear sky, typical concentrations of ozone in the atmosphere, half-lives integrated for the entire day. The column given for 50th degree latitude is typical for conditions of region central Europe.

Table B.8.4.1.2.1-7: 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 ₅₀ (days)		
		Minimum	Mean	Maximum
January	0.482×10^{-8}	790	1700	7600
February	0.117×10^{-7}	330	680	3000
March	0.279×10^{-7}	150	290	1200
April	0.552×10^{-7}	81	150	580
May	0.775×10^{-7}	65	100	410
June	0.925×10^{-7}	58	87	350
July	0.841×10^{-7}	64	95	320
August	0.784×10^{-7}	68	100	340
September	0.411×10^{-7}	110	200	720
October	0.188×10^{-7}	230	430	1900
November	0.637×10^{-8}	550	1300	6300
December	0.288×10^{-8}	1300	2800	14000

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

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.

RMS comments and conclusion

The study followed the OECD test guideline 316 and is considered acceptable.

B.8.4.1.2.2 Indirect phototransformation in water

The indirect photolysis of foramsulfuron was investigated in:

- sterile natural water at pH 8.3 in two studies following application of phenyl-UL-¹⁴C- or pyrimidine-2-¹⁴C-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).

Since indirect photolysis was not a data requirement it 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.

Reference:	KCA 7.2.1.3 /01;Meyer, B. N.;2009;M-346695-01 [Phenyl-UL- ¹⁴ C]foramsulfuron: Phototransformation in natural water
Report No.:	MEFSU004
Guideline:	US EPA Subdivision N, Section 161-2;not specified
GLP:	Yes
Previous evaluation:	Submitted for the purpose of renewal
	Acceptable

Material and Methods

A. Materials

1. Test Material: [Phenyl-UL-¹⁴C]Foramsulfuron

Specific radioactivity: 5.16 MBq/mg (63.1 mCi/mmol; 309605 dpm/μg)

Radiochemical purity: 97.8%

Chemical purity: not reported

Sample ID: C-1103

2. Test water

The natural water used for the test was freshly collected (0 to 15 cm depth) from a lake at Olathe, Johnson County, KS, US. Water samples were characterized as summarised in Table B.8.4.1.2.2-1.

Table B.8.4.1.2.2-1: 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 ₃ -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)	0.5

Before start of irradiation the corresponding ¹⁴C-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-UL-¹⁴C-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/m² 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 (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 ^{14}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 ^{14}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 ^{14}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 model³ for fitting. Values for half-lives and DT_{90} were calculated for each set of data. The quality of fit was expressed in terms of Chi^2 error.

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 ± 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 B.8.4.1.2.2-2. 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}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 90.7% 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 B.8.4.1.2.2-2).

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

³ SFO = Single First Order

maximum (day 4). The major and distinct transformation products observed requiring further assessment in environmental exposure assessments are summarised in Table B.8.4.1.2.2-3.

The resulting photolytic pathway is summarised for both positions of radiolabel investigated in Figure B.8.4.1.2.2-1.

Figure B.8.4.1.2.2-1: Indirect photolytic degradation after application of phenyl- or pyrimidine-labelled foramsulfuron to sterile natural water

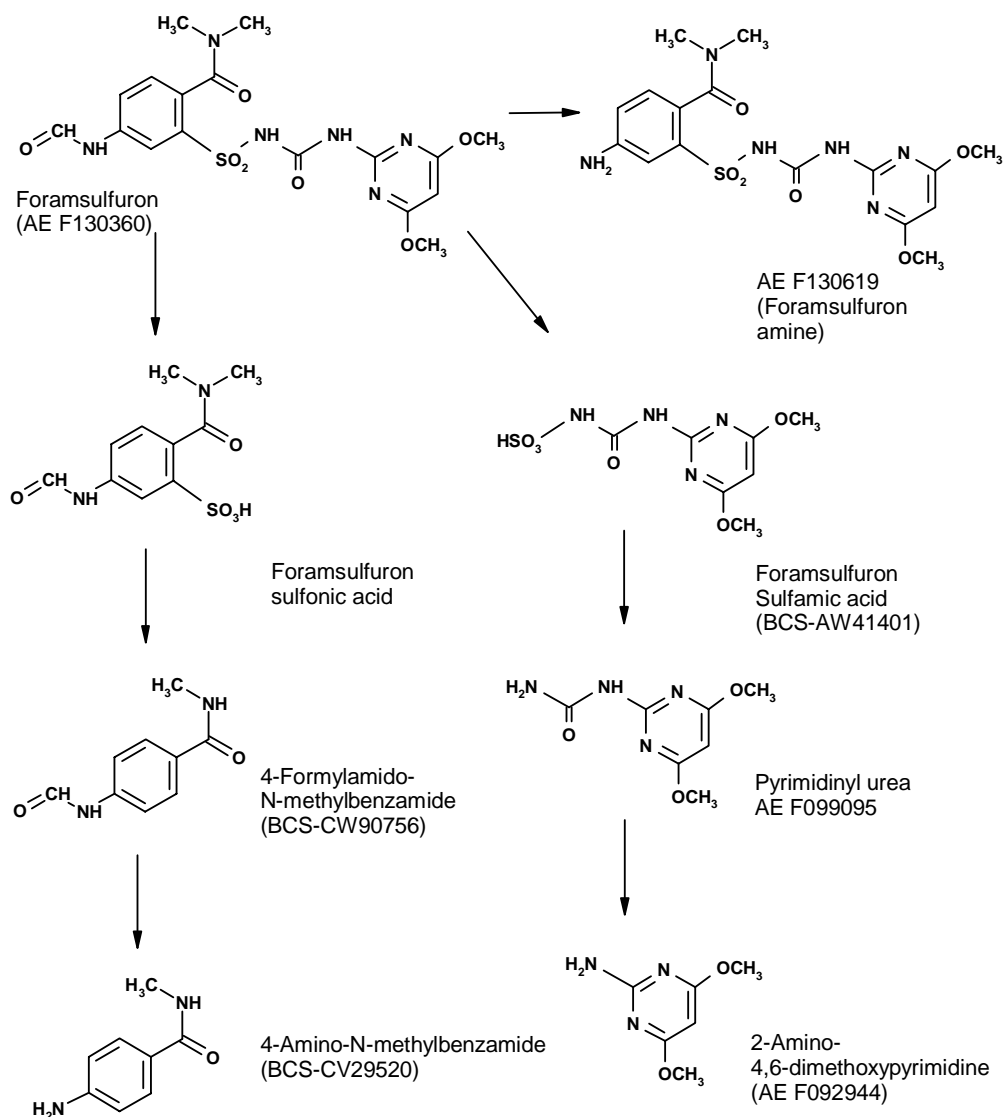


Table B.8.4.1.2.2-2: Phototransformation of [phenyl-UL-¹⁴C]foramsulfuron in sterile natural water, expressed as percentage of total applied radioactivity

Component		Sampling interval (days)						
	Irradiated	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 ± 11.2	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	7.5 ± 0.1	10.7 ± 1.3	9.2 ± 1.3	7.9 ± 1.1	5.9 ± 1.5	2.6 ± 3.7
	Dark control	5.6 ± 0.2	-	5.4 ± 0.4	5.9 ± 0.1	5.9 ± 0.3	-	6.0 ± 0.8
4-Formamido-N- methylbenzamide (BCS-CW90756)	Irradiated	0.0 ± 0.0	4.1 ± 0.2	8.6 ± 1.8	13.4 ± 0.7	19.7 ± 4.5	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 ± 0.1	6.7 ± 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 ± 0.1	5.4 ± 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 ± 2.9	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	5	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
¹⁴ 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

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 B. 8.4.1.2.2-3: Products of indirect photochemical degradation of phenyl-UL-¹⁴C-labeled foramsulfuron in sterile natural water

Label	Label position	Component	Maximum fraction (% AR)	Maximum occurrence after days *
1	phenyl	AE F130619 (Foramsulfuron amine)	10.7	1
		4-Formamido-N-methylbenzamide (BCS-CW90756, FMB)	19.7	3
		4-Amino-N-methylbenzamide (BCS-CV29520, AMB)	12.8	4

* Total duration was 5 days (118 hours)

The experimental DT₅₀ values for foramsulfuron in irradiated and in dark control samples were calculated by applying a simple first order kinetic model (Figure B.8.4.1.2.2-2).

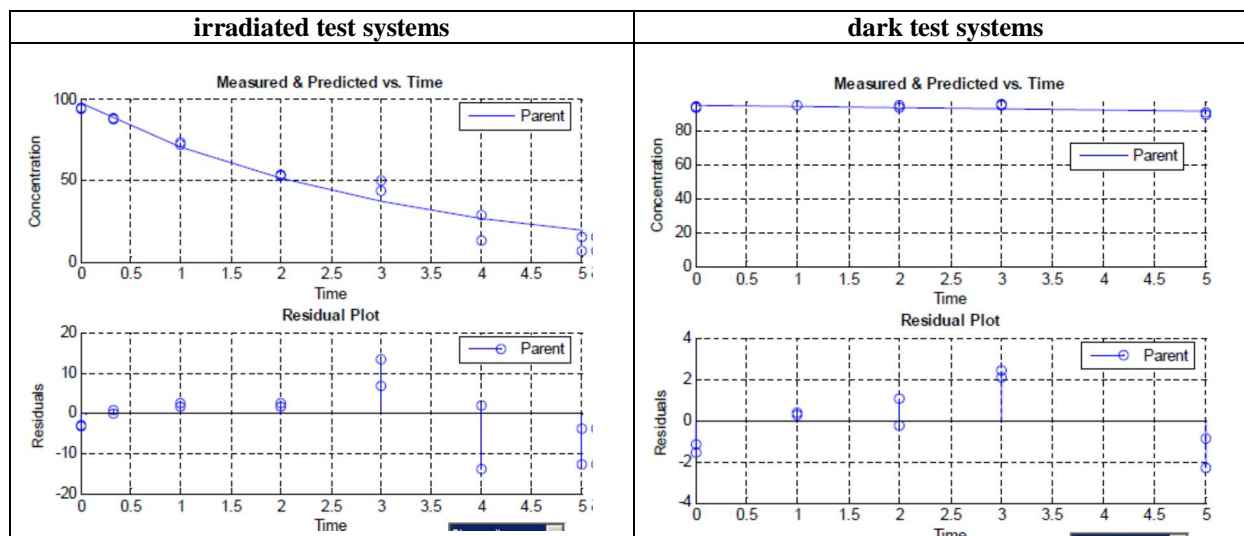
For phenyl-labelled foramsulfuron the experimental half-life was determined to 2.1 days for irradiated samples while degradation was slow in dark controls showing a DT₅₀ of 92.4 days. The experimental DT₅₀ has been calculated to 2.1 days (Table B.8.4.1.2.2-4) with no correction for (insignificant) degradation 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 B.8.4.1.2.2-4: Kinetics of indirect photochemical degradation of phenyl-UL-¹⁴C-labeled foramsulfuron in sterile natural water

Single First Order Model					Calculated for natural light conditions at			
					Tokyo, Japan		Athens, Greece*	
Test system	Experimental DT ₅₀ (days)	Rate constant (days ⁻¹)	Chi ² Err	Prob> t	DT ₅₀ (days)	DT ₉₀ (days)	DT ₅₀ (days)	DT ₉₀ (days)
Irradiated	2.1	0.3211	8.09	<0.05	14.6	49.3	10.7	36.0
Dark control	92.4	0.0075	1.19	<0.05	n.a.	n.a.	n.a.	n.a.

* Values re-calculated from DT₅₀ and DT₉₀ for Tokyo light conditions

Figure B.8.4.1.2.2-2. SFO kinetic model output for degradation of foramsulfuron in natural water: visual fits.



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.

Application of phenyl-UL-¹⁴C-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.

RMS comments and conclusion

The use of natural water with pH 8.3 is acceptable since foramsulfuron is hydrolytically stable at this pH and hence hydrolysis does not affect the degradation. The study followed the OECD test guideline 316: Phototransformation of Chemicals in Water – Direct Photolysis. Duplicate samples were continuously irradiated in a @Suntest system at 25 ± 1 °C with simulated sunlight. However, the range of wave length spectrum was 290 – 3000 nm though it should be the range of wave length spectrum 290-800 nm. However, the UV-VIS absorption spectra of foramsulfuron showed one adsorption maximum at 249 nm. Therefore RMS considers the study as acceptable.

According to the Commission regulation No 283/2013 amending the regulation 1107/2009 the indirect photochemical degradation is not a mandatory data requirement. However, the results show that indirect photolysis may contribute to some extent to degradation of foramsulfuron in the aquatic environment, at least in alkaline environment where hydrolysis is not relevant route of degradation. Therefore the major metabolites formed have to be considered in the aquatic risk assessment.

Reference:	KCA 7.2.1.3 /02; Meyer, B. N.; 2008; M-327230-01 [Pyrimidine-2- ¹⁴ C] foramsulfuron: Phototransformation in natural water
Report No.:	MEFSU001
Guideline:	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.
GLP:	Yes
Previous evaluation:	Submitted for the purpose of renewal
	Acceptable

Material and Methods

A. Materials

1. Test Material: [Pyrimidine-2-¹⁴C]Foramsulfuron

Specific radioactivity: 4.51 MBq/mg (55.2 mCi/mmol; 270840 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 Olathe, Johnson County, KS, US. Water samples were characterized as summarised in Table B.8.4.1.2.2-5.

Table B.8.4.1.2.2-5: 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 ₃ -equiv.; mg/L)	113
Electrical conductivity (mmho/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 ¹⁴C-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-2-¹⁴C-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/m² 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 ^{14}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 ^{14}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 ^{14}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 model⁴ for fitting. Values for half-lives and DT_{90} were calculated for each set of data. The quality of fit was expressed in terms of Chi^2 error.

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 B.8.4.1.2.2-6. The mean material balances were $100.8\% \pm 0.6\%$ AR for irradiated samples and $99.8\% \pm 2.8\%$ 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 ^{14}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.

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 5 days (Table B.8.4.1.2.2-6).

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.

⁴ SFO = Single First Order

Additionally, AE F130619 (foramsulfuron amine) was found as a minor product at 6.1% AR in maximum (day 1).

The major and distinct transformation products observed requiring further assessment in environmental exposure assessments are summarised in Table B.8.4.1.2.2-7.

The resulting photolytic pathway is summarised in Figure B.8.4.1.2.2-3.

Figure B.8.4.1.2.2-3: Indirect photolytic degradation after application of phenyl- or pyrimidine labelled foramsulfuron to sterile natural water

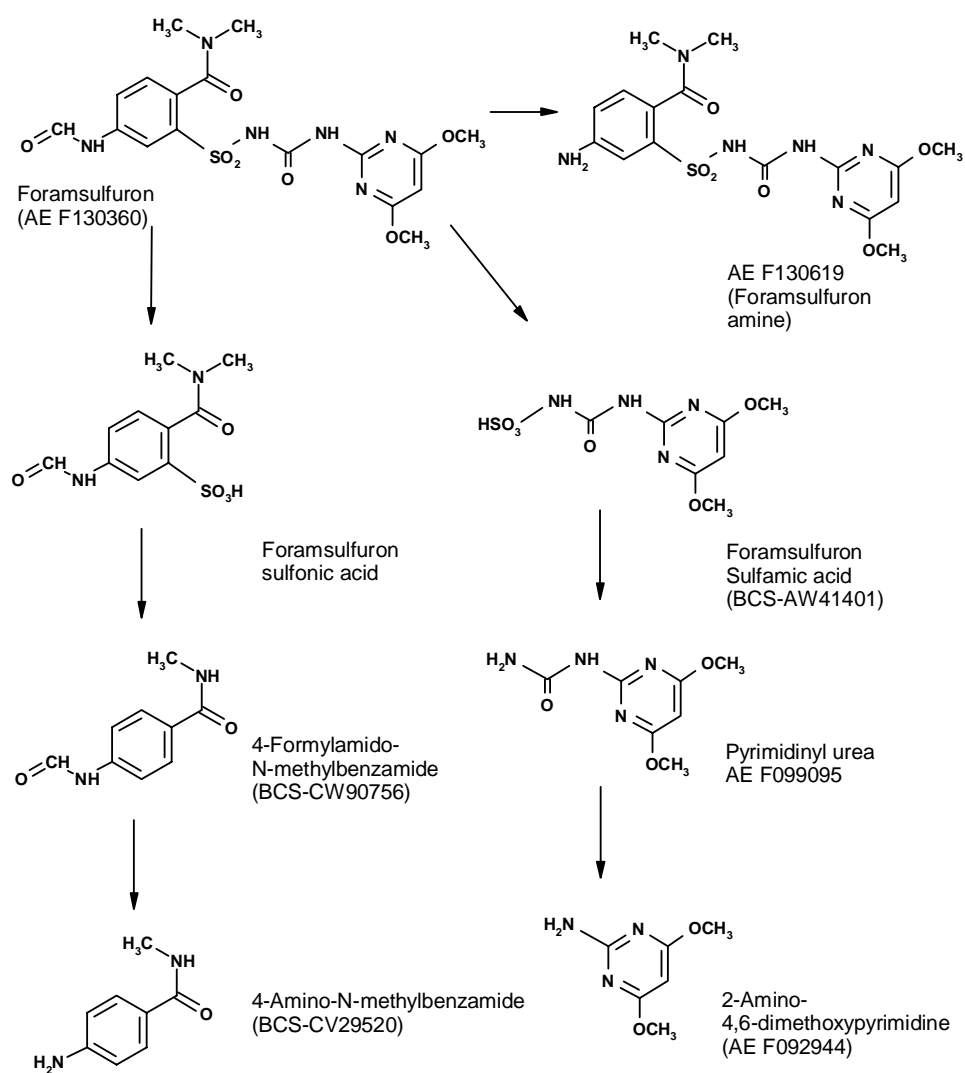


Table B.8.4.1.2.2-6: Indirect phototransformation of [pyrimidine-2-¹⁴C]foramsulfuron in sterile natural water, expressed as percentage of total applied radioactivity

Component		Sampling interval (days)						
	Irradiated	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 ± 7.0	13.5 ± 9.7
	Dark control	97.5 ± 1.1	-	99.0 ± 0.4	90.8 ± 0.7	96.1 ± 0.2	-	92.8 ± 0.1
AE F130619 (Foramsulfuron amine)	Irradiated	0.0 ± 0.0	3.8 ± 1.7	6.1 ± 1.5	4.4 ± 0.5	5.2 ± 0.2	2.4 ± 2.3	2.3 ± 0.4
	Dark control	0.0 ± 0.0	-	0.0 ± 0.0	1.0 ± 0.2	1.3 ± 0.1	-	1.5 ± 0.5
AE F099095 (Foramsulfuron urea)	Irradiated	0.0 ± 0.0	2.1 ± 0.6	7.0 ± 0.5	10.5 ± 2.6	13.7 ± 2.5	16.3 ± 4.8	19.7 ± 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	3.1 ± 1.1	9.7 ± 0.9	12.3 ± 2.1	15.5 ± 0.8	15.6 ± 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 ± 2.2	17.4 ± 3.3	19.9 ± 0.9	26.5 ± 6.9
	Dark control	2.5 ± 0.3	-	3.4 ± 0.0	3.3 ± 0.7	3.7 ± 0.0	-	6.2 ± 0.3
Total unidentified radioactivity (each <8%)	Irradiated	0.0 ± 0.0	0.6 ±0.8	1.5 ± 0.2	7.7 ± 0.2	12.5 ± 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	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
¹⁴ 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

* Value for polar mixture consisting of multiple components

Table B.8.4.1.2.2-7: Products of indirect phototransformation of [pyrimidine-2-¹⁴C]foramsulfuron in sterile natural water

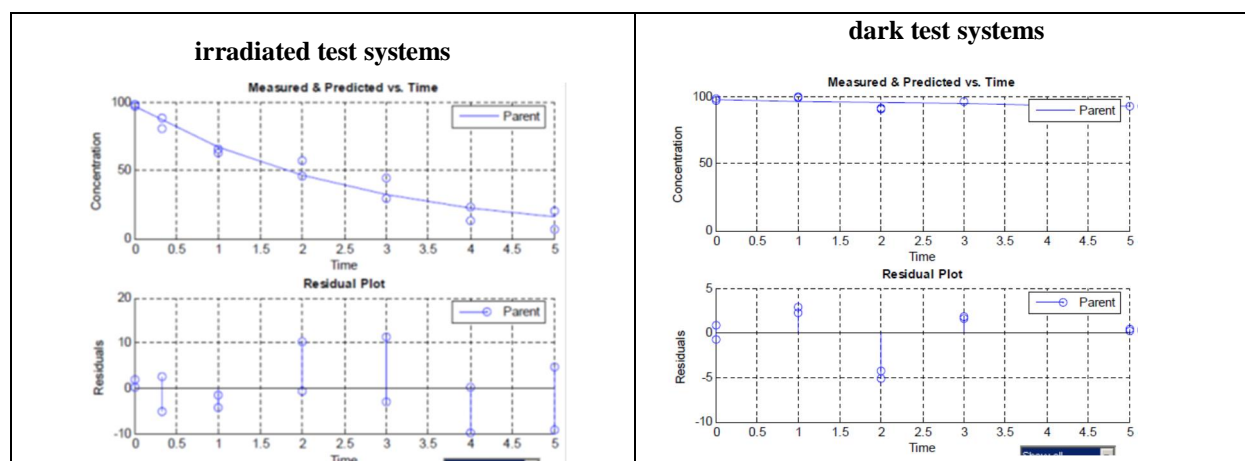
Label	Label position	Component	Maximum fraction (% AR)	Maximum occurrence after days *
2	2- pyrimidyl	AE F099095 (Foramsulfuron urea)	19.7	5
		Foramsulfuron sulfamic acid (BCS-AW41401)	17.6	5
		AE F092944 (Foramsulfuron pyrimidinamine, 2-Amino-4,6-dimethoxypyrimidine)	26.5	5

* Total duration was 5 days (119 hours)

The experimental DT₅₀ values for foramsulfuron in irradiated and in dark control samples were calculated by applying a simple first order kinetic model (Figure B.8.4.1.2.2-4). The experimental half-life foramsulfuron was determined to 1.9 days for irradiated samples while degradation was slow in dark controls showing a DT₅₀ of 65.9 days. The experimental DT₅₀ has been calculated to 1.9 days (Table B.8.4.1.2.2-8) 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 B.8.4.1.2.2-8: Kinetics of indirect phototransformation of [pyrimidine-2-¹⁴C]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 ₅₀ (days)	Rate constant (days ⁻¹)	Chi ² Err	DT ₅₀ (days)	DT ₉₀ (days)	DT ₅₀ (days)	DT ₉₀ (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.

Figure B.8.4.1.2.2-4. SFO kinetic model output for degradation of foramsulfuron in natural water: visual fits.

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-2-¹⁴C-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.

RMS comments and conclusion

The use of natural water with pH 8.3 is acceptable since foramsulfuron can be considered hydrolytically stable at this pH and therefore hydrolysis does not affect the degradation. The study followed the OECD test guideline 316: Phototransformation of Chemicals in Water – Direct Photolysis. The quality criteria for recovery were met, since the mean material balances were 100.8% ± 0.6% AR for irradiated samples and 99.8% ± 2.8% for dark controls. Duplicate samples were continuously irradiated in a @Suntest system at 25 ± 1 °C with simulated sunlight (xenon burner). However, the range of wave length spectrum was 290 – 3000 nm though it should be the range of wave length spectrum 290-800 nm. The relevance of the wave lengths of 800 - 3000 nm to the degradation of chemicals is unknown for the RMS. Otherwise RMS considers the study as acceptable.

According to the Commission Regulation No 283/2013 amending the regulation 1107/2009 the indirect photochemical degradation is not a mandatory data requirement. However as available, the results show that indirect photolysis may contribute to some extent to degradation of foramsulfuron in the aquatic environment, at least in alkaline environment where hydrolysis is not a relevant route of degradation. Therefore the major metabolites have to be considered in the aquatic risk assessment.

B.8.4.2 Biological degradation in water

B.8.4.2.1 Ready biodegradability

The ready biodegradability of foramsulfuron was not investigated experimentally.

The data requirement was 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.

B.8.4.2.2 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-¹⁴C-labeled active substance (KCA 7.2.2.2 /01).

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.

Reference:	KCA 7.2.2.2 /01;Fahrbach, M.;2013;M-453421-01 [phenyl-UL-14C]Foramsulfuron: Aerobic Mineralization in surface water
Report No.:	D62860
Guideline:	OECD Test Guideline No. 309;not specified
GLP:	Yes
Previous evaluation:	Submitted for the purpose of renewal
	Acceptable

Material and Methods

A. Materials

- Test Material:** [Phenyl-UL-¹⁴C]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 Froeschweiher Pond, Moehlin, Aargau (AG), Switzerland. Water samples were characterized as summarised in Table B.8.4.2.2-1.

Table B.8.4.2.2-1: Physico-chemical characteristics of test water

Water	Froeschweiher Pond
pH	7.5
Colour	Light yellow-brown
Dissolved oxygen concentration at collection (mg/L)	7.1
Total hardness (°dH)	12.0
Biological oxygen demand (mg/L)	<4.0
Total organic carbon (TOC, mg/kg)	13.1
Dissolved Organic Carbon (DOC, mg/L)	14.1
Total phosphorus (mg/L)	0.21
Dissolved orthophosphate (mg/L)	0.003
Total nitrogen (mg/L)	3.76
Nitrate NO ₃ ⁻ (mg/L)	6.54
Nitrite NO ₂ ⁻ (mg/L)	<0.8
Ammonium NH ₄ ⁺ (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 300 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-¹⁴C-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 ¹⁴C-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-¹⁴C-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.

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 ¹⁴C-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 ¹⁴C-flow-through detection techniques. Samples of the low dose were analysed by TLC followed by ¹⁴C-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.

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 UL-¹⁴C-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 B.8.4.2.2-2 (low dose) and Table B.8.4.2.2-3 (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 ¹⁴C-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 B.8.4.2.2-3).

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 DT₅₀-value for foramsulfuron was calculated.

Table B.8.4.2.2-2: Degradation of [phenyl-UL-¹⁴C]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	93.8	
	SD	±0.7	±0.9	±0.1	±0.7	±0.7	±0.6	
Unknown Peak 1	Mean*	4.5	3.3	3.8	3.2	3.0	4.0	
	SD	±0.5	±0.1	±0.5	±0.3	±0.6	±1.0	
Unknown Peak 2	Mean*	0.0	0.0	0.0	0.0	0.0	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	±0.2	±0.1	
¹⁴ CO ₂	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	±0.2	±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

Table B.8.4.2.2-3: Degradation of [phenyl-UL-¹⁴C]foramsulfuron in high dosed samples of aerobic natural water, expressed as percentage of total applied radioactivity

Component		Sampling interval (days)						
		0	7	14	21	28	58	sterile
Foramsulfuron	Mean*	98.3	97.0	97.6	94.5	95.3	94.3	95.9
	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	3.0	2.5	4.5	4.6
	SD	±1.3	±0.2	±0.1	±0.5	±0.5	±0.1	±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	±0.3	±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	±0.1	±0.0	±0.0
¹⁴ CO ₂	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	±0.2	±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

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 DT₅₀ of foramsulfuron in water under conditions of aerobic mineralisation testing.

RMS comments and conclusion

The study followed the OECD TG 309: Aerobic mineralization in surface water. The tested concentrations were according to the TG and the pH of the tested natural water was 7.5 in which pH the hydrolysis is insignificant. According to the TG the most stable part should be ¹⁴C labelled to ensure the determination of the total mineralisation. In this study only [phenyl-UL-¹⁴C] foramsulfuron was used. This can be considered acceptable, since there was no degradation of the active substance in the test. In addition, the water/sediment study (under Point 8.4.2.3) shows that phenyl and pyrimidyl labelled foramsulfuron does not mineralise in any significant level. Biological activity of the test water was confirmed by the degradation of reference substance UL-¹⁴C-benzoic acid within 14 days of incubation.

The reference substance degraded within two weeks and the mean material balances were 99.8% ± 0.9% AR for low dose samples and 100.4% ± 1.7% for the high dose. Therefore RMS considers the study as acceptable and agrees to the conclusion that no major transformation products were observed requiring consideration in environmental risk assessments.

B.8.4.2.3 Degradation in water sediment system

Reference:	KCA 7.2.2.3 /01; Judge, D. N.; Abbott, P. B.; Allen, R.; 2000; M-238019-01 Degradation of [U-14C-phenyl] and [2-14C-pyrimidyl]-AE F130360 in two contrasting sediment-water systems under laboratory aerobic conditions at 20°C
Report No.:	B002256
Guideline:	EU (=EEC): 7.2.1.3.2; PMRA: T-1-255; USEPA (=EPA): 162-4; Deviation not specified
GLP:	Yes
Previous evaluation:	in DAR
	Acceptable

Materials and methods

The kinetics and metabolism of [U-14C-phenyl]-foramsulfuron and [2-14C-pyrimidyl]-foramsulfuron were studied in two contrasting sediment-water systems, a silty clay loam from Pikeville, North Carolina (USA) and a sand sediment from Hoechst, Germany and their respective overlying water.

The water/sediment systems differed, in addition to soil texture, in respect with pH. The Pikeville water/sediment system was acidic in nature having sediment pH of 5.7 and water pH of 6.2 whereas the Hoechst system was alkaline having sediment pH of 7.8 and water pH of 8.4. It is possible that hydrolysis may have contributed to the degradation of foramsulfuron in the acidic water/sediment system. The study was not re-evaluated, since it was performed according to the US EPA: 162-4 which is in line with OECD Test guideline No. 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (2002). Only the results and the new kinetic evaluation of the degradation of the active substance and the metabolites are given below.

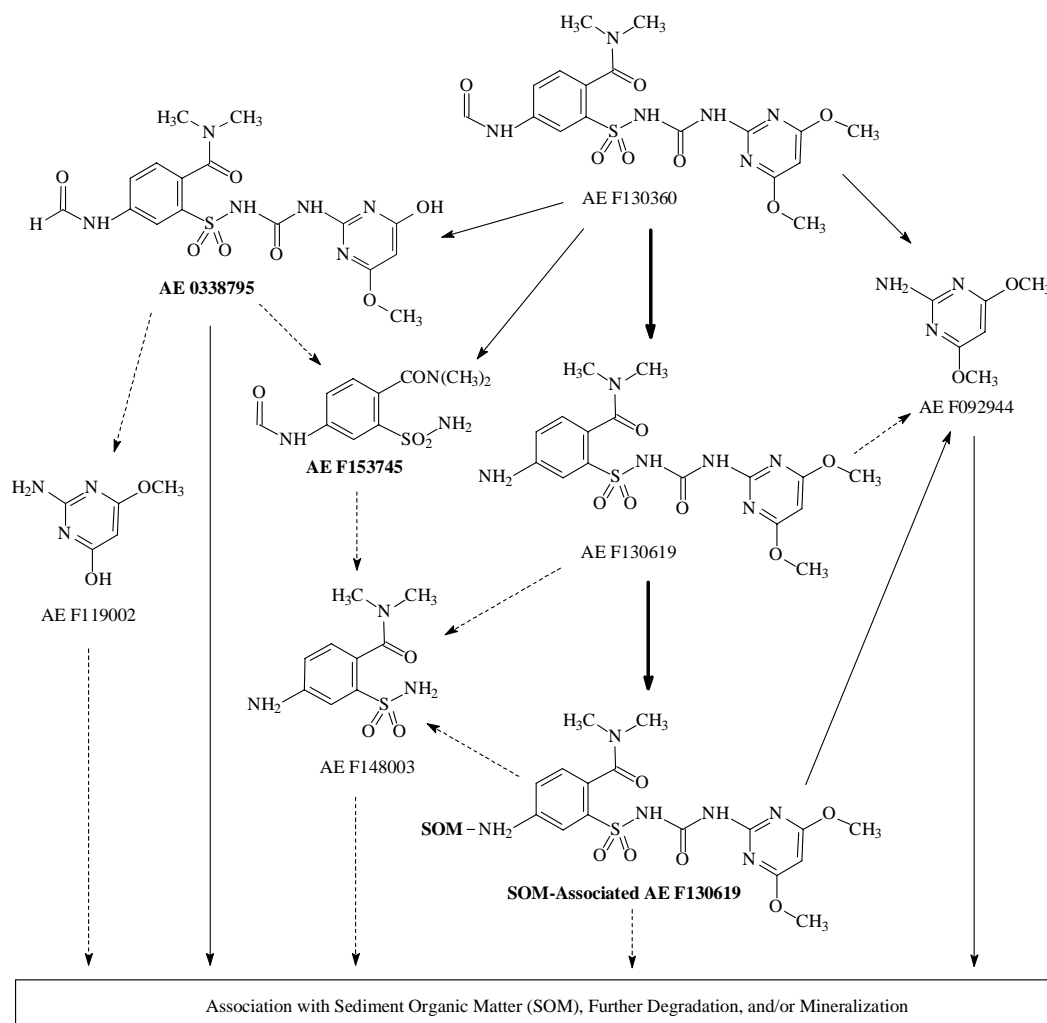
Results

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. 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 F130619 while hydrolysis at the 'sulfonyl urea bridge' resulted in the formation of AE F153745 and AE F092944. Degradation of foramsulfuron is facilitated by lower pH and microbial activity. 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. The actual measured amounts of foramsulfuron and metabolites are given in Tables from B.8.4.2.3-1 to B.8.4.2.3-26 together with the degradation kinetics.

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 F153745 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 B.8.4.2.3-1.

Figure B.8.4.2.3-1: Proposed pathway of metabolism of foramsulfuron in water/sediment systems



Reference:	KCA 7.2.2.3 /04;Schmitt, W.; Mikolasch, B.;2013;M-454536-01 Kinetic evaluation of aerobic aquatic metabolism of foramsulfuron and its metabolites in water / sediment systems according to FOCUS kinetics
Report No.:	EnSa-13-0228
Guideline:	not applicable
GLP:	No
Previous evaluation:	Submitted for the purpose of renewal
	Acceptable

The kinetics of dissipation from water and sediment and the degradation of foramsulfuron in total system were evaluated from data of tests performed in two water/sediment systems with two positions of radiolabel described above. 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.

According to the recommendations of FOCUS (2006), (Level I) dissipation half-lives of foramsulfuron and its metabolites AE F130619, AE F153745, AE F092944 and AE 00338795 for water and sediment were determined as well as the degradation DT_{50} for the total systems.

Material and Methods

The kinetic evaluation was based on data of a water-sediment study described above 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_2 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_2 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.
- Residue 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.

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 triggers 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 B.8.4.2.3-1 was converted into multi-compartment models illustrated in Figure B.8.4.2.3-2 (phenyl-label) and Figure B.8.4.2.3-3 (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.

Figure B.8.4.2.3-2: Compartment model for kinetic evaluation of residues from phenyl-labeled foramsulfuron and metabolites in total water-sediment systems (Level I)

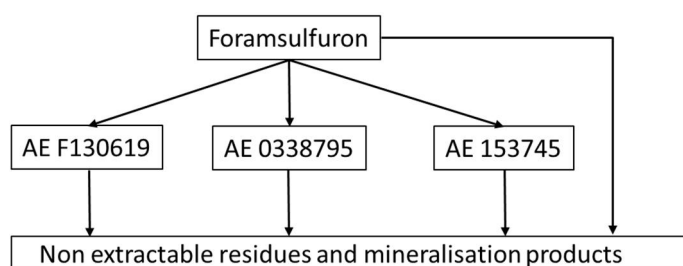
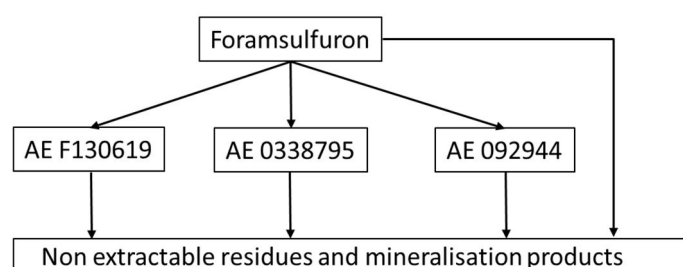


Figure B.8.4.2.3-3: Compartment model for kinetic evaluation of residues from pyrimidine-labeled foramsulfuron and metabolites in total water-sediment systems (Level I)



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 $DT_{90 \text{ bi-phasic}}$ 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 (χ^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 ϵ was used which was derived from χ^2 -error via the following function:

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

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 χ^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 ϵ .

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 χ^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 χ^2 being higher, but with fits still representing a reasonable description of their formation and degradation behaviour.

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 χ^2 -errors there was also no sign of systematic variations of the residuals. Consequently, no further testing of other kinetic models was considered necessary

System Pikeville

Fitting the model to the residue data for the total system Pikeville (phenyl label), using SFO kinetics for all compartments, led to the results shown in Figure B.8.4.2.3-4. The DT₅₀ values for foramsulfuron and its metabolites together with the results of the statistical evaluation are summarised in Table B.8.4.2.3-2. For AE F03387995, the large scatter in the observed data led to a very high value for the Chi²-error. Therefore, the fit was not considered acceptable and no DT₅₀ was derived. In the case of AE F153745, the calculated curve showed some systematic deviation from the observed values. This obviously led to a conservative estimate of the degradation. The fit was nevertheless accepted and a DT₅₀ was derived.

Table B.8.4.2.3-1: Time course of the degradation of phenyl labelled foramsulfuron (AE F130360) and formation and decline of metabolites in Pikeville silty clay loam sediment/water total system (% of applied radioactivity)

Time [days]	Phenyl radiolabeled components (PH)							
	AE F130360	AE F130619	AE 0338795	AE F153745	Others	PH-NER	PH- ¹⁴ CO ₂	Total
0	92.5	0.3	--	0.5	6.0	--	--	99.1
7	77.6	1.1	0.8	3.7	9.8	5.0	0.1	98.0
14	68.8	1.4	5.0	6.4	7.3	8.0	0.1	97.0
29	51.0	1.0	14.0	10.2	13.0	10.4	0.2	96.9
57	16.4	0.6	7.7	24.6	11.4	34.9	0.4	94.7
84	6.8	0.6	10.0	22.7	14.9	48.2	0.5	92.4
119	3.3	0.0	3.7	13.8	11.2	57.8	0.5	88.8
211	1.2	--	--	2.7	7.7	82.0	1.1	94.8
365	--	--	--	--	--	77.3	0.7	82.4

-- = Not detected (< limit of detection LOD of 0.002% of applied radioactivity)

Table B.8.4.2.3-2: Summary of the kinetic evaluation of the degradation of phenyl labelled foramsulfuron and its metabolites in total system Pikeville

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ ² [%]	prob > t _k	parameter k: CI	
									lower	upper
Foramsulfuron	SFO	98.1		k = 0.0267	26.0	86.3	6.6	k: <0.0002	0.0234	0.030
AE F130619	SFO		0.10	k = 0.1288	5.4	17.9	16.2	k: 0.0002	0.0647	0.193
AE 0338795	SFO		0.30	k = 0.0369	n.d.	n.d.	49.4	k: 0.009	0.0081	0.066
AE F153745	SFO		0.35	k = 0.0096	72.1	239.5	26.8	k: 0.002	0.0037	0.016
Study conclusion (Schmitt & Mikolasch 2013): Foramsulfuron SFO: fit visually and statistically acceptable (χ ² 6.6 %) (comment RMS: agreed) AE F130619 SFO: fit visually acceptable, statistically not acceptable (χ ² 16.2 %); (comment RMS: χ ² can be >15% for metabolites if visually acceptable, therefore considered acceptable) AE 0338795 SFO: fit visually and statistically not acceptable (χ ² 49.4 %); (comment RMS: agreed*) AE F153745 SFO: fit visually acceptable, statistically not acceptable (χ ² 26.8 %); (comment RMS: χ ² can be >15% for metabolites if visually acceptable, therefore considered acceptable)										
*For AE F03387995, the large scatter in the observed data led to a very high value for the Chi ² -error.										

Figure B.8.4.2.3-4. Result of model fit to residue data for foramsulfuron and its metabolites in total system Pikeville (phenyl label) using SFO kinetic for foramsulfuron.

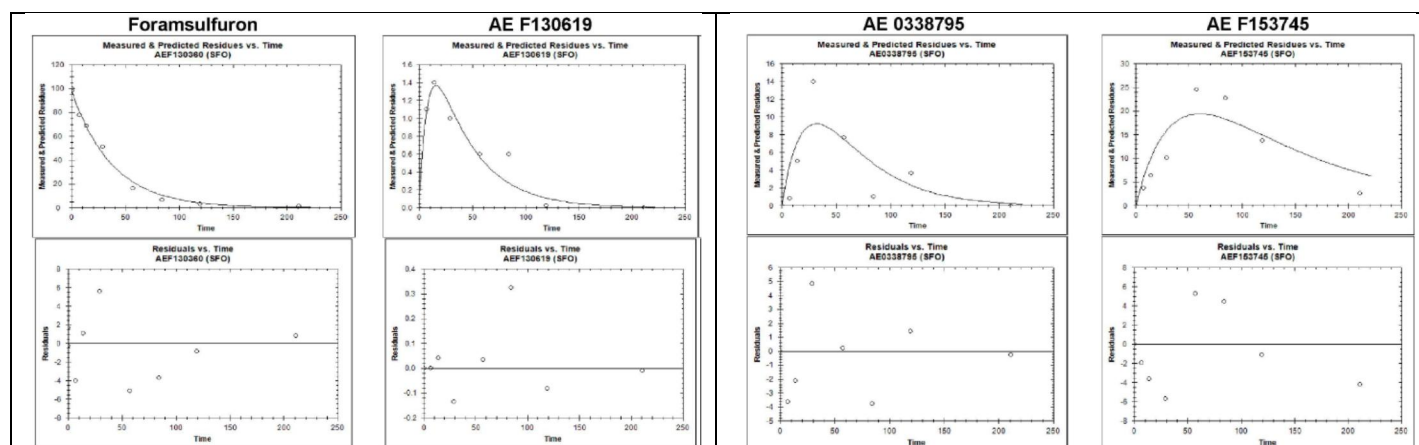


Table B.8.4.2.3-3: Time course of the degradation of pyrimidyl labelled foramsulfuron (AE F130360) and formation and decline of metabolites in Pikeville silty clay loam sediment/water total system (% of applied radioactivity)

Time [days]	Pyrimidyl radiolabeled components (PH)							
	AE F130360	AE F130619	AE 0338795	AE F092944	Others	PH- NER	PH- ¹⁴ CO ₂	Total
0	95.4	0.5	--	2.0	2.6	--	--	100.2
7	80.1	0.8	0.8	3.2	9.8	5.5	0.0	99.4
14	69.9	1.1	5.4	2.2	7.3	8.3	0.1	97.9
27	57.2	0.3	13.6	3.6	13.0	--	0.1	93.9
57	25.2	0.2	13.9	7.3	11.4	33.7	1.3	91.8
84	9.9	0.7	4.3	6.7	14.9	49.3	2.0	88.5
118	3.7	0.0	0.7	5.8	11.2	68.1	4.3	86.7
210	1.1	0.2	--	3.7	7.7	75.4	6.2	89.0
363	--	--	--	--	--	93.1	1.4	98.8

-- = Not detected (< limit of detection LOD of 0.003% of applied radioactivity)

Fitting the model to the residue data for the total system Pikeville (pyrimidyl label) using SFO kinetics for all compartments led to the results shown in Figure B.8.4.2.3-5. The DT₅₀ values for foramsulfuron and its metabolites together with the results of the statistical evaluation are summarised in Table B.8.4.2.3-4.

For AE F130619, large scatter in the observed data and for AE F0338795, a systematic variation of the residuals led to high values for ϵ . Therefore, the fits were not considered acceptable and no DT₅₀s were derived Table B.8.4.2.3-4.

Table B.8.4.2.3-4: Summary of the kinetic evaluation of the degradation of pyrimidyl labelled foramsulfuron and its metabolites in total system Pikeville

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
Foramsulfuron	SFO	99.4		k = 0.0242	28.7	95.3	5.0	k: <0.0001	0.0217	0.027
AE F130619	SFO		0.13	k = 0.2864	n.d.	n.d.	45.7	k: 0.1442	-0.2324	0.805
AE 0338795	SFO		0.36	k = 0.0323	n.d.	n.d.	43.6	k: 0.002	0.0121	0.052
AE F092944	SFO		0.11	k = 0.0063	109.6	363.6	14.4	k: 0.0004	0.0030	0.010

Study conclusion (Schmitt & Mikolasch 2013):

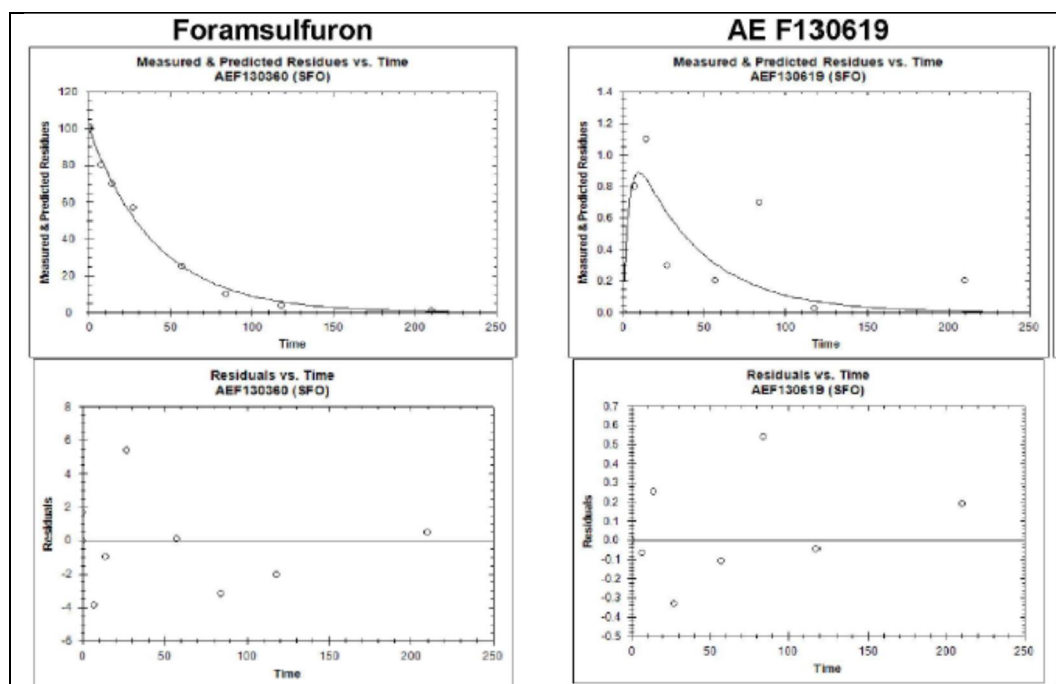
Foramsulfuron SFO: fit visually and statistically acceptable (χ^2 5.0 %) (comment RMS: agreed)

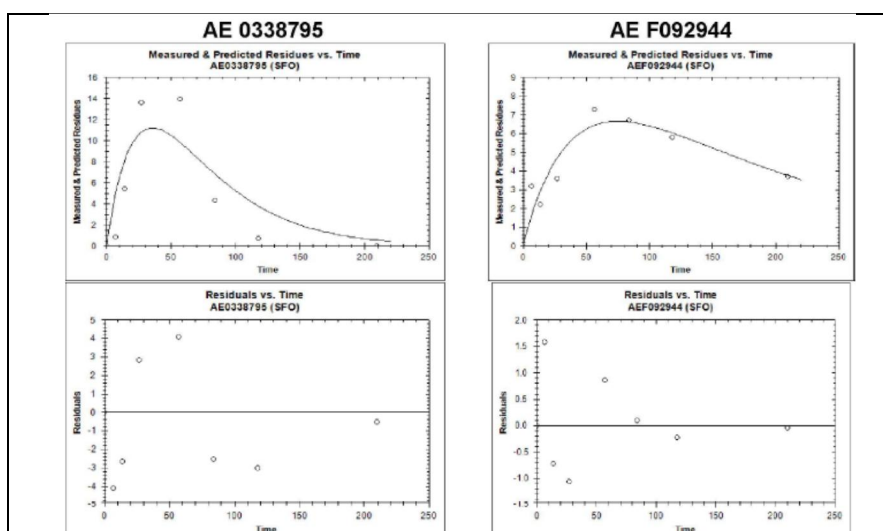
AE F130619 SFO: fit visually not acceptable, statistically not acceptable (χ^2 45.7 %); (comment RMS: agreed)

AE 0338795 SFO: fit visually not acceptable, statistically not acceptable (χ^2 43.6 %); (comment RMS: agreed)

AE F092944 SFO: fit visually and statistically acceptable (χ^2 14.4 %)

Figure B.8.4.2.3-5. Result of model fit to residue data for foramsulfuron and its metabolites in total system Pikeville (pyrimidyl label) using SFO kinetic for foramsulfuron.





System Hoechst

Table B.8.4.2.3-5: Time course of the degradation of phenyl labelled foramsulfuron (AE F130360) and formation and decline of metabolites in Hoechst sand sediment/water total system (% of applied radioactivity)

Time [days]	Phenyl radiolabeled components (PH)							
	AE F130360	AE F130619	AE 0338795	AE F153745	Others	PH-NER	PH- ¹⁴ CO ₂	Total
0	93.4	0.9	--	--	3.5	--	--	97.8
7	81.7	3.2	1.3	0.9	7.8	1.6	--	96.6
14	78.2	3.7	7.8	1.4	5.2	2.3	0.2	98.9
31	55.3	5.6	6.0	0.7	26.3	3.8	0.1	97.8
57	31.7	5.1	14.5	0.6	35.1	8.7	0.2	96.0
84	--	--	--	--	--	13.5	0.3	93.9
119	14.0	5.4	9.8	12.7	26.9	27.1	0.8	96.5
211	1.0	1.8	5.3	1.6	27.1	51.4	1.5	89.7
365	--	--	--	--	24.0	40.4	0.7	83.4

-- = Not detected (< limit of detection LOD of 0.002% of applied radioactivity)

Fitting the model to the residue data for the total system Pikeville (pyrimidyl label) using SFO kinetics for all compartments, led to the results shown in Figure B.8.4.2.3-6. The DT₅₀ values for foramsulfuron and its metabolites together with the results of the statistical evaluation are summarised in Table B.8.4.2.3-6. For AE F153745, the non-systematic time course of the residues prevented finding an acceptable fit and the derivation of any DT₅₀s.

Table B.8.4.2.3-6: Summary of the kinetic evaluation of the degradation of phenyl labelled foramsulfuron and its metabolites in total system Hoechst

	kinetic model	M_0	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
Foramsulfuron	SFO	97.5		k = 0.0182	37.9	126.0	4.0	k: <0.0002	0.0165	0.020
AE F130619	SFO		0.17	k = 0.0156	44.2	146.8	17.7	k: 0.0001	0.0089	0.023
AE 0338795	SFO		0.27	k = 0.0110	62.5	208.0	25.1	k: 0.0003	0.0055	0.017
AE F153745	SFO		0.08	k = 0.0050	n.d.	459.2	111.3	k: 0.005	-0.0041	0.014

Study conclusion (Schmitt & Mikolasch 2013):

Foramsulfuron SFO: fit visually and statistically acceptable (χ^2 4 %) (comment RMS: agreed)

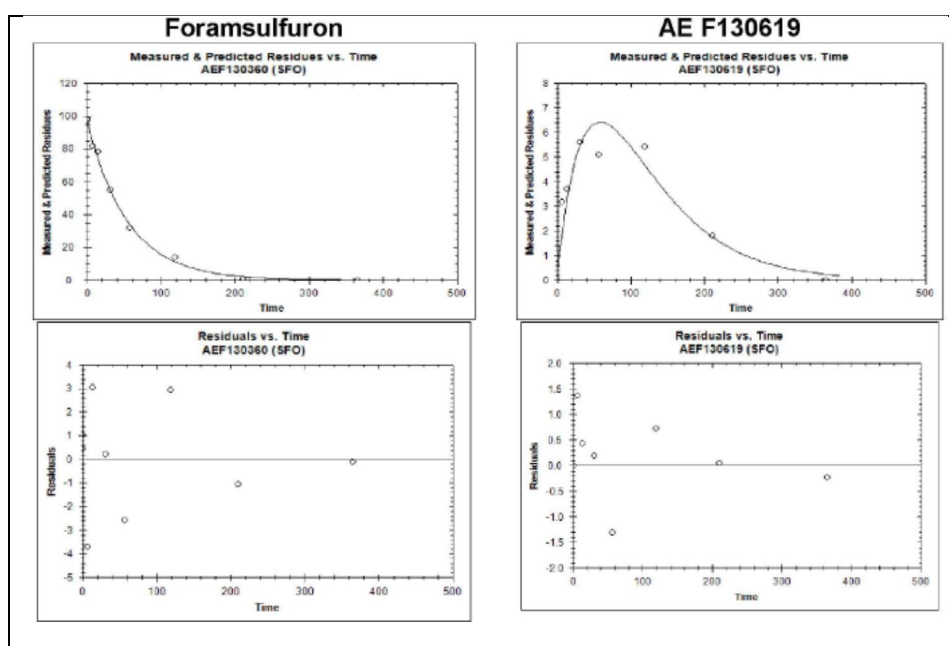
AE F130619 SFO: fit visually acceptable, statistically not acceptable (χ^2 17.7 %); (comment RMS: χ^2 can be >15% for metabolites if visually acceptable, therefore considered acceptable)

AE 0338795 SFO: fit visually acceptable and statistically not acceptable (χ^2 25.1 %); (comment RMS: χ^2 can be >15% for metabolites if visually acceptable, therefore considered acceptable)

AE F153745 SFO: fit visually and statistically not acceptable (χ^2 111.3 %); (RMS comment: agreed*)

* For AE F153745, the non-systematic time course of the residues prevented finding an acceptable fit and the derivation of any DT50s.

Figure B.8.4.2.3-6. Result of model fit to residue data for foramsulfuron and its metabolites in total system Hoechst (phenyl label) using SFO kinetic for foramsulfuron.



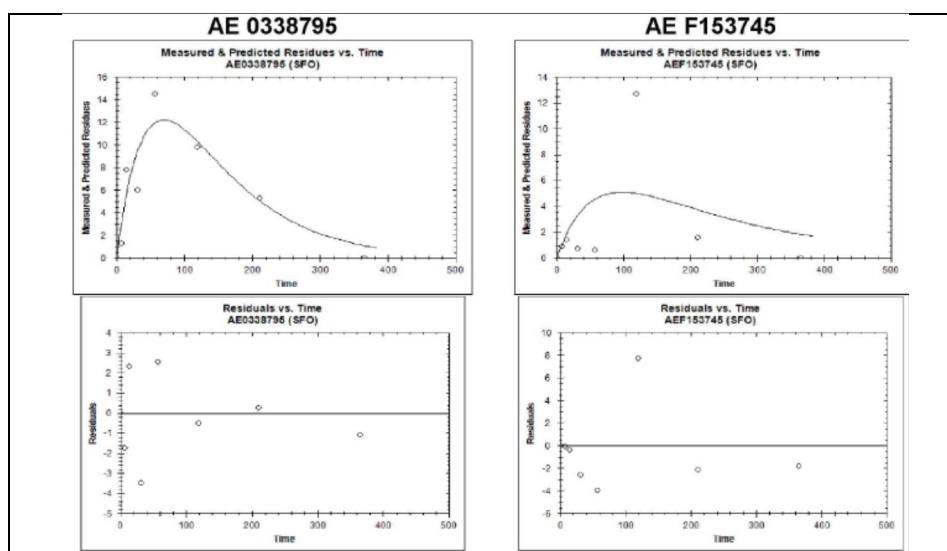


Table B.8.4.2.3-7: Time course of the degradation of pyrimidyl labelled foramsulfuron (AE F130360) and formation and decline of metabolites in Hoechst sand sediment/water total system (% of applied radioactivity)

Time [days]	Pyrimidyl radiolabeled components (PH)							
	AE F130360	AE F130619	AE 0338795	AE F153745	Others	PH-NER	PH- ¹⁴ CO ₂	Total
0	95.3	0.7	--	1.4	2.8	--	--	99.7
7	80.0	1.9	1.2	1.4	3.4	1.7	--	98.1
14	60.1	3.1	3.6	0.8	7.9	2.3	--	97.7
29	35.4	5.9	7.0	0.4	7.3	4.0	0.1	97.5
57	80.0	7.0	23.7	1.2	18.4	9.5	0.2	95.5
84	--	--	--	--	--	15.9	1.3	96.8
118	17.7	5.3	17.9	0.7	27.1	28.5	2.7	99.9
210	3.1	2.8	5.2	0.5	28.9	53.4	5.0	98.9
363	--	--	--	--	19.9	53.8	1.7	76.8

-- = Not detected (< limit of detection LOD of 0.003% of applied radioactivity)

Fitting a model to the residue data for the total system Pikeville (pyrimidyl label) using SFO kinetics for all compartments led to the results shown in Figure B.8.4.2.3-7. The DT₅₀ values for foramsulfuron and its metabolites together with the results of the statistical evaluation are summarised in Table B.8.4.2.3-8.

In case of AE 0338795, the fit was accepted despite the increased ϵ value because the time course of the residues was reasonably well described. For AE F092944, however, no reliable DT₅₀ could be derived because of the large Chi²-error and the high t-test probability.

Table B.8.4.2.3-8: Summary of the kinetic evaluation of the degradation of pyrimidyl labelled foramsulfuron and its metabolites in total system Hoechst

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
Foramsulfuron	SFO	99.3		k = 0.0167	41.4	137.4	3.0	k: <0.0001	0.0155	0.018
AE F130619	SFO		0.18	k = 0.0146	47.4	157.4	6.4	k: <0.0001	0.0123	0.017
AE 0338795	SFO		0.39	k = 0.0101	68.5	227.5	37.4	k: 0.002	0.0038	0.016
AE F092944	SFO		0.43	k = 0.5431	n.d.	n.d.	46.9	k: 0.24	-0.9732	2.059

Study conclusion (Schmitt & Mikolasch 2013):

Foramsulfuron SFO: fit visually and statistically acceptable (χ^2 3.0 %) (comment RMS: agreed)

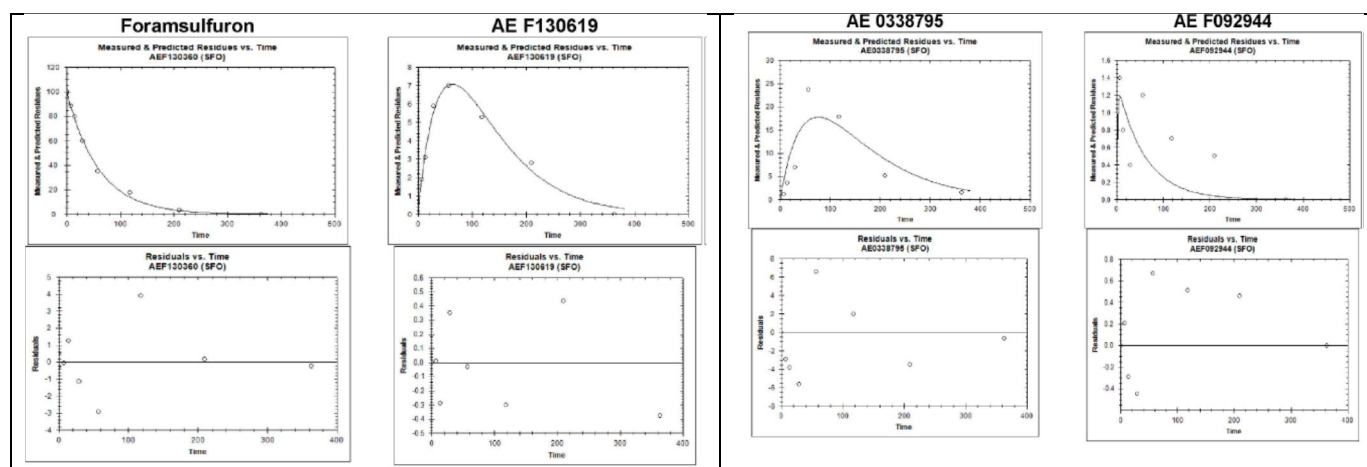
AE F130619 SFO: fit visually and statistically acceptable (χ^2 6.4 %); (comment RMS: agreed)

AE 0338795 SFO: fit visually acceptable, statistically not acceptable (χ^2 37.4 %); (comment RMS: χ^2 can be >15% for metabolites if visually acceptable, therefore considered acceptable)

AE F092944 SFO: fit visually and statistically not acceptable (χ^2 14.4 %)

In case of AE 0338795, the fit was accepted despite the increased ϵ value because the time course of the residues was reasonably well described.

For AE F092944, however, no reliable DT₅₀ could be derived because of the large Chi²-error and the high t-test probability.

Figure B.8.4.2.3-7. Result of model fit to residue data for foramsulfuron and its metabolites in total system Hoechst (pyrimidyl label) using SFO kinetic for foramsulfuron.

Summary of DT₅₀ values obtained for total system

The total system DT₅₀ values derived from the kinetic evaluations of the different tested systems for use as input values in environmental fate models are compiled in Table B.8.4.2.3-9. Values for the same system were averaged (geometric mean) before calculating the overall geometric mean. For the metabolites, except AE F130619 only a value for one water-sediment system could be obtained.

All half-lives provided in Table B.8.4.2.3-9 are also the persistence endpoints for degradation in the total water-sediment system.

Table B.8.4.2.3-9: Total system DT₅₀ values derived for use as input in environmental fate models.

Compound	System	Label	DegT ₅₀ (days)
Foramsulfuron	Pikeville	1	26.0
		2	28.7
	Mean (geometric)		27.3
	Hoechst Sand	1	37.9
		2	41.4
	Mean (geometric)		39.6
Mean (geometric)			32.9
AE F130619	Pikeville	1	5.4
		2	n.d.
	Mean (geometric)		5.4
	Hoechst Sand	1	44.2
		2	47.4
	Mean (geometric)		45.8
Mean (geometric)			15.7
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
Mean (geometric)			65.4
AE F153745	Pikeville	1	72.1
		2	-
	Mean (geometric)		72.1
	Hoechst Sand	1	n.d.
		2	-
	Mean (geometric)		n.d.
Mean (geometric)			72.1
AE F092944	Pikeville	1	-
		2	109.6
	Mean (geometric)		109.6
	Hoechst Sand	1	-
		2	n.d.
	Mean (geometric)		n.d.
Mean (geometric)			110

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.

Pikeville system

Table B.8.4.2.3-10: Time course of the degradation of phenyl labelled foramsulfuron (AE F130360) and formation and decline of metabolites in the water of Pikeville silty clay loam sediment/water system (% of applied radioactivity)

Time [days]	Phenyl radiolabeled components (PH)					
	AE F130360	AE F130619	AE 0338795	AE F153745	% Sum of Unknowns	% Remaining
0	92.5	0.3	--	0.5	--	6.0
7	56.3	1.0	--	0.6	--	8.8
14	45.4	1.1	2.6	3.9	--	6.1
29	32.6	0.5	9.0	7.0	6.0	1.1
57	1.8	0.2	6.2	11.0	1.1	6.3
84	0.3	0.1	0.6	9.8	5.4	2.3
119	0.2	0.0	3.7	1.9	1.4	5.1
211	n a	n a	n a	n a	n a	n a
365	n a	n a	n a	n a	n a	n a

n a: not analysed; -- = Not detected (< limit of detection LOD of 0.002% of applied radioactivity)

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 system Pikeville (pyrimidyl label) with the results shown in Table B.8.4.2.3-11.

The DT₅₀ values for foramsulfuron and its metabolites and results of the statistical evaluation are summarised in Table B.8.4.2.3-11.

Table B.8.4.2.3-11: Summary of the kinetic evaluation of the degradation of phenyl labelled foramsulfuron and its metabolites in water Pikeville

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
Foramsulfuron	SFO	91.2		k = 0.0471	14.7	48.9	12.8	k: <0.0001	0.0355	0.059
AE F130619	SFO	1.1		k = 0.0443	15.6	52.0	8.3	k: 0.0015	0.0345	0.054
AE 0338795	SFO	9.0		k = 0.0192	n.d.	n.d.	28.8	k: 0.1051	-0.0015	0.04
AE F153745	SFO	11.0		k = 0.0179	n.d.	n.d.	22.3	k: 0.1940	-0.0065	0.042
Study conclusion (Schmitt & Mikolasch 2013):										
Foramsulfuron SFO: fit visually and statistically acceptable (χ^2 12.8 %) (comment RMS: agreed)										
AE F130619 SFO: fit visually and statistically acceptable (χ^2 8.3 %); (comment RMS: agreed)										
AE 0338795 SFO: fit visually and statistically not acceptable (χ^2 28.8 %); (comment RMS: only few data points were available not allowing reliable fits)										
AE F153745 SFO: fit visually and statistically not acceptable (χ^2 22.3 %); (comment RMS: only few data points were available not allowing reliable fits)										

Figure B.8.4.2.3-8. Result of model fits to residue data for foramsulfuron in water system Pikeville (phenyl label) evaluated with different kinetic models.

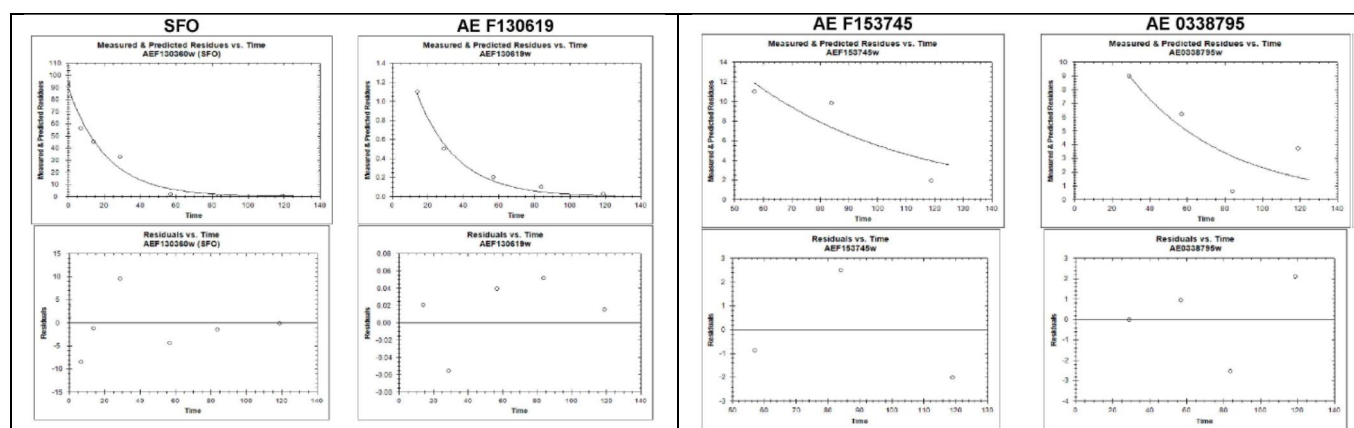


Table B.8.4.2.3-12: Time course of the degradation of pyrimidyl labelled foramsulfuron (AE F130360) and formation and decline of metabolites in the water of Pikeville silty clay loam sediment/water system (% of applied radioactivity)

Time [days]	Pyrimidyl radiolabeled components (PY)					
	AE F130360	AE F130619	AE 0338795	AE F092944	% Sum Unknowns	% Remaining
0	95.3	0.6	--	2.0	-	2.9
7	57.0	--	--	2.2	-	8.1
14	43.7	0.8	3.2	1.0	-	8.2
27	36.3	0.6	7.9	1.6	1.4	5.5
57	7.4	0.3	9.4	1.6	5.0	3.3
84	1.4	0.2	0.9	--	6.3	5.0
118	0.1	--	--	0.1	-	2.6
210	n a	n a	n a	n a	n a	n a
363	n a	n a	n a	n a	n a	n a

n a = not analysed; -- = Not detected (< limit of detection LOD of 0.003% of applied radioactivity)

There was no sign of a systematic variation of residuals when fitting the parent data using the 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 water system Pikeville (pyrimidyl label) with the results shown in Figure B.8.4.2.3-9.

The DT₅₀ values for foramsulfuron and its metabolites and results of the statistical evaluation are summarised in Table B.8.4.2.3-13.

Table B.8.4.2.3-13: Summary of the kinetic evaluation of the degradation of pyrimidyl labelled foramsulfuron and its metabolites in water Pikeville

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
Foramsulfuron	SFO	94.2		k = 0.0465	14.9	49.5	13.0	k: <0.0001	0.0345	0.059
AE F130619	SFO	0.8		k = 0.0383	18.1	60.1	10.9	k: <0.0015	0.0266	0.050
AE 0338795	SFO	9.4		k = 0.8711	8.0	26.4	0.7	k: 0.0068	0.0835	0.091
AE F092944	SFO			k =	n.d.	n.d.	37.2	k: 0.0883		

Study conclusion (Schmitt & Mikolasch 2013):

Foramsulfuron SFO: fit visually and statistically acceptable (χ^2 13.0 %) (comment RMS: agreed)

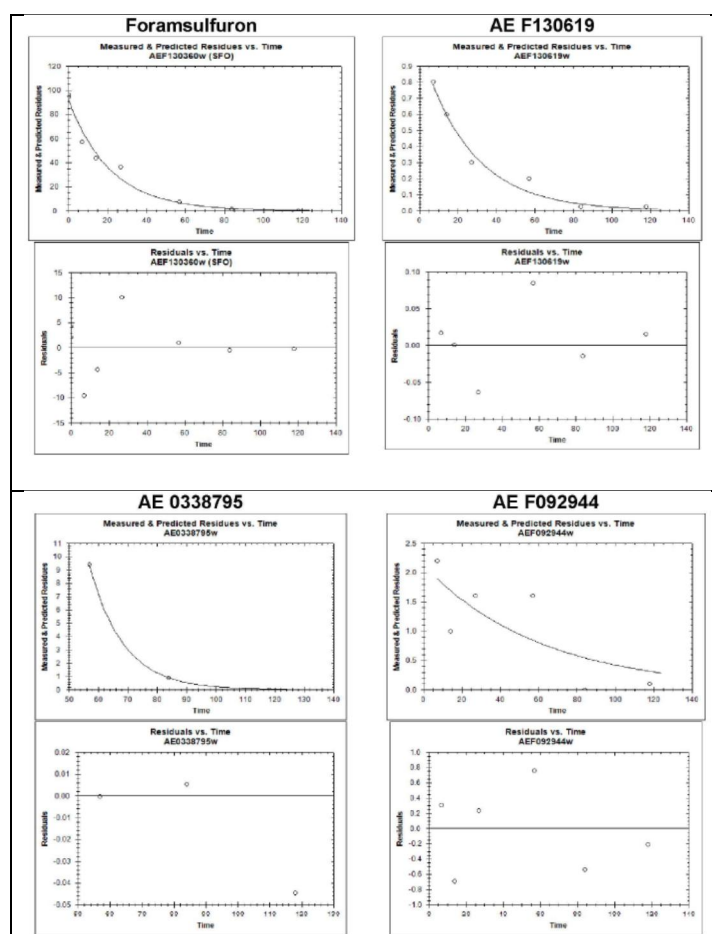
AE F130619 SFO: fit visually and statistically acceptable (χ^2 10.9 %); (comment RMS: agreed)

AE 0338795 SFO: fit visually and statistically acceptable (χ^2 0.7 %)

AE F092944 SFO: fit visually and statistically not acceptable (χ^2 37.2 %)

For AE F092944, however, no reliable DT50 could be derived because of the large Chi²-error.

Figure B.8.4.2.3-9. Result of model fit to residue data for foramsulfuron and its metabolites in water system Pikeville (pyrimidyl label).



Hoechst system**Table B.8.4.2.3-14: Time course of the degradation of phenyl labelled foramsulfuron (AE F130360) and formation and decline of metabolites in the water of the Hoechst sand sediment/water system (% of applied radioactivity)**

Time [days]	Phenyl radiolabeled components (PH)					
	AE F130360	AE F130619	AE 0338795	AE F153745	% Sum of Unknowns	% Remaining
0	93.4	0.9	--	--	--	3.5
7	66.4	2.6	--	0.9	--	6.9
14	60.6	3.1	4.5	0.9	2.3	2.5
31	39.5	4.5	--	0.2	--	23.2
57	20.7	3.9	8.6	0.6	27.4	3.0
84	Values not reported due to artifact in HPLC samples					
119	10.2	4.4	5.7	12.3	20.3	0.7
211	1.0	1.6	5.3	1.6	14.9	4.3
365	n a	n a	n a	n a	14.8	3.0

n a = not analysed; -- = Not detected (< limit of detection LOD of 0.002% of applied radioactivity)

In the case of foramsulfuron, fitting the SFO-model to residue values in the water system Hoechst (phenyl label) resulted in an acceptable fit but with systematically varying residuals. Therefore, additionally a FOMC kinetic was fitted to the residue data. This improved the visual fit and the ϵ value (Figure B.8.4.2.3-10 and Table B.8.4.2.3-15). Therefore, the best fit $DT_{50} = 22.4$ days derived with the FOMC model is considered an appropriate persistence endpoint, while the DT_{50} for modelling purpose is 34.4 days (pseudo SFO value calculated as $DT_{90}(\text{FOMC})/3.32$).

Fitting SFO models to the metabolite residue led to the results shown in Figure B.8.4.2.3-10. In the case of AE F130619 and AE 0338795, the observed data show some un-systematic variation. Therefore, ϵ and t-test probability are somewhat increased. The fitted models seemed, however, to provide a conservative description of the decline of the respective residues and were therefore accepted anyway. The DT_{50} values for the metabolites of foramsulfuron and the results of statistical evaluation are summarised in Table B.8.4.2.3-15.

Table B.8.4.2.3-15: Summary of the kinetic evaluation of the degradation of phenyl labelled foramsulfuron and its metabolites in water system Hoechst

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
Foramsulfuron	SFO	92.7		k = 0.0271	25.6	85.0	8.6	k: <0.0002	0.0220	0.032
Foramsulfuron	FOMC			α = 2.0989 β = 57.276	22.4*	114.3	6.4	α : 0.0178 β : 0.0423	0.5751 2.8832	3.623 111.668
AE F130619	SFO	4.5		k = 0.0050	137.5	456.9	20.3	k: 0.048	0.0009	0.009
AE 0338795	SFO	8.6		k = 0.0055	124.2	412.7	19.1	k: 0.0689	0.0010	0.01
AE F153745	SFO	12.3		k = 0.0222	31.2	103.7	0.6	k: 0.0051	0.2151	0.023

Study conclusion (Schmitt & Mikolasch 2013):

Foramsulfuron SFO: fit visually not acceptabl, statistically acceptable (χ^2 8.6 %) (comment RMS: residual plot shows systematic deviations and therefore not acceptable)

Foramsulfuron FOMC: fit visually and statistically acceptable (χ^2 6.4 %) (comment RMS: agreed)

Best fit model / trigger endpoint for foramsulfuron: FOMC / 22.4 d
***Modelling endpoint for foramsulfuron: Pseudo-SFO DT50 = FOMC DT90/3.32 = 34.4 d**

AE F130619 SFO: fit visually acceptable, statistically not acceptable (χ^2 20.3 %); (comment RMS: χ^2 can be >15% for metabolites if visually acceptable, therefore considered acceptable)

AE 0338795 SFO: fit visually acceptable and statistically not acceptable (χ^2 19.1 %); (comment RMS: χ^2 can be >15% for metabolites if visually acceptable, therefore considered acceptable)

AE F153745 SFO: fit visually and statistically acceptable (χ^2 0.6 %) (comment RMS: agreed)

Figure B.8.4.2.3-10. Result of model fits to residue data for foramsulfuron in water system Hoechst (phenyl label).

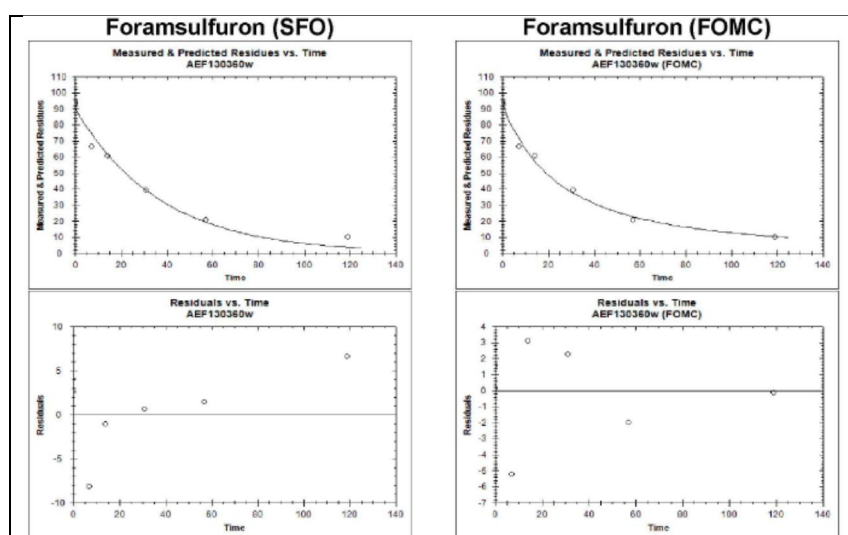


Figure B.8.4.2.3-10. Continued. Result of model fits to residue data for foramsulfuron metabolites in water system Hoechst (phenyl label).

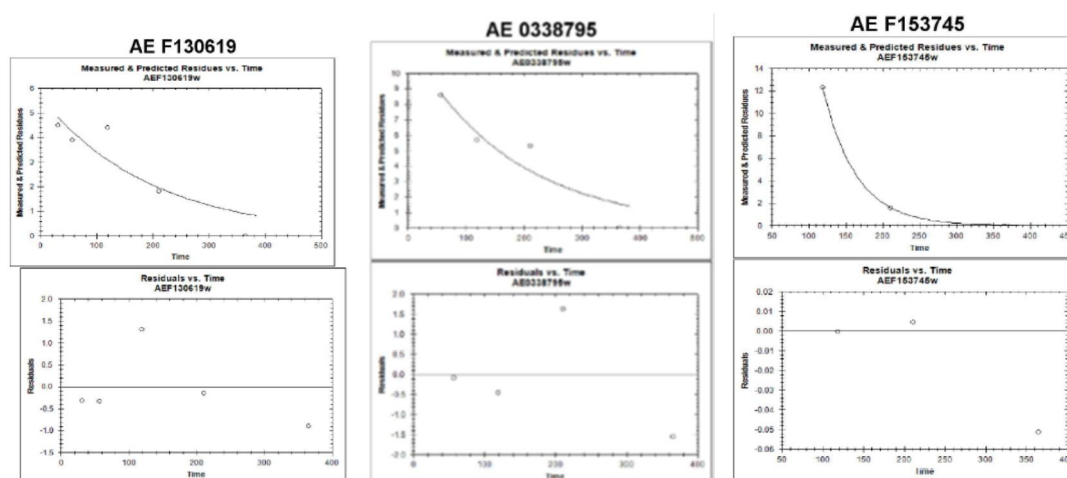


Table B.8.4.2.3-16: Time course of the degradation of pyrimidyl labelled foramsulfuron (AE F130360) and formation and decline of metabolites in the water of the Hoechst sand sediment/water system (% of applied radioactivity)

Time [days]	Pyrimidyl radiolabeled components (PY)					
	AE F130360	AE F130619	AE 0338795	AE F092944	% Sum Unknowns	% Remaining
0	95.3	0.7	--	1.4	--	2.8
7	73.2	1.7	--	1.4	--	3.0
14	54.6	2.3	4.5	0.8	--	6.8
29	43.8	4.8	0.8	--	1.5	3.7
57	25.4	5.7	17.0	1.2	10.3	4.2
84	Values not reported due to artifact in HPLC samples					
118	12.6	4.2	13.4	0.7	20.4	1.4
210	2.1	2.1	3.3	0.3	16.9	7.3
363	n a	n a	n a	--	7.0	8.6

n a = not analysed; Not detected (< limit of detection LOD of 0.003% of applied radioactivity)

In the case of foramsulfuron, fitting a SFO-model to residue values in the water system Hoechst (pyrimidyl label) resulted in clearly systematically varying residuals and was not accepted. Therefore, a DFOP kinetic was fitted to the residue data since more than 10 % of the applied amount remained at the end of the trial period. This improved the visual fit and the ϵ value (Figure B.8.4.2.3-11 and Table B.8.4.2.3-17). Therefore, the real DFOP $DT_{50} = 21.6$ days is considered an appropriate persistence endpoint. For modelling purposes, the slow phase rate (k_1 in this case) of the DFOP fit is taken for the calculation of the endpoint, which is then 53.3 days.

For AE F092944, no decline fit could be performed because no clear maximum could be identified in the observed data. Fitting the SFO-model to the residue data of the remaining two metabolites led to the results shown in Figure B.8.4.2.3-11.

Table B.8.4.2.3-17: Summary of the kinetic evaluation of the degradation of pyrimidyl labelled foramsulfuron and its metabolites in water system Hoechst

	kinetic model	M_0	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
Foramsulfuron	SFO	95.5		k = 0.0257	26.9	89.5	8.9	k: 0.0004	0.0187	0.033
Foramsulfuron	DFOP			k ₁ = 0.0134 k ₂ = 0.0986 g = 0.6059	21.6	134.4	3.6	k1: 0.0115 k2: 0.0399 g: 0.0072	0.0073 0.0245 0.374	0.019 0.173 0.838
AE F130619	SFO			k = 0.0072	96.2	319.5	10.9	k: 0.0211		
AE 0338795	SFO			k =	87.2	289.6	15.0	k: 0.0366		

Study conclusion (Schmitt & Mikolasch 2013):

Foramsulfuron SFO: fit visually not acceptable, but statistically acceptable (χ^2 8.9 %) (comment RMS: residual plot shows systematic deviations and therefore not acceptable)

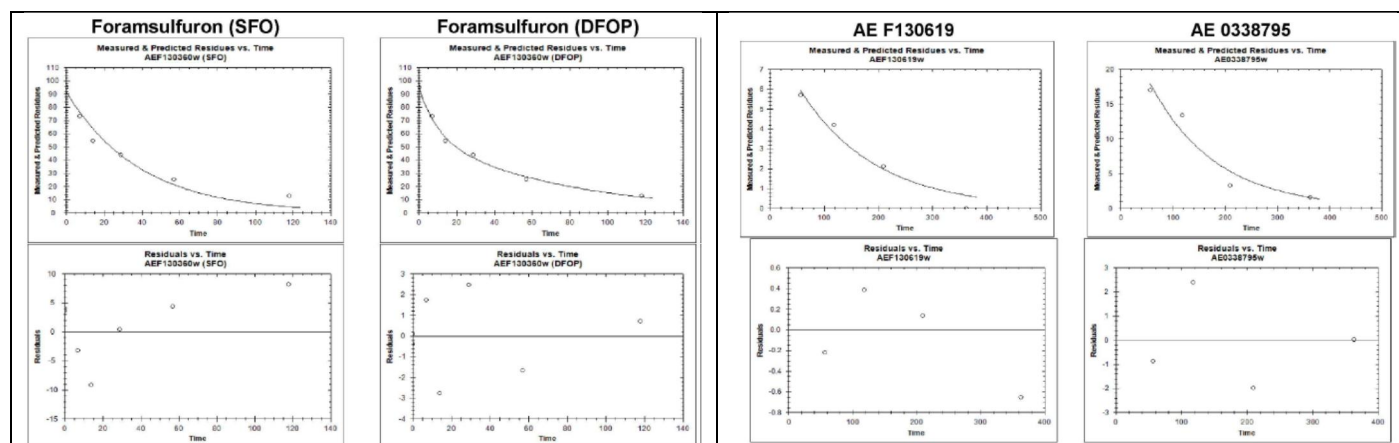
Foramsulfuro--DFOP: fit visually and statistically acceptable (χ^2 3.6 %) (comment RMS: agreed)

Best fit model / trigger endpoint for foramsulfuron: DFOP / 21.6 d
Modelling endpoint for foramsulfuron: Pseudo-SFO DT50 = DFOP ln(2)/k₁ = 53.3 d

AE F130619 SFO: fit visually and statistically acceptable (χ^2 6.4 %); (comment RMS: agreed)

AE 0338795 SFO: fit visually acceptable, statistically not acceptable (χ^2 37.4 %); (comment RMS: χ^2 can be >15% for metabolites if visually acceptable, therefore considered acceptable)

Figure B.8.4.2.3-11: Result of model fit to residue data for pyrimidyl labelled foramsulfuron and its metabolites in water system Hoechst (pyrimidyl label).



Summary of DisT₅₀ values in water phase

The dissipation half-lives of foramsulfuron and its metabolites for water are given in Table B.8.4.2.3-18. For AE F092944 no DT₅₀ for water could be derived. Persistence endpoints for dissipation from water or sediments deviating from the DT₅₀ values for modeling purposes were only determined for the water phase in system Hoechst, where the best fit half-lives for foramsulfuron were 22.4 days (phenyl label) and 21.6 days (pyrimidyl label).

Table B.8.4.2.3-18: DT₅₀ values for dissipation from water derived for use as input in environmental fate models.

Compound	System	Label	DisT ₅₀ (days)
Foramsulfuron	Pikeville	1	14.7
		2	14.9
	Mean (geometric)		14.8
	Hoechst Sand	1	34.4*
		2	53.3**
	Mean (geometric)		42.8
Mean (geometric)			25.2
AE F130619	Pikeville	1	15.6
		2	18.1
	Mean (geometric)		16.8
	Hoechst Sand	1	137.5
		2	96.2
	Mean (geometric)		115.0
Mean (geometric)			44.0
AE 0338795	Pikeville	1	n.d.
		2	8.0
	Mean (geometric)		8.0
	Hoechst Sand	1	124.2
		2	87.2
	Mean (geometric)		104.0
Mean (geometric)			28.8
AE F153745	Pikeville	1	n.d.
		2	n.d.
	Mean (geometric)		n.d.
	Hoechst Sand	1	31.2
		2	-
	Mean (geometric)		31.2
Mean (geometric)			31.2
AE F092944	Pikeville	1	-
		2	-
	Mean (geometric)		-
	Hoechst Sand	1	-
		2	-
	Mean (geometric)		-
Mean (geometric)			-

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

* DT₅₀-value from SFO model was 25.9 days. For persistence evaluation, FOMC best fit resulted in a DT₅₀ of 22.4 days; and pseudo SFO=FOMC DT₉₀/3.32 = 34.4 days for modelling.

** DT₅₀-value from SFO model was 26.9 days. For persistence evaluation, the DFOP best fit resulted in a DT₅₀ 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 (in this case k₁) of the DFOP curve (DT₅₀ = ln2/k₁).

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 were 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.

Pikeville system

Table B.8.4.2.3-19: Time course of the degradation of phenyl labelled foramsulfuron (AE F130360) and formation and decline of metabolites in the sediment of the Pikeville silty clay loam sediment/water system (% of applied radioactivity)

Time [days]	Phenyl radiolabeled components (PH)							
	AE F130360	AE F130619	AE 0338795	AE F153745	% Sum of Unknowns	% Remaining	NER	Sediment total
0	n a	n a	n a	n a	n a	n a	n a	na
7	21.3	0.1	0.8	3.1	--	1.0	5.0	31.3
14	23.4	0.3	2.5	2.5	--	1.2	8.0	37.9
31	18.4	0.5	5.0	3.2	--	2.8	10.4	40.3
57	14.6	0.4	1.5	13.6	--	2.7	34.9	67.8
84	6.4	0.5	0.4	12.9	2.1	2.7	48.2	73.2
119	3.1	--	--	12.0	--	1.4	57.8	74.5
211	1.2	--	0.2	2.7	--	1.5	820	88.0
365	n a	n a	n a	n a	n a	n a	77.3	79.4

na = not analyzed; Not detected (< limit of detection LOD of 0.002% of applied radioactivity)

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 (phenyl label) with the results shown in Figure B.8.4.2.3-12.

For the metabolites AE F130619 and AE F153745, no visually acceptable fit could be achieved. Therefore, for those metabolites, no DT_{50} was derived. The DT_{50} values determined for foramsulfuron and AE 0338795 together with the results of the statistical evaluations are summarised in Table B.8.4.2.3-20.

Table B.8.4.2.3-20: Summary of the kinetic evaluation of the degradation of phenyl labelled foramsulfuron and its metabolites in sediment Pikeville

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
Foramsulfuron	SFO			k = 0.0161	42.9	142.7	8.9	k: <0.004		
AE F130619	SFO			k = 0.0124	n.d.	n.d.	37.7	k: 0.11		
AE 0338795	SFO			k = 0.0441	15.7	52.2	2.9	k: <0.0001	0.0414	0.047
AE F153745	SFO	13.6		k = 0.0441	n.d.	n.d.	14.3	k: 0.07		

Study conclusion (Schmitt & Mikolasch 2013):

Foramsulfuron SFO: fit visually and statistically acceptable (χ^2 10.2 %) (comment RMS: agreed)

AE F130619 SFO: fit visually and statistically acceptable (χ^2 37.7 %); (comment RMS: only few data points were available not allowing reliable fits)

AE 0338795 SFO: fit visually and statistically acceptable (χ^2 2.9 %); (comment RMS: agreed)

AE F153745 SFO: fit visually not acceptable and statistically acceptable (χ^2 14.3 %); (comment RMS: only few data points were available not allowing reliable fits)

Figure B.8.4.2.3-12. Result of model fit to residue data for foramsulfuron and its metabolites in sediment system Pikeville (phenyl label)

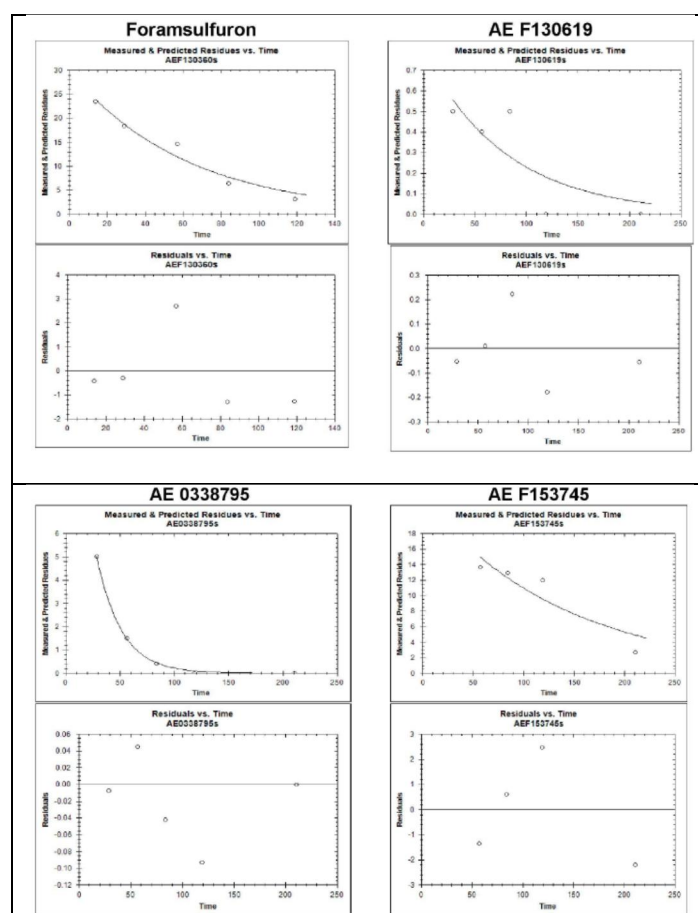


Table B.8.4.2.3-21: Time course of the degradation of pyrimidyl labelled foramsulfuron (AE F130360) and formation and decline of metabolites in the sediment of the Pikeville silty clay loam sediment/water system (% of applied radioactivity)

Time [days]	Pyrimidyl radiolabeled components (PH)							
	AE F130360	AE F130619	AE 0338795	AE F092944	% Sum of Unknowns	% Remaining	NER	Sediment total
0	n a	n a	n a	n a	n a	n a	n a	n a
7	23.1	--	0.8	1.0	--	0.9	5.5	31.3
14	26.2	0.5	2.2	1.1	--	2.8	8.3	41.2
29	20.9	--	5.7	2.0	--	1.3	11.0	40.8
57	17.8	--	4.5	5.7	--	2.0	33.7	63.6
84	8.4	0.6	3.3	6.7	--	2.5	49.3	71.0
119	3.6	--	0.7	5.8	--	1.6	68.1	79.7
211	1.1	0.2	--	3.7	--	0.8	75.4	81.2
365	n a	n a	n a	n a	n a	n a	93.1	96.5

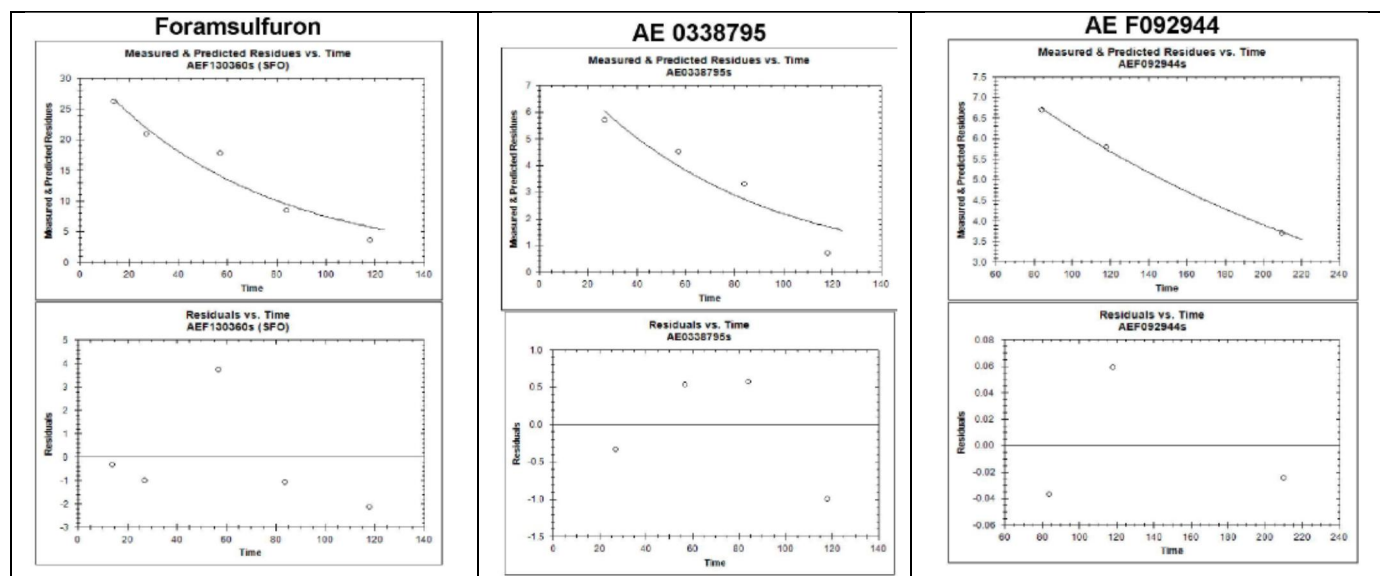
n a = not analysed; -- = Not detected (< limit of detection LOD of 0.003% of applied radioactivity)

No sufficient residue data were available for AE F130619 for the sediment of system Pikeville (pyrimidyl label). The remaining datasets were evaluated using SFO models with the results shown in Figure B.8.4.2.3-13. The DT_{50} values derived from the fits for foramsulfuron and its metabolites together with the results of statistical evaluation are summarised in Table B.8.4.2.3-22.

Table B.8.4.2.3-22: Summary of the kinetic evaluation of the degradation of pyrimidyl labelled foramsulfuron and its metabolites in sediment Pikeville

	kinetic model	M_0	ff	parameter	DT_{50} [days]	DT_{90} [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
Foramsulfuron	SFO	26.2		k = 0.0147	47.1	156.3	10.6	k: 0.007	0.0091	0.02
AE 0338795	SFO	5.7		k = 0.0140	49.6	164.9	15.1	k: 0.05	0.0050	0.023
AE F092944	SFO	6.7		k = 0.0047	147.4	489.6	0.7	k: 0.01	0.0044	0.005
<p>Study conclusion (Schmitt & Mikolasch 2013):</p> <p>Foramsulfuron SFO: fit visually and statistically acceptable (χ^2 10.6 %) (comment RMS: agreed)</p> <p>AE 0338795 SFO: fit visually and statistically not acceptable (χ^2 15.1 %); (comment RMS: χ^2 can be >15% for metabolites if visually acceptable, therefore considered acceptable)</p> <p>AE F092944 SFO: fit visually and statistically acceptable (χ^2 0.7 %) (comment RMS: agreed)</p> <p>No sufficient residue data were available for AE F130619 for the sediment of system Pikeville (pyrimidyl label)</p>										

Figure B.8.4.2.3-13. Result of model fit to residue data for foramsulfuron and its metabolites in sediment system Pikeville (pyrimidyl label).



Hoechst system

Table B.8.4.2.3-23: Time course of the degradation of phenyl labelled foramsulfuron (AE F130360) and formation and decline of metabolites in the sediment of the Hoechst sand sediment/water system (% of applied radioactivity)

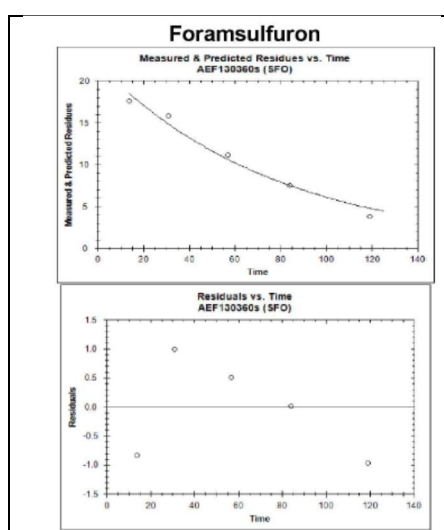
Time [days]	Phenyl radiolabeled components (PH)							
	AE F130360	AE F130619	AE 0338795	AE F153745	% Sum of Unknowns	% Remaining	NER	Sediment total
0	n a	n a	n a	n a	n a	n a	n a	n a
7	15.3	0.6	1.3	--	--	0.8	1.6	19.8
14	17.6	0.6	3.3	0.5	--	0.4	2.3	25.0
31	15.8	1.2	6.0	0.5	--	2.5	38	30.4
57	11.1	1.2	5.9	--	1.3	2.2	8.7	31.7
84	7.5	0.5	6.1	0.4	--	4.9	13.5	335
119	3.8	1.0	4.1	0.4	1.2	3.0	27.1	42.2
211	n a	n a	n a	n a	n a	n a	51.4	59.3
365	n a	n a	n a	n a	n a	n a	40.4	63.3

n a = not analyzed; -- = Not detected (< limit of detection LOD of 0.002% of applied radioactivity)

For the system Hoechst (phenyl label), for none of the metabolites a clear decline phase was established in the residue data. Also, only very low residue levels were reached during the study. Therefore, only the parent data were evaluated with the results presented in Figure B.8.4.2.3-14 and Table B.8.4.2.3-24.

Table B.8.4.2.3-24: Summary of the kinetic evaluation of the degradation of phenyl labelled foramsulfuron and its metabolites in sediment system Hoechst

	kinetic model	M ₀	ff	parameter	DT ₅₀ [days]	DT ₉₀ [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
Foramsulfuron	SFO	17.6		k = 0.0128	53.8	178.8	5.4	k: 0.0013	0.0102	0.016
Study conclusion (Schmitt & Mikolasch 2013):										
Foramsulfuron SFO: fit visually and statistically acceptable (χ^2 5.4 %) (RMS comment:agreed)										

Figure B.8.4.2.3-14. Result of model fit to residue data for foramsulfuron and its metabolites in water system Hoechst (phenyl label).**Table B.8.4.2.3-25: Time course of the degradation of pyrimidyl labelled foramsulfuron (AE F130360) and formation and decline of metabolites in the sediment of the Hoechst sand sediment/water system (% of applied radioactivity)**

Time [days]	Pyrimidyl radiolabeled components (PY)							
	AE F130360	AE F130619	AE 0338795	AE F092944	% Sum of Unknowns	% Remaining	NER	Sediment total
0	n a	n a	n a	n a	n a	n a	n a	n a
7	15.3	0.2	1.2	--	--	0.4	1.7	18.9
14	25.3	0.9	3.6	--	--	1.1	2.3	33.2
29	16.3	1.1	6.3	0.4	--	2.1	4.0	30.1
57	10.0	1.3	6.8	--	--	3.9	9.5	31.6
84	8.4	1.4	6.1	--	1.5	3.8	15.9	37.0
118	5.1	1.1	4.5	--	--	5.4	28.5	44.6
210	1.0	0.6	1.9	0.2	--	4.8	53.4	61.9
363	n a	n a	n a	n a	n a	n a	53.8	58.0

n a = not analysed; -- = Not detected (< limit of detection LOD of 0.003% of applied radioactivity)

No sufficient residue data were available for AE F092944 for the sediment of system Hoechst (pyrimidyl label). The remaining datasets were evaluated using SFO models with the results shown

in Figure B.8.4.2.3-15. The DT_{50} values derived from the fits for foramsulfuron and its metabolites together with the results of statistical evaluation are summarised in Table B.8.4.2.3-26.

Table B.8.4.2.3-26: Summary of the kinetic evaluation of the degradation of pyrimidyl labelled foramsulfuron and its metabolites in sediment system Hoechst

	kinetic model	M_0	ff	parameter	DT_{50} [days]	DT_{90} [days]	χ^2 [%]	prob > t	parameter CI	
									lower	upper
Foramsulfuron	SFO	25.3		k = 0.0174	39.9	132.5	9.2	k: 0.004	0.0120	0.023
AE F130619	SFO	1.4		k = 0.0068	102.6	340.9	0.5	k: 0.0074	0.0064	0.007
AE 0338795	SFO	6.8		k = 0.0078	89.0	295.7	4.5	k: 0.0086	0.0058	0.01

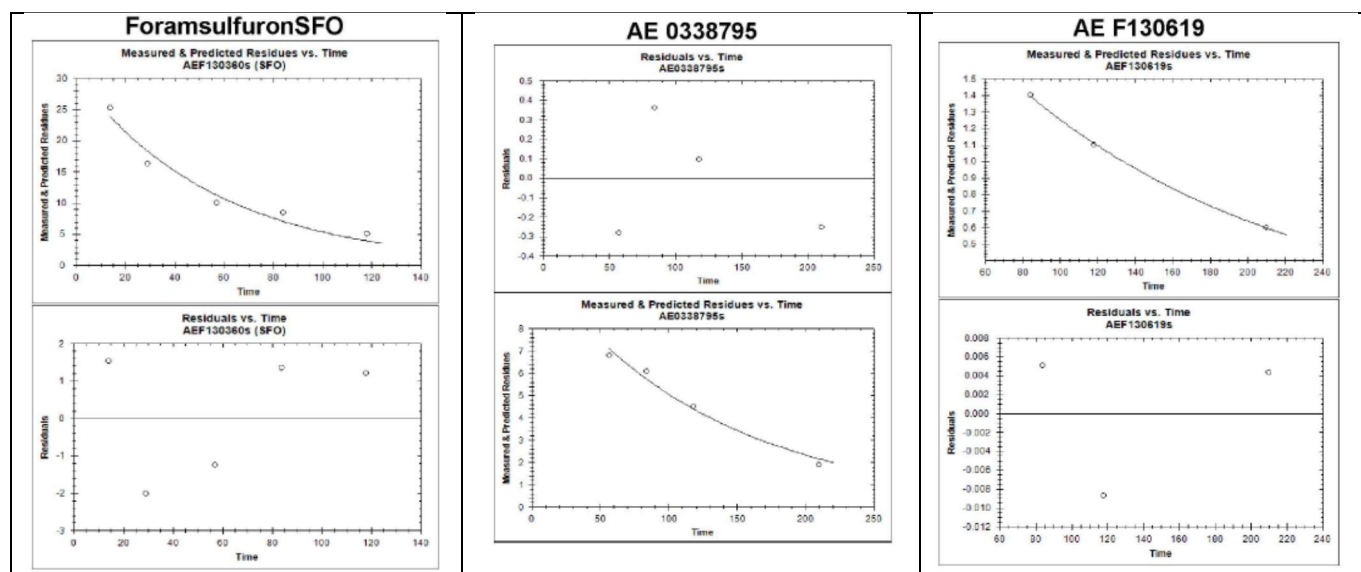
Study conclusion (Schmitt & Mikolasch 2013):

Foramsulfuron SFO: fit visually and statistically acceptable (χ^2 9.2 %) (RMS comment:agreed)

AE F130619 SFO: fit visually and statistically acceptable (χ^2 0.5 %); (comment RMS: agreed)

AE 0338795 SFO: fit visually and statistically acceptable (χ^2 37.4 %); (comment RMS:agreed)

Figure B.8.4.2.3-15. Result of model fit to residue data for foramsulfuron and its metabolites in sediment system Hoechst (pyrimidyl label).



The dissipation half-lives of foramsulfuron and its metabolites for sediment are given in Table B.8.4.2.3-27. For AE F153745 no DT₅₀ for water could be derived for sediment.

Table B.8.4.2.3-27: DT₅₀ values for dissipation from sediment derived for use as input in environmental fate models.

Compound	System	Label	DisT ₅₀ (days)
Foramsulfuron	Pikeville	1	42.9
		2	47.1
		Mean (geometric)	
	Hoechst Sand	1	53.8
		2	39.9
		Mean (geometric)	
Mean (geometric)			45.6
AE F130619	Pikeville	1	n.d.
		2	-
		Mean (geometric)	
	Hoechst Sand	1	-
		2	103
		Mean (geometric)	
Mean (geometric)			103
AE 0338795	Pikeville	1	15.7
		2	49.6
		Mean (geometric)	
	Hoechst Sand	1	-
		2	89.0
		Mean (geometric)	
Mean (geometric)			49.8
AE F153745	Pikeville	1	n.d.
		2	-
		Mean (geometric)	
	Hoechst Sand	1	-
		2	-
		Mean (geometric)	
Mean (geometric)			
AE F092944	Pikeville	1	-
		2	147
		Mean (geometric)	
	Hoechst Sand	1	-
		2	-
		Mean (geometric)	
Mean (geometric)			147

Label 1 = phenyl, Label 2 = pyrimidine

n.d. = not determined

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 residue data showed a better fit to the data to result in a DisT_{50} of 22.4 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_{50} of 21.6 days from water for trigger evaluation of the parent compound. The results of kinetic evaluation in terms of DegT_{50} - and DisT_{50} -values derived for the various compartments investigated are summarised in Table B.8.4.2.3-28.

In total systems and for use as modelling endpoint the kinetic evaluation resulted in a geometric mean value for the DegT_{50} 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_{50} 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_{50} is 25.2 days for the parent compound. For the metabolites these values are 44.0 days for AE F130619, 28.8 days for AE 0338795 and 31.2 days for AE F153745. No DisT_{50} from water could be derived for AE F092944.

For evaluation against persistence triggers the worst case DisT_{50} of the parent compound from water 22.0 days (Hoechst system)⁵. For the metabolites these values are 115.0 days for AE F130619, 104.0 days for AE 0338795 and 31.2 days for AE F153745. No DisT_{50} 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_{50} is 45.6 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_{50} from sediment could be derived for AE F153745.

For evaluation against persistence triggers the worst case DisT_{50} of the parent compound from sediment is 46.3 days (Hoechst 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_{50} from sediment could be derived for AE F153745.

⁵ This geometric mean value is derived from 22.4 days (FOMC-model, phenyl-label) and 21.6 days (DFOP-model, pyrimidine-label).

Table B.8.4.2.3-28: Mean values of half-lives for the dissipation of foramsulfuron from water and sediment and degradation in total systems according to FOCUS Level I for use in environmental modelling (all values SFO DT₅₀ values, except for foramsulfuron Hoechst Sand for which pseudo-SFO DT₅₀ value has been calculated) and worst case DT₅₀ values for each substance and each compartment for evaluation against persistence triggers

Compound	System	DegT ₅₀ , total system (days)	DisT ₅₀ , water (days)	DisT ₅₀ , sediment (days)
Foramsulfuron	Pikeville	27.3	14.8	45.0
	Hoechst Sand	39.6	42.8*/**	46.3
	Mean (geometric)	32.9	25.2	45.6
AE F130619	Pikeville	5.4	16.8	n.d.
	Hoechst Sand	45.8	115.0	103
	Mean (geometric)	15.7	44.0	103
AE 0338795	Pikeville	n.d.	8.0	27.9
	Hoechst Sand	65.4	104.0	89.0
	Mean (geometric)	65.4	28.8	49.8
AE F153745	Pikeville	72.1	n.d.	n.d.
	Hoechst Sand	n.d.	31.2	-
	Mean (geometric)	72.1	31.2	-
AE F092944	Pikeville	110	-	147
	Hoechst Sand	-	-	-
	Mean (geometric)	110	-	147

Label 1 = phenyl, Label 2 = pyrimidine

* For persistence evaluation only, DisT₅₀-value from water following FOMC best fit was of 22.4 days (phenyl-label)

** For persistence evaluation only, DisT₅₀-value from water following DFOP best fit was of DT₅₀ of 21.6 days (pyrimidine-label).

= Geomean DT₅₀ value 22.0 days

RMS comments and conclusion

The study followed the OECD TG 308: Aerobic transformation in Aquatic Sediment system. Foramsulfuron was degraded to major metabolites AE 0338795 (which was subsequently degraded completely) and AE F130619 and to minor metabolites AE F153745 and AE F092944. The degradation was accompanied by significant formation of non-extractable residues (NER; max 93.1 %) and insignificant formation of CO₂ (max 6.2 %).

The kinetic evaluation of the phenyl and pyrimidyl labelled foramsulfuron and its metabolites was performed according to the DegKinetics Report (2006). 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. Level I dissipation half-lives of foramsulfuron and its metabolites AE F130619, AE F153745, AE F092944 and AE 00338795 for water and sediment were determined as well as the degradation-T₅₀ for the total system. The dissipation from the sediment was 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. RMS agrees that the Level 1 values, system DegT_{50/90}; water column--isT_{50/90} and sediment DisT_{50/90} can be used for persistence end point evaluation.

Reference:	KCA 7.2.2.3 /02; Abbott, P.; Huang, M. N.; Ramanarayanan, T.; 2000; M-238016-01 The degradation of [U-14C-phenyl] and [2-14C-pyrimidyl]- AE F130360 in an anaerobic sediment/water system under laboratory conditions at 20°C: AE F130360
Report No.:	B002252
Guideline:	PMRA: T-1-255; USEPA (=EPA): 162-3; Deviation not specified
GLP:	Yes
Previous evaluation:	i--AR
	Acceptable

Reference:	KCA 7.2.2.3 /03; Huang, M. N.; Creech, T. F.; Ramanarayanan, T. S.; 2000; M-238381-01 Degradation of [U-14C-phenyl] and [2-14C-pyrimidyl] -AE F130360 in an anaerobic sediment/water under laboratory anaerobic conditions at 10°C: AE F130360
Report No.:	B002642
Guideline:	PMRA: T-1-255; USEPA (=EPA): 162-3; Deviation not specified
GLP:	Yes
Previous evaluation:	i--AR
	Acceptable

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

The data had been 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.

RMS comments and conclusion

RMS agrees that the an anaerobic water/sediment study is not required according to the Commission regulations (EU) No 283/2013 and No 284/2013 amending the regulation 1107/2011 and therefore these studies are not considered further.

B.8.4.2.4 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.

B.8.4.3 Degradation in the saturated zone

This data requirement has been 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.

B.8.4.4 Summary of studies on fate and behaviour in water

Please see Vol 1, Level 2, section 2.8.2 for a summary of the fate and behavior in water.

B.8.5 Impact on water treatment procedures

Essentially no information was provided since lambda-cyhalothrin is not expected to contaminate groundwater (see separate Annex B.8 for product data).

B.8.6 Predicted environmental concentrations in surface water and in ground water (PEC_{sw}, PEC_{gw})**B.8.6.1 Predicted environmental concentrations in groundwater**

Please see separate Annex B.8 for product data.

B.8.6.2 Predicted environmental concentrations in surface water

Please see separate Annex B.8 for product data.

B.8.7 Fate and behaviour in air

Reference:	KCA 7.3.1 /01; Buerkle, L. W.;2000;M-194295-01 Estimation of the reaction with photochemically produced hydroxyl radicals in the atmosphere Code: AE F130360
Report No.:	C006613
Guideline:	
GLP:	No
Previous evaluation:	i--AR
	Acceptable

Route and rate of degradation in air

This data requirement has been 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 4.2×10^{-11} Pa at 20°C as reported in Appendix 1 of SANCO/10324/2002-Final from Nov 2002.

Transport via air

This new requirement had not been 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 (4.2×10^{-11} Pa at 20°C) indicating non-volatility to result in a low value for the Henry constant (5.8×10^{-12} Pa x m³ x mole⁻¹ 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^{-5} Pa for soil and 10^{-5} Pa for plant, no study on transport of the active substance foramsulfuron via air is necessary.

Local and global effects.

This new requirement had not been 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 (ODP), 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 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.

B.8.7.1 Studies on volatilisation

No studies submitted nor required.

B.8.7.2 Summary of fate and behavior in air

Please see Vol 1, Level 2, section 2.8.3 for a summary of the fate and behavior in air.

B.8.8 Predicted environmental concentrations in air (PEC_a)

Please see separate Annex B.8 for product data.

B.8.9 Definition of the residue

Please see Vol 1, Level 2, section 2.8.5 for the definition of residues.

B.8.10 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.

B.8.11 References relied on

Literature search:

The literature search carried out by the applicant was summarised in Document MCA section 9. The RMS considers the literature search provided as acceptable.

Databases: STN, a scientific information platform hosted by CAS, itself a division of the American Chemical Society, was selected as the preferred provider. Following data bases were used for the literature search: Agricola, Biosis, CABA, Chemical Abstracts, Derwent Drug File (DRUGU), EMBASE, Esbiobase, IPA, Medline, Pascal, PQSciTech, Registry, Scisearch, Toxcenter, Ulidat and FSTA.

Time window: January 1st 2004 – August 2nd 2013 for the parent compound and metabolites.

Input parameters: IUPAC name, CAS number, common name, code and abbreviation, molecular structure, molecular formula, molar mass and/or other names/codes, as far as available.

Results: A total of 430 identified and evaluated for potential relevance for foramsulfuron and its metabolites. Of these, 384 summary records were excluded after a rapid assessment of relevance, and 46 full-text documents were assessed in detail.

As a summary 45 studies were excluded from the risk assessment because the publications did not meet the relevance criteria for the detailed assessment. Moreover, one study was unclear of relevance and only one study from the whole literature search was revealed for further examination (KCA 8.6.2).

A reference list containing these 46 documents were included in Doc MCA section 9.

RMS agrees that other reference should not be identified as relevant for the assessment of fate and behaviour of foramsulfuron in the environment (as defined in the EFSA Guidance Document).

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 7.1.1.1 /01	Judge, D. N.; Abbott, P. B.; Allen, R.	2000	Degradation of (U-14C-phenyl) and (2-14C-pyrimidyl)-AE F130360 in three European soils under laboratory aerobic conditions at 20 degrees C Code: AE F130360 Aventis CropScience USA LP, Environmental Chemistry, Pikeville, NC, USA Report No.: C003294, Report includes Trial Nos.: 522CF Edition Number: M-185910-01-1 EPA MRID No.: 45109713 Date: 2000-02-24 GLP/GEP: yes, unpublished ...also filed: KCA 7.1.2.1.1 /01 ...also filed: KCA 7.1.2.1.2 /01	N	N	Not relevant	Bayer Crop Science	Y

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 7.1.1.1 /02	Judge, D. N.	1999	Degradation of (U-14C-phenyl) and (2-14C-pyrimidyl)-AE F130360 in two U.S. soils under laboratory aerobic conditions at 25 degrees C Code: AE F130360 AgrEvo USA Company, Environmental Chemistry, Pikeville, NC, USA Report No.: C003704, Report includes Trial Nos.: 513CF Edition Number: M-186637-01-1 EPA MRID No.: 45109714 Date: 1999-11-30 GLP/GEP: yes, unpublished ...also filed: KCA 7.1.2.1.1 /02 ...also filed: KCA 7.1.2.1.2 /02	N	N	Not relevant	Bayer Crop Science	Y
KCA 7.1.1.1 /03	Allen, R.; Fisher, R.	2002	Assessment of the risk from non-extractable soil residues of foramsulfuron Aventis CropScience USA LP, RTP, NC, USA Report No.: B003727, Report includes Trial Nos.: 602CF Edition Number: M-240732-01-1 GLP/GEP: no, unpublished	N	N	Not relevant	Bayer Crop Science	Y
KCA 7.1.1.2 /01	Meyer, B. N.; Pate, M. C.	2000	Degradation of [U-14C-phenyl] and [2-14C-pyrimidyl] AE F130360 in a European soil under laboratory anaerobic conditions at 20°C: AE F130360 Aventis CropScience USA LP, Environmental Chemistry, Pikeville, NC, USA Report No.: B002603, Report includes Trial Nos.: CF97E524 CF97E524A Edition Number: M-238343-02-1 EPA MRID No.: 45109715 Date: 2000-01-07 ...Amended: 2000-02-29 GLP/GEP: yes, unpublished ...also filed: KCA 7.1.2.1.3 /01	N	N	Not relevant	Bayer Crop Science	Y
KCA 7.1.1.3 /01	Burri, R.	2000	Photolysis of 14C-AE F130360 on soil surface under laboratory conditions RCC Umweltchemie AG, Environmental Chemistry & Pharamanalytics, Itingen, Switzerland Report No.: C006964, Edition Number: M-194958-01-1 EPA MRID No.: 45109716 Date: 2000-01-05 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropSci ence	Y

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 7.1.1.3 /02	Hall, L. R.	2012	[Phenyl-UL-14C]foramsulfuron: Phototransformation on soil Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MEFSL009, Edition Number: M-422619-01-1 Date: 2012-01-17 GLP/GEP: yes, unpublished	N	Y	New study to provide information on the fate of foramsulfuron (2nd label position)	Bayer Crop Science	N
KCA 7.1.2.1. 1 /01	Judge, D. N.; Abbott, P. B.; Allen, R.	2000	Degradation of (U-14C-phenyl) and (2-14C-pyrimidyl)-AE F130360 in three European soils under laboratory aerobic conditions at 20 degrees C Code: AE F130360 Aventis CropScience USA LP, Environmental Chemistry, Pikeville, NC, USA Report No.: C003294, Report includes Trial Nos.: 522CF Edition Number: M-185910-01-1 EPA MRID No.: 45109713 Date: 2000-02-24 GLP/GEP: yes, unpublished ...also filed: KCA 7.1.1.1 /01 ...also filed: KCA 7.1.2.1.2 /01	N	N	Not relevant	Bayer Crop Science	Y
KCA 7.1.2.1. 1 /02	Judge, D. N.	1999	Degradation of (U-14C-phenyl) and (2-14C-pyrimidyl)-AE F130360 in two U.S. soils under laboratory aerobic conditions at 25 degrees C Code: AE F130360 AgrEvo USA Company, Environmental Chemistry, Pikeville, NC, USA Report No.: C003704, Report includes Trial Nos.: 513CF Edition Number: M-186637-01-1 EPA MRID No.: 45109714 Date: 1999-11-30 GLP/GEP: yes, unpublished ...also filed: KCA 7.1.1.1 /02 ...also filed: KCA 7.1.2.1.2 /02	N	N	Not relevant	Bayer Crop Science	Y

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 7.1.2.1. 1 /03	Judge, D. N.; Abbott, P. B.; Ramanaray an, T. S.	2000	Degradation of [U-14C-phenyl] and [2-14- pyrimidyl] AE F130360 in a European soil under laboratory aerobic conditions at 10' C: AE F130360 Aventis CropScience USA LP, Environmental Chemistry, Pikeville, NC, USA Report No.: B002565, Report includes Trial Nos.: CF97E523 Edition Number: M-238314-01-2 EPA MRID No.: 45109718 Date: 2000-02-24 GLP/GEP: yes, unpublished ...also filed: KCA 7.1.2.1.2 /03	N	N	Not relevant	Bayer Crop Science	Y
KCA 7.1.2.1. 1 /04	Allen, R.	2000	Kinetic Evaluation of the Aerobic Degradation of AE F130360 and its Metabolites in Five Different Soils using TopFit 2.0 AgrEvo USA Company, USA Report No.: B002763, Report includes Trial Nos.: CF00E578 Edition Number: M-238491-01-2 EPA MRID No.: 45109719 Date: 2000-01-20 GLP/GEP: yes, unpublished ...also filed: KCA 7.1.2.1.2 /05	N	N	Not relevant	Bayer CropSci ence	Y
KCA 7.1.2.1. 1 /05	Schmitt, W.; Mikolasch, B.	2013	Kinetic evaluation of laboratory aerobic soil degradation of foramsulfuron and its metabolites according to Focus Bayer CropScience, Report No.: EnSa-12-0246, Edition Number: M-453563-02-1 Date: 2013-03-14 ...Amended: 2013-07-19 GLP/GEP: no, unpublished ...also filed: KCA 7.1.2.1.2 /08	N	N	Not relevant	Bayer Crop Science	Y

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 7.1.2.1. 2 /01	Judge, D. N.; Abbott, P. B.; Allen, R.	2000	Degradation of (U-14C-phenyl) and (2-14C-pyrimidyl)-AE F130360 in three European soils under laboratory aerobic conditions at 20 degrees C Code: AE F130360 Aventis CropScience USA LP, Environmental Chemistry, Pikeville, NC, USA Report No.: C003294, Report includes Trial Nos.: 522CF Edition Number: M-185910-01-1 EPA MRID No.: 45109713 Date: 2000-02-24 GLP/GEP: yes, unpublished ...also filed: KCA 7.1.1.1 /01 ...also filed: KCA 7.1.2.1.1 /01	N	N	Not relevant	Bayer Crop Science	Y
KCA 7.1.2.1. 2 /02	Judge, D. N.	1999	Degradation of (U-14C-phenyl) and (2-14C-pyrimidyl)-AE F130360 in two U.S. soils under laboratory aerobic conditions at 25 degrees C Code: AE F130360 AgrEvo USA Company, Environmental Chemistry, Pikeville, NC, USA Report No.: C003704, Report includes Trial Nos.: 513CF Edition Number: M-186637-01-1 EPA MRID No.: 45109714 Date: 1999-11-30 GLP/GEP: yes, unpublished ...also filed: KCA 7.1.1.1 /02 ...also filed: KCA 7.1.2.1.1 /02	N	N	Not relevant	Bayer Crop Science	Y
KCA 7.1.2.1. 2 /03	Judge, D. N.; Abbott, P. B.; Ramanarayan, T. S.	2000	Degradation of [U-14C-phenyl] and [2-14-pyrimidyl] AE F130360 in a European soil under laboratory aerobic conditions at 10' C: AE F130360 Aventis CropScience USA LP, Environmental Chemistry, Pikeville, NC, USA Report No.: B002565, Report includes Trial Nos.: CF97E523 Edition Number: M-238314-01-2 EPA MRID No.: 45109718 Date: 2000-02-24 GLP/GEP: yes, unpublished ...also filed: KCA 7.1.2.1.1 /03	N	N	Not relevant	Bayer Crop Science	Y

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 7.1.2.1. 2 /04	Judge, D. N.; Abbott, P. B.; Allen, R.	2000	Degradation of [U-14C-phenyl] and [2-14C-pyrimidyl]-AE F130619 in four soils under laboratory aerobic conditions at 20' C: AE F130619 Aventis CropScience USA LP, Environmental Chemistry, Pikeville, NC, USA Report No.: B002706, Report includes Trial Nos.: CF99E548 CF99E548A Edition Number: M-238440-02-1 EPA MRID No.: 45109720 Date: 2000-02-25 ...Amended: 2000-03-22 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer Crop Science	Y
KCA 7.1.2.1. 2 /05	Allen, R.	2000	Kinetic Evaluation of the Aerobic Degradation of AE F130360 and its Metabolites in Five Different Soils using TopFit 2.0 AgrEvo USA Company, USA Report No.: B002763, Report includes Trial Nos.: CF00E578 Edition Number: M-238491-01-2 EPA MRID No.: 45109719 Date: 2000-01-20 GLP/GEP: yes, unpublished ...also filed: KCA 7.1.2.1.1 /04	N	N	Not relevant	Bayer Crop Science	Y
KCA 7.1.2.1. 2 /06	Shepherd, J. J.; Ripperger, R. J.	2012	[Phenyl-UL-14C]foramsulfuron sulfonamide: Aerobic soil metabolism in four US soils Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MEFSL008, Edition Number: M-425904-01-1 Date: 2012-02-23 GLP/GEP: yes, unpublished	N	Y	Study to determine reliable degradation rate of AE F153745 in aerobic soil	Bayer Crop Science	N

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 7.1.2.1. 2 /07	Voelkel, W.	2006	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 (partA) of the review programme referred to in article 8(2) of council directive 91/414/EEC - Volume 3, Annex , B.8 RCC Umweltchemie AG Bayer CropScience, Report No.: 384480, Edition Number: M-469999-01-1 GLP/GEP: n.a., unpublished	N	N	Not relevant	Public (DAR)	Y
KCA 7.1.2.1. 2 /08	Schmitt, W.; Mikolasch, B.	2013	Kinetic evaluation of laboratory aerobic soil degradation of foramsulfuron and its metabolites according to Focus Bayer CropScience, Report No.: EnSa-12-0246, Edition Number: M-453563-02-1 Date: 2013-03-14 ...Amended: 2013-07-19 GLP/GEP: no, unpublished ...also filed: KCA 7.1.2.1.1 /05	N	N	Not relevant	Bayer Crop Science	Y
KCA 7.1.2.1. 3 /01	Meyer, B. N.; Pate, M. C.	2000	Degradation of [U-14C-phenyl] and [2-14C-pyrimidyl] AE F130360 in a European soil under laboratory anaerobic conditions at 20°C: AE F130360 Aventis CropScience USA LP, Environmental Chemistry, Pikeville, NC, USA Report No.: B002603, Report includes Trial Nos.: CF97E524 CF97E524A Edition Number: M-238343-02-1 EPA MRID No.: 45109715 Date: 2000-01-07 ...Amended: 2000-02-29 GLP/GEP: yes, unpublished ...also filed: KCA 7.1.1.2 /01	N	N	Not relevant	Bayer Crop Science	Y

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 7.1.2.2. 1 /01	Norris, F. A.	2000	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 00 WG50 A107; Aventis CropScience USA LP, RTP, NC, USA Report No.: B004767, Report includes Trial Nos.: CF97R003 Edition Number: M-238506-02-1 Date: 2000-03-27 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer Crop Science	Y
KCA 7.1.3.1. 1 /01	Allan, J. P.; Pate, M. C.; Allan, J. G.; Pate, M. C.	2000	The adsorption/desorption of (14C)-AE F130360 on five soils Code: AE F130360 Aventis CropScience USA LP, Environmental Chemistry, Pikeville, NC, USA Report No.: A57846, Report includes Trial Nos.: 514CF CF96E514A Edition Number: M-141563-02-1 EPA MRID No.: 45109723 Date: 2000-01-04 ...Amended: 2000-03-08 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer Crop Science	Y
KCA 7.1.3.1. 2 /01	Reynolds, J. L.	1999	Adsorption and desorption of [14-C]-AE F153475 in US and European soils AgrEvo USA Company, Pikeville, NC, USA Report No.: B002593, Report includes Trial Nos.: CF99E547 XBL99031 Edition Number: M-238339-01-2 EPA MRID No.: 45109724 Date: 1999-11-12 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer Crop Science	Y
KCA 7.1.3.1. 2 /02	Allan, J. G.; Pate, M. C.	2000	The adsorption/desorption of [14C]-AE F130619 in US and European soils: AE F130619 Aventis CropScience UK Ltd., Environmental Chemistry, Ongar, United Kingdom Report No.: B002457, Report includes Trial Nos.: CF99E546 Edition Number: M-238202-01-2 EPA MRID No.: 45109725 Date: 2000-01-04 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer Crop Science	Y

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 7.1.3.1. 2 /03	Schollmeier , M.; Eyrich, U.	1992	Adsorption/Desorption of 2-Amino-4,6- dimethoxypyrimidine (Hoe 092944) in the system soil/water Hoechst AG, Frankfurt am Main, Germany Report No.: A48097, Edition Number: M-136973-01-1 EPA MRID No.: 45109726 Date: 1992-03-10 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer Crop Science	Y
KCA 7.1.4.2 /01	Mackenzie, E.	2000	[2-4C-PYRIMIDYL]-AE F130360:Leaching in outdoor Lysimeters [2-4C-PYRIMIDYL]-AE F130360 Aventis CropScience, Environmental Sciences, United Kingdom Report No.: C006906, Report includes Trial Nos.: ENVIR/101CF Edition Number: M-194838-01-1 EPA MRID No.: 45109727 Date: 2000-02-03 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer Crop Science	Y
KCA 7.1.4.2 /02	Burr, C. M.; Mackenzie, E.	2001	(2-14C-pyrimidyl)-AE F130360 leaching in outdoor lysimeter Aventis CropScience UK Ltd., United Kingdom Report No.: C014861, Edition Number: M-207434-01-1 Date: 2001-09-20 GLP/GEP: yes, unpublished	N	Y	Informat ion on leaching behavio ur	Bayer Crop Science	N
KCA 7.2.1.1 /01	Allan, J. G.; Allen, R.	2000	The hydrolysis of [14C]-AE F130360 in aqueous buffer at pH 4,5, 7, and 9: AE F130360 Aventis CropScience USA LP, Environmental Chemistry, Pikeville, NC, USA Report No.: B002464, Report includes Trial Nos.: CF97E517 Edition Number: M-238210-01-2 EPA MRID No.: 45109324 Date: 2000-02-07 GLP/GEP: yes, unpublished ...also filed: KCA 2.8 /02	N	N	Not relevant	Bayer Crop Science	Y

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 7.2.1.2 /01	Schmidt, W.; Buerkle, L. W.	1999	Aqueous photolysis under laboratory conditions Code: (U-14C-phenyl)-AE F130360 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: C006901, Edition Number: M-194828-01-1 EPA MRID No.: 45109325 Date: 1999-12-21 GLP/GEP: yes, unpublished ...also filed: KCA 2.8 /03	N	N	Not relevant	Bayer Crop Science	Y
KCA 7.2.1.2 /02	Hall, L. R.	2012	Phototransformation of [14C]foramsulfuron in aqueous pH 7 buffer Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MEFSL011, Edition Number: M-425561-01-1 Date: 2012-02-22 GLP/GEP: yes, unpublished	N	Y	2nd label position and lower test concentr ation resolvin g formal contradi ction between results of existing buffer photolys is and natural water study perform ed later	Bayer Crop Science	N

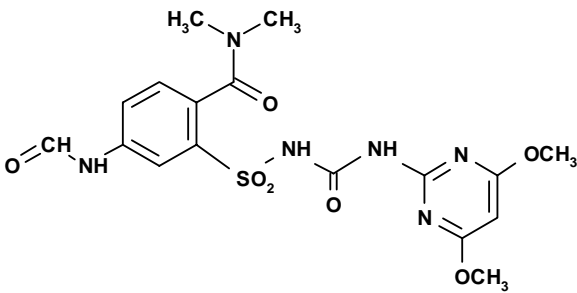
Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 7.2.1.2 /03	Heinemann, O.	2013	Foramsulfuron: Determination of the quantum yield and assessment of the environmental half-life of the direct photo-degradation in water Bayer CropScience, Report No.: EnSa-13-0305, Edition Number: M-460124-01-1 Date: 2013-07-16 GLP/GEP: yes, unpublished	N	Y	Triggere d by new data require ment in Tox (phototo xicity and – mutagen icity) and contrasti ng results from existing photolys is study	Bayer Crop Science	N
KCA 7.2.1.3 /01	Meyer, B. N.	2009	[Phenyl-UL-14C]foramsulfuron: Phototransformation in natural water Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MEFSU004, Edition Number: M-346695-01-1 Date: 2009-05-04 GLP/GEP: yes, unpublished	N	Y	Study originall y conduct ed to fulfil Japanes e data require ments resulting in informat ion on behavio ur under conditio ns of indirect photolys is	Bayer Crop Science	N

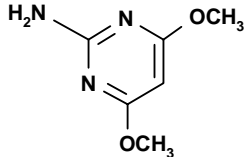
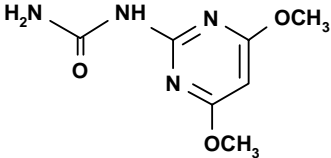
Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 7.2.1.3 /02	Meyer, B. N.	2008	[Pyrimidine-2-14C] foramsulfuron: Phototransformation in natural water Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MEFSU001, Edition Number: M-327230-01-1 Date: 2008-12-23 GLP/GEP: yes, unpublished	N	Y	Study originally conducted to fulfil Japanese data requirements resulting in information on behaviour under conditions of indirect photolysis	Bayer Crop Science	N
KCA 7.2.2.2 /01	Fahrbach, M.	2013	[phenyl-UL-14C]Foramsulfuron: Aerobic Mineralization in surface water Harlan Laboratories Ltd., Itingen, Switzerland Bayer CropScience, Report No.: D62860, Edition Number: M-453421-01-1 Date: 2013-04-22 GLP/GEP: yes, unpublished	N	Y	New data requirement according to Regulation 1107/2009	Bayer Crop Science	N
KCA 7.2.2.3 /01	Judge, D. N.; Abbott, P. B.; Allen, R.	2000	Degradation of [U-14C-phenyl] and [2-14C-pyrimidyl]-AE F130360 in two contrasting sediment-water systems under laboratory aerobic conditions at 20°C AgrEvo USA Company, Environmental Chemistry, Pikeville, NC, USA Report No.: B002256, Report includes Trial Nos.: CF97E521 Edition Number: M-238019-01-2 EPA MRID No.: 45109728 Date: 2000-01-06 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer Crop Science	Y

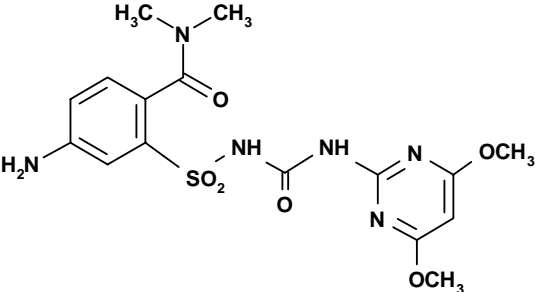
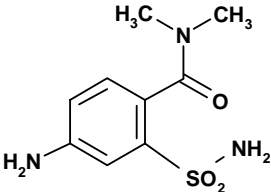
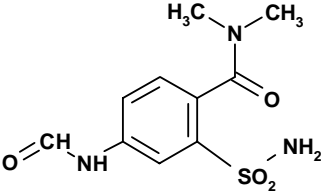
Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 7.2.2.3 /02	Abbott, P.; Huang, M. N.; Ramanarayan, T.	2000	The degradation of [U-14C-phenyl] and [2-14C-pyrimidyl]- AE F130360 in an anaerobic sediment/water system under laboratory conditions at 20°C: AE F130360 Aventis CropScience USA LP, Environmental Chemistry, Pikeville, NC, USA Report No.: B002252, Report includes Trial Nos.: CF97E519 Edition Number: M-238016-01-2 EPA MRID No.: 45109729 Date: 2000-02-02 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer Crop Science	Y
KCA 7.2.2.3 /03	Huang, M. N.; Creech, T. F.; Ramanarayan, T. S.	2000	Degradation of [U-14C-phenyl] and [2-14C-pyrimidyl] -AE F130360 in an anaerobic sediment/water under laboratory anaerobic conditions at 10°C: AE F130360 Aventis CropScience USA LP, Environmental Chemistry, Pikeville, NC, USA Report No.: B002642, Report includes Trial Nos.: CF97E520 Edition Number: M-238381-01-2 EPA MRID No.: 45109730 Date: 2000-02-21 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer Crop Science	Y
KCA 7.2.2.3 /04	Schmitt, W.; Mikolasch, B.	2013	Kinetic evaluation of aerobic aquatic metabolism of foramsulfuron and its metabolites in water / sediment systems according to FOCUS kinetics Bayer CropScience, Report No.: EnSa-13-0228, Edition Number: M-454536-01-1 Date: 2013-05-17 GLP/GEP: no, unpublished	N	N	Not relevant	Bayer Crop Science	N
KCA 7.3.1 /01	Buerkle, L. W.	2000	Estimation of the reaction with photochemically produced hydroxyl radicals in the atmosphere Code: AE F130360 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: C006613, Edition Number: M-194295-01-1 EPA MRID No.: 45109327 Date: 2000-01-12 GLP/GEP: no, unpublished ...also filed: KCA 2.14 /03	N	N	Not relevant	Bayer Crop Science	

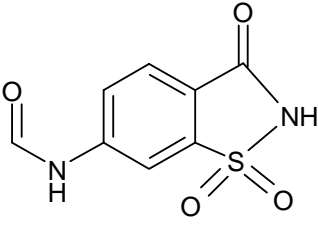
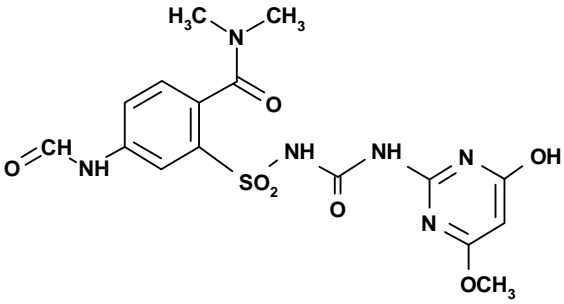
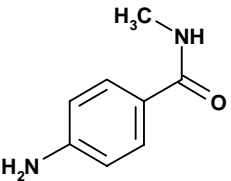
Appendix 1: List of metabolites observed in environmental fate testing

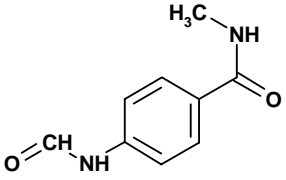
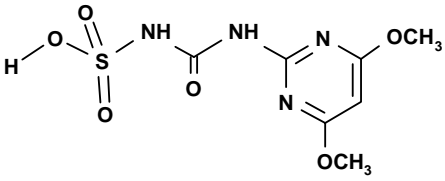
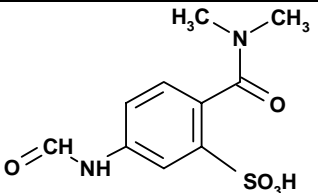
In the original study reports on biotic or abiotic transformation of foramsulfuron the metabolites are denominated by different synonyms. In order to present a common system of nomenclature for the evaluation in the dossier a list of metabolites observed in environmental fate testing is included.

	Report name Structure IUPAC name CAS name [CAS registry number]	Molecular formula molar mass Other names / codes	Occurrence
a.s.	<p>Foramsulfuron (parent substance)</p>  <p>N,N-dimethyl-2-[3-(4,6-dimethoxypyrimidin-2-yl)ureidosulfonyl]-4-formylaminobenzamide (IUPAC) 2-[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]-4-formylaminobenzamide (CAS) CAS no: 173159-57-4</p>	<p>C₁₇ H₂₀ N₆ O₇ S 452.49 g/mol</p> <p>Foramsulfuron (common name) AE F130360 BCS-AH47626</p>	Parent substance used as test material in all reports

	Report name Structure IUPAC name CAS name [CAS registry number]	Molecular formula molar mass Other names / codes	Occurrence
M01	<p>AE F092944</p>  <p>2-amino-4,6-dimethoxypyrimidine (IUPAC) 4,6-Dimethoxy-2-pyrimidinamine (CAS) CAS no: 36315-01-2</p>	<p>C₆ H₉ N₃ O₂ 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>
M02	<p>AE F099095</p>  <p>4,6-dimethoxypyrimidin-2-ylurea (IUPAC) (4,6-dimethoxy-2-pyrimidinyl)urea (CAS) CAS no: 151331-81-6</p>	<p>C₇ H₁₀ N₄ O₃ 198.18 g/mol</p> <p>AE F099095 BCS-AB40283 Foramsulfuron-urea 05537 DMPU Metabolite B</p>	<p>Soil, aerobic Soil, anaerobic Soil photolysis Photolysis, buffer Photolysis, nat. water</p>

	Report name Structure IUPAC name CAS name [CAS registry number]	Molecular formula molar mass Other names / codes	Occurrence
M03	<p>AE F130619</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: 190520-75-3</p>	<p>C₁₆ H₂₀ N₆ O₆ S 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>AE F148003</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>C₉ H₁₃ N₃ O₃ S 243.31 g/mol</p> <p>AE F148003 BCS-AU73987</p>	<p>Soil, aerobic Soil, anaerobic Hydrolysis, buffer Water/Sediment</p>
M05	<p>AE F153745</p>  <p>4-formylamino-N,N-dimethyl-2-sulfamoylbenzamide (IUPAC) 2-(aminosulfonyl)-4-(formylamino)-N,N-dimethylbenzamide (CAS) CAS no: 173159-94-9</p>	<p>C₁₀ H₁₃ N₃ O₄ S 271.32 g/mol</p> <p>AE F153745 BCS-AU80017</p>	<p>Soil, aerobic Soil, anaerobic Hydrolysis, buffer Water/Sediment</p>

	Report name Structure IUPAC name CAS name [CAS registry number]	Molecular formula molar mass Other names / codes	Occurrence
M06	AE 0014940		
	 <p>N-(1,1-dioxido-3-oxo-2,3-dihydro-1,2-benzothiazol-6-yl)formamide (IUPAC) 6-formamido-1,2-benzisothiazol-3(2H)-one 1,1-dioxide (IUPAC) CAS no: NA</p>	<p>C₈ H₆ N₂ O₄ S 226.21 g/mol</p> <p>AE 0014940 BCS-AW41697</p>	Hydrolysis, buffer Water/Sediment
M07	AE 0338795		
	 <p>4-formylamino-2-[3-(4-hydroxy-6-methoxypyrimidin-2-yl)ureidosulfonyl]-N,N-dimethylbenzamide (IUPAC) CAS no: NA</p>	<p>C₁₆ H₁₈ N₆ O₇ S 438.42 g/mol</p> <p>AE 0338795 BCS-AW78711 4-(formylamino)-2-[[[(4-hydroxy-6-methoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]-N,N-dimethylbenzamide</p>	Water/Sediment
M08	4-Amino-N-methylbenzamide		
	 <p>4-amino-N-methylbenzamide (IUPAC) benzamide, 4-amino-N-methyl (CAS) CAS no: 6274-22-2</p>	<p>C₈ H₁₀ N₂ O 150.18 g/mol</p> <p>AMB BCS-CV29520</p>	Photolysis, buffer Photolysis, nat. water

	Report name Structure IUPAC name CAS name [CAS registry number]	Molecular formula molar mass Other names / codes	Occurrence
M09	4-Formamido-N-methylbenzamide		
	 <p>4-formamido-N-methylbenzamide (IUPAC) CAS no: NA</p>	<p>C₉ H₁₀ N₂ O₂ 178.19 g/mol</p> <p>FMB BCS-CW90756</p>	<p>Photolysis, buffer Photolysis, nat. water</p>
M10	Foramsulfuron sulfamic acid		
	 <p>[4,6-dimethoxypyrimidin-2-yl]carbamoylsulfamic acid (IUPAC) Sulfamic acid, N-[[4,6-dimethoxy-2-pyrimidinyl]amino]carbonyl]- (CAS) CAS no: 591747-53-4</p>	<p>C₇ H₁₀ N₄ O₆ S 278.24 g/mol</p> <p>BCS-AW41401</p>	<p>Photolysis, buffer Photolysis, nat. water</p>
M11	Sulfonic acid		
	 <p>2-(dimethylcarbamoyl)-5-formamidobenzenesulfonic acid (IUPAC) CAS no: NA</p>	<p>C₁₀ H₁₂ N₂ O₅ S 272.28 g/mol</p> <p>BCS: n.a. Foramsulfuron-sulfonic acid</p>	<p>Photolysis, nat. water</p>